Evaluation of PEPFAR

Committee on the Outcome and Impact Evaluation of Global HIV/AIDS Programs Implemented Under the Lantos-Hyde Act of 2008

Board on Global Health
Board on Children, Youth, and Families

INSTITUTE OF MEDICINE
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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Preface

The HIV/AIDS pandemic has beleaguered the world for over three decades. The countries suffering most continue to be in sub-Saharan Africa, home to an estimated two-thirds of people living with HIV. There have been major increases in both international aid assistance and national commitments and investments for HIV prevention, treatment, care, and capacity building activities. Yet, a funding gap persists relative to meeting the estimated immediate and projected needs.

In 2003, in response to the devastating consequences of the HIV pandemic, the U.S. Congress funded a major new U.S. global health initiative that became known as the President's Emergency Plan for AIDS Relief (PEPFAR).[2] PEPFAR remains the largest bilateral initiative to address HIV/AIDS. At the time of initial authorization, PEPFAR was seen as a bold initiative, testing, among other strategies, whether treatment could be successfully and intensively scaled up in low-resource settings. To help guide this innovative program, the initial authorizing language mandated that the Institute of Medicine (IOM) assess the progress of PEPFAR implementation. The findings and recommendations of that study, published in 2007, informed PEPFAR processes, policies, and activities and subsequently, the reauthorization legislation, known in short as the Lantos-Hyde Act of 2008.[3]

The reauthorization legislation mandated the Institute of Medicine (IOM) to assess the performance of United States–assisted global HIV/AIDS programs and evaluate the impact on health of prevention, treatment, and care efforts supported by U.S. funding (see Appendix A for the Statement of Task). This report aims to inform Congress and the Department of State and also to provide the scientific community, program implementers, policy makers, civil society, people living with and affected by HIV/AIDS, and international stakeholders in global public health with a rigorous, evidence-based, multidisciplinary, and independent evaluation of PEPFAR.

In response to this mandate, the IOM first convened a planning committee to develop a strategic approach for the evaluation, which was published in 2010. This strategic approach addressed the complexities of evaluating an initiative with the scale and diversity of programs that PEPFAR supports and with the range of countries in which it operates. The dynamism of an initiative that was operating and evolving over the course of the evaluation presented additional complexity.

To carry out the evaluation, the IOM convened a diverse expert committee, with considerable overlap with the planning committee. Guided by the strategic approach, the committee, IOM staff, and consultants carried out a mixed-methods approach. Qualitative data included extensive document review and over 400 semi-structured interviews conducted from 2010 to 2012. Each member of the committee visited at least one PEPFAR partner country, and in total the evaluation team conducted thirteen data collection visits to partner countries and heard the perspectives of a wide range of stakeholders. PEPFAR headquarters and mission staff,

[2] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong., 1st sess. (May 27, 2003).

[3] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

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partner country stakeholders and global partners all generously contributed their time and experience to the committee. Quantitative data included financial data, program and clinical monitoring data, and epidemiological information. The committee struggled with the quantitative data available to address some of the elements of the statement of task. Beyond whether or not the specificity of this legislated task could be answered, however, is the critical imperative that, as the initiative moves forward, PEPFAR determine the key questions to ask in order to assess its own performance and effectiveness, and to plan in advance for the collection of meaningful data to answer those questions and guide the ongoing evolution of PEPFAR.

The 2008 reauthorization of PEPFAR placed an increased emphasis on transitioning the program from an initial emergency response to a longer-term model of enhancing sustainability, promoting country ownership, and strengthening health systems. One of the clear findings that emerged from this evaluation is that as PEPFAR evolves in this vein, major dilemmas emerge that create tensions for decision making related to a country's HIV response; these dilemmas require attention going forward. As the HIV response becomes more country-driven, PEPFAR—and any other external donor effort—will need to focus its contribution on national efforts, rather than direct provision of services and attribution of results. This has consequences for program planning, implementation, and evaluation. Furthermore, focusing on country ownership will require relinquishing some control over the response with unknown consequences for quality and access to services that PEPFAR and partner countries will have to grapple with together.

PEPFAR has been globally transformative—changing in many ways the paradigm of global health and what can be accomplished with ambitious goals, ample funding, and humanitarian commitment to a public health crisis. As it moves forward, PEPFAR must continue to be bold in its vision, implementation, and global leadership, this time towards its aim of continuing to strengthen capacity in partner countries in responding to the pandemic. The committee hopes that this evaluation will serve as a tool to achieve these aims.

The committee extends its gratitude to all those who provided information to assist in the evaluation. The committee has continuing deep admiration for those carrying out the difficult work of responding to the pandemic. I was privileged to serve as the chair for both the planning committee and the evaluation committee. I would like to express my appreciation to the members of both committees, for the expertise and perspective they contributed, for their robust participation in discourse and deliberation, and for the immeasurable time and energy they volunteered. The IOM committee staff, very ably led by study co-directors Bridget Kelly and Kimberly Scott, have been highly professional, thoughtful, and committed to ensuring the most responsive and rigorous evaluation possible. I thank the entire staff and the committee consultants for their tireless efforts in support of the committee.

Robert E. Black, *Chair*
Committee on the Outcome and Impact Evaluation
of Global HIV/AIDS Programs Implemented
Under the Lantos-Hyde Act of 2008

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Acronyms and Abbreviations

AIDS	acquired immune deficiency syndrome
APR	annual program results
ART	antiretroviral therapy
ARV	antiretroviral
BCC	behavior change communication
CD4	cluster of differentiation 4
CDC	U.S. Centers for Disease Control and Prevention
COP	country operational plan
COPRS	Country Operational Plan Reporting System
CRC	Committee on the Rights of the Child
CTX	cotrimoxazole
DHS	Demographic and Health Surveys
DoS	U.S. Department of State
EID	early infant diagnosis of HIV
FY	fiscal year
GHI	The U.S. Global Health Initiative
Global Fund	The Global Fund to Fight AIDS, Tuberculosis, and Malaria
HAPSAT	HIV/AIDS Program Sustainability Analysis Tool
HIV	human immunodeficiency virus
IOM	Institute of Medicine
IPTp	intermittent preventive treatment of malaria for pregnant women
ITNs	insecticide-treated nets
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MICS	Multiple Indicator Cluster Survey
MSM	men who have sex with men
NGO	nongovernmental organization
OECD	Organisation for Economic Co-operation and Development
OGAC	Office of the U.S. Global AIDS Coordinator
OI	opportunistic infection
OMB	Office of Management and Budget
OVC	orphans and vulnerable children
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	The President's Emergency Plan for AIDS Relief
PEPFAR I	The President's Emergency Plan for AIDS Relief (2004–2008)
PEPFAR II	The President's Emergency Plan for AIDS Relief (2009–2013)
PHE	public health evaluation
PLHIV	people living with HIV/AIDS
PMI	The President's Malaria Initiative
PMTCT	prevention of mother-to-child transmission
PrEP	pre-exposure prophylaxis

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SI	strategic information
SAPRs	semi-annual program results
TAB	Technical Advisory Board
TB	tuberculosis
TWG	Technical Working Group
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

INTERVIEW CITATION ABBREVIATIONS

Country Visit Exit Synthesis: Country # + ES
Country Visit Interview: Country # + Interview # + Organization Type
Non–country Visit Interview: "NCV" + Interview # + Organization Type

Organization Types

USG	U.S. government
USNGO	U.S. nongovernmental organization
USPS	U.S. private sector
USACA	U.S. academia
PCGOV	partner country government
PCNGO	partner country nongovernmental organization
PCPS	partner country private sector
PCACA	partner country academia
CCM	country coordinating mechanism
ML	multilateral organization
OBL	other (non-U.S. and non–partner country) bilateral
OGOV	other government
ONGO	other (non-U.S. and non–partner country) nongovernmental organization

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Summary

The U.S. government supports global HIV programs through an initiative known as the President's Emergency Plan for AIDS Relief (PEPFAR).[1] As the largest donor to the global response to HIV, the U.S. government is making an historic contribution, benefitting in particular countries that have limited available resources and infrastructure and a great need for support of their national responses to HIV.

PEPFAR is a large, multifaceted, and complex initiative that is implemented in the cultural, social, economic, and political landscapes of each partner country as well as in the presence of HIV and health programs supported by other funding sources. Working through many implementing partners, PEPFAR supports a range of activities for all aspects of the HIV response, including direct service provision, programmatic support, technical assistance, and policy facilitation.

In light of the magnitude of the HIV crisis at the time, PEPFAR initially focused on the urgent need to scale up HIV services, accompanied by expectations for accountability and performance measurement. In addition, the authorizing legislation recognized the need for a long-term, comprehensive, international response. PEPFAR has achieved—and in some cases surpassed—its initial ambitious aims. These efforts have saved and improved the lives of millions of people around the world. That success has in effect "reset" the baseline and shifted global expectations for what can be achieved in partner countries. The reauthorization of PEPFAR not only set new aims to continue to scale up services, but also heightened the emphasis on health systems strengthening and sustainability, a shift in focus that has been increasingly reflected in the initiative's policies, activities, and dialogue with stakeholders.

EVALUATION APPROACH

The statement of task for this evaluation was derived from the legislation that reauthorized PEPFAR, which mandated that the Institute of Medicine (IOM) assess PEPFAR's performance and its effects on health.[2] Specifically, the task was to evaluate progress in meeting prevention, care, and treatment targets; the impact of PEPFAR-supported HIV prevention,

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[1] PEPFAR was authorized by the U.S. Congress in two phases: PEPFAR I (FY 2004–FY 2008) in the United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (P.L.108-25) and PEPFAR II (FY 2009–FY 2013) in the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (P.L. 110-293).

[2] Lantos-Hyde Act of 2008 at §101(c), 22 U.S.C. 7611(c). The complete Statement of Task can be found in Appendix A.

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treatment, and care programs; the effects of PEPFAR on health systems; PEPFAR's efforts to address gender-specific aspects of HIV/AIDS; and the impact of PEPFAR on child health and welfare.

To conduct a rigorous assessment that took into account PEPFAR's complexity and varied contexts, the IOM committee employed a mix of methods using financial data, program monitoring indicators and clinical data, extensive document review, and primary data collection carried out through more than 400 semi-structured interviews and site visits. A range of stakeholders were interviewed in 13 PEPFAR partner countries, at the U.S. headquarters of PEPFAR, and at other institutions and multilateral agencies.

The availability of the data needed to address all the health outcomes and impacts in the mandate was limited, and few data sources exist that are comparable and comprehensive across all PEPFAR partner countries. Therefore, the evaluation relied on sources from which robust information could be gathered on subsets of countries and select components within programmatic areas. Then, by assessing convergence and consistency among findings from different yet complementary data sources and methods, the committee analyzed and interpreted the available data to develop reasonable conclusions and recommendations about performance, impact, and progress across the whole of PEPFAR.

EVALUATION CONCLUSIONS AND RECOMMENDATIONS

PEPFAR has made remarkable progress in meeting its aims, reflecting the U.S. government's commitment and capability to respond to humanitarian crises through the use of health and development assistance and health diplomacy. PEPFAR's efforts have saved and improved the lives of millions of people by supporting HIV prevention, care, and treatment services; meeting the needs of children affected by the epidemic; building capacity; strengthening systems; engaging with partner country governments and other stakeholders; increasing knowledge about the epidemic in partner countries; and ensuring that attention be paid to vulnerable populations in the response to HIV.

While PEPFAR has achieved great things, its work is unfinished. The committee offers several recommendations to improve the U.S. government's support for the global response to HIV. They appear below in bold text, each followed by an indication of the chapter in the report in which it appears, and where additional considerations for its implementation are also described.[3,4]

The recommendations are presented in this summary in four main areas: scaling up HIV programs, strengthening systems for the HIV response in partner countries, transitioning to a sustainable response in partner countries, and transforming knowledge management to improve effectiveness.

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[3] The recommendations with their implementation considerations are compiled in Appendix B.

[4] The report is structured in four parts. Part I presents background information and details the evaluation's scope and approach. Part II discusses PEPFAR's organization and investment. Part III assesses programmatic activities serving both general and key populations as well as health systems strengthening. For pragmatic reasons the different program areas are discussed in separate chapters (Prevention, Care and Treatment, Children and Adolescents, Gender, and Health Systems Strengthening). However, each chapter also recognizes the inherent relatedness of these program areas in a continuum of services. Part IV examines the future role of the U.S. government in the global response, with themes of sustainability and knowledge management.

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Scaling Up HIV Programs

PEPFAR has provided a "proof of principle" that HIV services can be successfully delivered on a large scale in countries with a high burden of disease and limited available resources and infrastructure.

PEPFAR has increased the availability of and access to HIV testing, counseling, and diagnosis; as a result, many individuals have learned their HIV status. PEPFAR has also made it possible for an increasing number of adults and children living with HIV to receive clinical care and treatment, including antiretroviral therapy, through an expansion of the number and geographic distribution of clinical care and treatment sites, training and support for providers, procurement and delivery of drugs, improvements in laboratory services, and support for the adoption and implementation of national policies and guidelines in partner countries.

Despite such remarkable and substantial progress, ongoing challenges across the continuum of clinical care and treatment services must be addressed to achieve positive health outcomes for people living with HIV and to ensure that care and treatment programs are contributing to a sustainable HIV response. One critical need is to improve linkages from HIV counseling and testing to care and treatment and also to prevention services aimed at reducing HIV transmission. Another essential need is to improve retention and adherence among patients in care and treatment.

In addition to clinical care and treatment services, PEPFAR has also supported nonclinical care and support services for adults and has provided unprecedented support for programs for orphans and vulnerable children infected with or affected by HIV. However, these services span a diffuse array of activities and often lack the strategic development in program portfolios necessary to maximize contributions to defined outcomes.

> **To contribute to sustainable care and treatment programs in partner countries, PEPFAR should build on its experience and support efforts to develop, implement, and scale up more effective and efficient facility- and community-based service delivery models for the continuum of adult and pediatric testing, care, and treatment. These efforts should aim to enhance equitable access, improve retention, increase clinical and laboratory monitoring, ensure quality, and implement cost efficiencies.** *(Chapter 6)*

> **To assess PEPFAR-supported HIV care and treatment programs and to evaluate new service delivery models, the Office of the U.S. Global AIDS Coordinator[5] should support an enhanced, nested program monitoring effort in which additional longitudinal data on core outcomes for HIV-positive adults and children enrolled in care and treatment are collected and centrally reported from a coordinated representative sample across multiple countries and implementing partners.** *(Chapter 6)*

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[5] It is the committee's intent that actions recommended to be taken by Office of the U.S. Global AIDS Coordinator (OGAC) should be carried out through PEPFAR's interagency coordination mechanism, which involves not only the OGAC staff but also the leadership and technical staff of the U.S. government implementing agencies.

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This effort would serve as a nested evaluation within routine program monitoring systems to allow for long-term operational assessment of performance and outcomes for care and treatment across a representative sample of PEPFAR-supported programs. The aim would be to focus on key areas for the assessment and improvement of programs as PEPFAR supports innovations in service delivery and transitions to new models of implementation. Data collected and reported for this sample should be harmonized with existing data collection whenever possible. Priorities for longitudinal assessment should include quality measures; core outcomes related to clinical care and treatment, including those in key challenge areas such as adherence and retention; and outcomes related to the reduction of HIV transmission through biomedical and behavioral prevention interventions for people living with HIV. Program measures, such as service costs, that can provide valuable information to identify efficiencies and promote sustainable management should also be included.

> **To improve the implementation and assessment of non-clinical care and support programs for adults and children, including programs for orphans and vulnerable children, the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.** *(Chapters 6 and 7)*

To enable this shift to a more outcomes-oriented approach, partner countries will need support and assistance to prioritize outcomes and target services. For orphans and vulnerable children in particular, PEPFAR should improve the targeted coverage and quality of services by more explicitly and narrowly defining eligibility for PEPFAR-supported services at the country program level based on country-specific assessments of needs.

While services for people living with HIV are one foundation for the sustainable management of an HIV response, prevention is also paramount as part of a balanced attempt to change the trajectory of the HIV epidemic. PEPFAR's support for the scale-up of HIV prevention activities has been a valuable contribution to the HIV response in partner countries. PEPFAR has become more flexible over time in its approach to prevention, shifting from required budgetary allocations for specific intervention approaches to enabling the activities it supports to be tailored according to a country's epidemiological information and the available evidence for intervention effectiveness. As a result, PEPFAR's prevention programming has evolved from a limited number of behavioral and biomedical interventions initially to a greatly expanded portfolio of supported interventions based on existing and emergent evidence. A notable and measurable success in prevention has come in the area of the prevention of mother-to-child transmission, in which PEPFAR support has made a major contribution toward meeting the needs of partner countries.

Targeting the specific populations that are vulnerable to HIV infection and transmission, which differ by country, is critical for prevention. Notwithstanding some restrictive U.S. and partner country policy and legal environments, PEPFAR has made progress in this area through its support for data collection in specific populations and for prevention and harm reduction programming; these efforts have resulted in positive effects for populations at elevated risk, including men who have sex with men, people who engage in sex work, people who inject drugs,

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and other populations identified as vulnerable. Populations at elevated risk remain an important focus for prevention programming, and they also continue to struggle with barriers to accessing care and treatment services.

PEPFAR has stated its ongoing commitment to overarching goals for prevention. However, PEPFAR lacks clear objectives for outcomes across all types of prevention interventions. Achieving measurable intermediate outcomes for prevention efforts is important for PEPFAR to achieve its goals for reducing HIV transmission. However, there are limitations, not unique to PEPFAR, in the methods for appropriately measuring the outcomes of prevention interventions and in the available evidence for effectiveness for some types of intervention. These challenges are particularly salient for behavioral and structural interventions, especially for the prevention of sexual transmission, the primary global driver of HIV infection. An effective response requires responsiveness not only to the available evidence on intervention effectiveness, but also to the epidemiological evidence about the drivers of the epidemic. Given that behavioral and structural drivers will not be addressed through biomedical approaches alone, PEPFAR can contribute to a more effective HIV response by serving as a platform for innovation to help fill this gap in the availability of effective interventions and of appropriate approaches to assess prevention interventions. This would allow for a more balanced and comprehensive operational approach to developing, implementing, and evaluating prevention portfolios that are aligned with the drivers of epidemics and the needs for prevention services.

> **To contribute to the sustainable management of the HIV epidemic in partner countries, PEPFAR should support a stronger emphasis on prevention. The prevention response should prioritize the reduction of sexual transmission, which is the primary driver of most HIV infections, while maintaining support for interventions targeted at other modes of transmission. The response should incorporate an approach balanced among biomedical, behavioral, and structural interventions that is informed by epidemiological data and intervention effectiveness evidence. PEPFAR should support advances in prevention science to expand the availability of effective interventions where knowledge is lacking.** *(Chapter 5)*

PEPFAR has articulated overarching aims for addressing gender-related factors that influence the HIV epidemic and response. In particular, PEPFAR has placed a strong emphasis on addressing gender-based violence, an important underlying driver of vulnerability in the HIV epidemic. PEPFAR's efforts have evolved from a focus on the HIV-related needs and vulnerabilities of women and girls to a more comprehensive focus that aims to also address the vulnerabilities of men and boys that arise as a result of social and cultural norms in partner countries about gender and sexuality. PEPFAR's gender efforts have scaled up slowly over time, in an ad hoc fashion, with little strategic guidance to facilitate comprehensive country portfolios that address gender norms and inequities and that incorporate gender-focused objectives within prevention, care, and treatment programs to improve service access, coverage, and quality for both men and women.

> **To achieve PEPFAR's stated aim of addressing gender norms and inequities as a way to reduce HIV risk and increase access to HIV services, the Office of the U.S. Global AIDS Coordinator (OGAC) should develop and clearly state objectives and desired outcomes for gender-focused efforts. OGAC should**

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issue guidance for how to operationalize, implement, monitor, and evaluate activities and interventions to achieve these objectives. *(Chapter 8)*

Despite remarkable scale-up in PEPFAR partner countries, an all-encompassing challenge is the substantial remaining unmet need for all services and programs that are part of an effective response to HIV. For example, for antiretroviral therapy, fundamental challenges are posed by the large numbers of currently enrolled patients who need to be maintained, the patients who are currently eligible but not yet enrolled, and the potential for expansion of eligibility under new World Health Organization guidelines. For infants, children, and adolescents, service coverage in the continuum of testing, care, and treatment remains proportionally much lower than the coverage for adults. Programs for orphans and vulnerable children and adolescents also struggle to cover service needs in this population. Across HIV programs, an important goal for the future is for PEPFAR to work with partner countries and global partners, in the face of limited resources, to sustain the gains made and to continue to make progress in controlling the HIV epidemic.

Strengthening Health Systems for the HIV Response in Partner Countries

PEPFAR has made considerable contributions in many areas of health system functioning in partner countries. Its substantial support for laboratory strengthening has had fundamentally positive effects for the response to HIV and has been leveraged to improve the functioning of entire health systems. PEPFAR has also improved the functional components of systems that supply essential medications and other commodities critical for providing all health services. Despite this improvement, in many countries challenges remain with the consistency and reliability of supply chain functioning, which in turn affects sustainability and cost-effectiveness. PEPFAR has expanded the health workforce with the capacity to provide HIV services in partner countries; these contributions are now transitioning appropriately to more pre-service education and training, including initiatives for strengthening academic institutions, degree programs, and long-course trainings in countries. PEPFAR has also supported individual and organizational capacity building for leadership and for program and financial management across the governmental, private, and civil society sectors.

PEPFAR has supported the development and strengthening of national health information systems, with investments primarily in training and analytics, supply chain management, human resource information systems, laboratory management systems, patient record management systems, and electronic health records. When PEPFAR began, its focus on collecting data to monitor and report on the implementation of its programs led, when this capability was not available in partner countries, to PEPFAR-specific systems; these systems are now being increasingly aligned with national data collection for health as well as with global HIV indicators. Tensions remain between PEPFAR's data requirements for its own accountability and its aims to align with data collection for national systems, but PEPFAR is seeking to resolve this issue through enhanced support to strengthen national health information systems.

In service delivery, PEPFAR's impressive achievements represent the success of a largely disease-specific approach. In some countries, an early emphasis on increasing service volume to meet service delivery targets did not always facilitate service integration. Many stakeholders in partner countries have identified a need for greater integration of HIV services into the general health system. This is now an articulated goal for PEPFAR, but best practices for effective and efficient service integration are needed to facilitate scale-up. Another important

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need is ensuring the ongoing quality of services provided and programs implemented, especially through future transitions in implementation models for PEPFAR-supported programs.

PEPFAR's reauthorization created strategic opportunities for more formal support of health systems strengthening as a key contributor to sustainability in partner countries, encompassing all six building blocks in the World Health Organization framework: medical products and technologies, workforce, leadership and governance, financing, information systems, and service delivery.

> **To support the delivery of HIV-related services, make progress toward sustainable management of the HIV response, and contribute to other health needs, PEPFAR should continue to implement and leverage efforts that have had positive effects within partner country health systems. PEPFAR should maintain efforts in all six building blocks but have a concerted focus on areas that will be most critical for sustaining the HIV response, especially workforce, supply chain, and financing.** *(Chapter 9)*

Enhancing service delivery through existing local systems and long-term infrastructure development will continue to strengthen and expand the capacity of health and other systems to provide the services that are fundamental to an effective response to HIV, one that can meet the current and future trajectory of need. There is a need for future U.S. government investments to support long-term capacity building that fosters the placement and retention of trained personnel in partner countries to accelerate progress toward country ownership and sustainability.

> **To contribute to a country-owned and sustainable HIV response, the Office of the U.S. Global AIDS Coordinator should develop a comprehensive plan for long-term capacity building in partner countries. The plan should target four key areas: service delivery, financial management, program management, and knowledge management.** *(Chapter 10)*

Transitioning to a Sustainable Response in Partner Countries

PEPFAR has increasingly supported partner countries in the development of national frameworks, policies, and strategic plans. Participating in an intergovernmental planning process with partner country governments—one that includes multisectoral government participation as well as other local stakeholders and external donors—is one of the primary tools that PEPFAR uses to enhance leadership and governance and to support country ownership through mutual transparency, responsibility, and accountability. The U.S. government, like all donors, has its own considerations and requirements for funding decisions, but PEPFAR has made progress in making its considerations a part of joint planning processes rather than a displacement of country priorities. This joint planning includes both local processes for national plans as well as PEPFAR-specific processes, especially Partnership Frameworks. By necessity, PEPFAR will gradually cede control as partner countries adopt more dominant roles in setting strategic priorities for investments in their HIV response and in accounting for their results.

OGAC has recently articulated PEPFAR's understanding of country ownership and provided clarity about ways to mutually assess progress towards sustainability of a more country-led response. This transition to sustainability will be affected by many criteria and

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decisions, most of which will vary by country. Transitioning will take time; it cannot be achieved on a prescribed generic timeline across PEPFAR. Along the way, major dilemmas, such as differences in how to prioritize services and target populations, will require mutual resolution. In addition, transitioning to new models of PEPFAR support, including less direct support for service delivery and more technical assistance and systems strengthening, is part of a reasonable strategy for achieving sustainable management, but it also carries the inherent risks that in the transition period the same level of targets and access to services will not be achievable and that the quality of services, programs, and data may diminish. At the same time, greater embedding of HIV services in national health systems may offer opportunities for better integration of care, greater efficiencies, and broader health benefits.

There is strong leadership in partner countries for the HIV response, but many of these countries rely heavily—and in some cases almost exclusively—on U.S. bilateral assistance or the Global Fund. This reliance creates fragility and the possibility that the response would be disrupted if funding were discontinued or severely reduced. It is not realistic to expect that partner countries would be able to independently finance the entirety of HIV programming as it is currently implemented, and the critical importance of a global commitment to the HIV response remains. Yet, this does not abate the importance of partner country governments finding ways to reduce the fragility and dependence of their response by increasing their funding contributions, diversifying the sources of external funding that they receive, and making strategic, albeit difficult, decisions about the efficient use of available resources.

Building on the Partnership Framework implementation process, PEPFAR should continue to work with partner country governments and other stakeholders to plan for sustainable management of the response to HIV. PEPFAR should support and participate in comprehensive country-specific planning that includes the following:

- **Ascertain the trajectory of the epidemic and the need for prevention, care and treatment, and other services.**
- **Identify gaps, unmet needs, and fragilities in the current response.**
- **Estimate costs of the current response and project resource needs for different future response scenarios.**
- **Develop plans for resource mobilization to increase and diversify funding, including internal country-level funding sources.**
- **Encourage and participate in country-led, transparent stakeholder coordination and sharing of information related to funding, activities, and data collection and use.**
- **Establish and clearly articulate priorities, goals, and benchmarks for progress.** *(Chapter 10)*

PEPFAR is not alone in trying to achieve locally led, sustainable health and development objectives. Contributing stakeholders, including partner countries, will need to set priorities and allocate resources, based on mutually agreed-upon principles, to achieve a strategic and ethical balance between maintaining current coverage and expanding to address unmet needs. Ongoing support in partner countries to strengthen capacity for decision making informed by evidence will be needed to ensure that gains are not lost in achieving sustainable management of HIV

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programs, equitable access to services for those who are most in need, and sustainable control of the HIV epidemic.

Transforming Knowledge Management to Improve Effectiveness

PEPFAR's ability to generate, use, and disseminate knowledge is fundamental for program management and improvement and, ultimately, for the sustainability of PEPFAR's efforts. PEPFAR has made strong efforts in this area, often at levels not seen in other development initiatives, by creating a program monitoring data collection system to track activities and program results; supporting epidemiologic and surveillance activities; strengthening partner country health information systems; implementing various program evaluation approaches; and supporting some research across a wide range of technical areas. PEPFAR has generally utilized the resulting knowledge to drive program activities, implement evidence-informed interventions, and make modifications as new knowledge and scientific evidence have emerged. Yet there are key areas where the information needed to assess efforts and guide future activities is not sufficient or is not available in a manner that facilitates use.

PEPFAR's indicators, like many program monitoring systems, are focused primarily on outputs, such as the number of individuals provided with a service. These serve an important function to monitor implementation of activities but do not reflect quality, efficiency, or effectiveness. Measuring program progress and effectiveness is not always best achieved through program monitoring systems. Therefore, strategic and coordinated evaluation and research are also critical activities that complement program monitoring indicators in order to assess meaningful outcomes and to continually improve the effectiveness and impact of PEPFAR investments. In addition, support for epidemiological data collection through surveillance and special studies in partner countries, which has been a cornerstone of PEPFAR's contribution, continues to be fundamental to supporting joint planning with partner countries.

PEPFAR would benefit from a more purposeful and strategic determination of which internal and external stakeholders need to know what information, at what level of the PEPFAR operational infrastructure, covering what scope of PEPFAR's efforts, and with what frequency. The limited personnel, time, and financial resources for knowledge management could then be allocated to monitoring, evaluation, research, and dissemination activities that meet these needs, while reducing the burden of collecting and reporting data and other information that is not useful.

PEPFAR will need to transform its approach to knowledge management in order to adapt to a transition from direct support for delivery of services and programs to increased support and technical assistance for systems strengthening, capacity building, and sustainable management of the response by partner country stakeholders. An investment now to develop reliable, credible approaches to assess the effectiveness of these efforts will be needed to document future progress and to continually improve future efforts. The ability to attribute results by counting services provided or beneficiaries reached will be become less relevant; in fact, direct attribution will no longer be an appropriate expectation for accountability. PEPFAR could seize this opportunity to work with others in the global health and development assistance communities to develop appropriate ways to assess contributions to the improved performance and effectiveness of national efforts.

The Office of the U.S. Global AIDS Coordinator (OGAC) should develop a comprehensive knowledge management framework, including a program

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monitoring and evaluation strategy, a prioritized and targeted research portfolio, and systems for knowledge dissemination. This framework should adapt to emerging needs to assess PEPFAR's models of implementation and contribution to sustainable management of the HIV response in partner countries. *(Chapter 11)*

This knowledge management framework will require that PEPFAR implement and strategically allocate resources for the following:

A. To better document PEPFAR's progress and effectiveness, OGAC should refine its program monitoring and evaluation strategy to streamline reporting and to strategically coordinate a complementary portfolio of evaluation activities to assess outcomes and effects that are not captured well by program monitoring indicators. Efforts should support innovation in methodologies and measures where needed. Both monitoring and evaluation should be specifically matched to clearly articulated data sources, methods, and uses at each level of PEPFAR's implementation and oversight.

OGAC's program monitoring reporting structure can be streamlined by focusing on program improvement at the partner level, monitoring at the country level, and strategic oversight of accountability for contribution at the headquarters level. To reduce duplicative efforts and investments in its evaluation portfolio, OGAC should coordinate among country programs to strategically plan and coordinate a subset of evaluations designed to be useful at the country level but also to enable comparability across programs and countries in order to assess performance and inform improvements across PEPFAR.

B. To contribute to filling critical knowledge gaps that impede effective and sustainable HIV programs, OGAC should continue to redefine permitted research within PEPFAR by developing a prioritized portfolio with articulated activities and methods. The planning and implementation process at the country and program level should inform and be informed by the research portfolio, which should focus on research that will improve the effectiveness, quality, and efficiency of PEPFAR-supported activities and will also contribute to the global knowledge base on implementation of HIV/AIDS programs.

PEPFAR's scope, scale, and experience mean that it is uniquely situated as a platform for research to spur innovation and to address knowledge gaps that can undermine the effective planning, implementation, and measurement of the effectiveness of programs at scale. Research and evaluation activities that emphasize in-country local participation and expertise can also enhance local capacity and contribute to country ownership.

C. To maximize the use of knowledge created within PEPFAR, OGAC should develop systems and processes for routine, active transfer and dissemination of knowledge both within and external to PEPFAR. As one

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component, OGAC should institute a data-sharing policy, developed through a consultative process. The policy should identify the data to be included and ensure that these stipulated data and results generated by PEPFAR or through PEPFAR-supported activities are made available in a timely manner to PEPFAR stakeholders, external evaluators, the research community, and other interested parties.

PEPFAR would benefit from building on its most successful current mechanisms for sharing data, information, and knowledge to develop more systematic documentation and dissemination; there is a particular need to more effectively facilitate the direct transfer of experiences, best practices, and lessons learned across countries, implementing partners, and sites.

CONCLUSION

PEPFAR is an unprecedented initiative implemented on behalf of the U.S. citizenry, with vast bilateral investment from the U.S. government. Its dynamism can be seen in its evolving scope and implementation, the changing context in which it operates, and its deepening interrelationship with health diplomacy. PEPFAR's support for HIV prevention, care, and treatment has had major positive effects on the health and well-being of individual beneficiaries, on institutions and systems in partner countries, and on the overall global response to HIV. In addition to the positive effects of PEPFAR's support for services, PEPFAR is generally recognized as providing good technical assistance; being a flexible donor that fills gaps and supports innovation within country structures; contributing to addressing the challenging nature of concentrated epidemics; advancing global expectations for performance measurement and accountability; and contributing to the global knowledge base. PEPFAR has also contributed to shaping global health policy and action for HIV and potentially other areas of health and development.

The committee's overall assessment is that PEPFAR has played a transformative role with its contribution to the global response to HIV. In the course of this evaluation, the committee heard repeatedly across countries the pride, gratitude, and appreciation expressed by partner country governments, implementing partners, providers working in PEPFAR-supported facilities and programs, and community-based and civil society organizations representing the beneficiaries of PEPFAR programs. PEPFAR was described as a lifeline, and people credit PEPFAR for restoring hope.

The future of PEPFAR's contribution lies in a new direction. PEPFAR is transitioning to new implementation models that enhance systems and capacity while facilitating capable leadership in partner countries to sustainably manage the response to HIV. This new era may not be one of rapid, dramatic results. Yet if it is successful, PEPFAR has the potential to again transform the way health assistance is envisioned and implemented, with ultimate long-term positive effects for health and well-being.

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PART I

Introduction

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Background

The U.S. government supports global HIV programs through an initiative known as the President's Emergency Plan for AIDS Relief (PEPFAR). This report presents the results of an Institute of Medicine (IOM) evaluation of PEPFAR. The U.S. Congress mandated that the IOM conduct a study that includes "an assessment of the performance of United States-assisted global HIV/AIDS programs" and "an evaluation of the impact on health of prevention, treatment, and care efforts that are supported by United States funding."[1] The complete statement of task for this evaluation, derived from the legislative mandate, can be found in Appendix A.

This report is organized into four principal parts. Part I provides an introduction to the report through this chapter, which provides background on PEPFAR and through Chapter 2, which describes the scope and approach for the evaluation. Part II describes how PEPFAR is organized and managed, and the investments made through PEPFAR over time. Part III describes the effects of PEPFAR-supported activities in its major programmatic areas, including the aspects of the program that are directly specified in the legislative mandate for this evaluation: Prevention, Care and Treatment, Children and Adolescents, Gender, and Health Systems Strengthening. For pragmatic reasons the different program areas are discussed in separate chapters. However, each chapter also recognizes the inherent relatedness of these program areas in a continuum of services. Part IV places these major programmatic areas in the context of a discussion of key issues that are not explicitly stated in the legislative mandate for the evaluation but that are integral to the committee's consideration of the future of USG involvement in the global response to HIV/AIDS. Here, there is particular emphasis on the evolution of PEPFAR to support sustainable, evidence-informed management of HIV and AIDS in partner countries. The Summary, preceding this chapter, synthesizes the major messages of this report, in particular highlighting key issues that cut across chapters; captures the overall achievements and challenges of PEPFAR; and presents together in one place the recommendations of the committee.

[1] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (P.L. 110-293) at §101(c), 22 U.S.C. 7611(c).

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GLOBAL BURDEN OF HIV

The first documented case of acquired immune deficiency syndrome (AIDS) appeared in 1981, and the cause of the disease, human immunodeficiency virus (HIV), was discovered several years later (CDC, 1981; UNAIDS, 2006). Since then, the pandemic nature of the virus has become recognized and the effort to control its spread has become a leading global health priority (UNAIDS, 2012). Worldwide, the number of new HIV infections peaked in 1997, while HIV prevalence has continued to rise due to increased access to treatment, improved treatment regimens, and the longer lifespan of people living with HIV (UNAIDS, 2012). In 2011, an estimated 34 million people were living with HIV and about 2.5 million people became newly infected with the virus. Of those newly infected, 330,000 were children. Although HIV continues to affect all regions of the world, the greatest burden of HIV falls on Sub-Saharan Africa, which is home to 69 percent of people living with HIV and, in 2011, had the highest number of new HIV infections. Asia is the second most affected region due to the large size of its population, with nearly 5 million people living with HIV in South, South-East, and East Asia combined; the Caribbean follows Sub-Saharan Africa in prevalence of HIV in adults (UNAIDS, 2012).

Due to successful scale-up of antiretroviral therapy (ART), people with HIV are living longer and healthier lives (UNAIDS, 2012). Nonetheless, despite the increased availability of ART, HIV/AIDS is still a major cause of death across the world. In 2011, AIDS led to the death of an estimated 1.7 million people and was a leading cause of death among people aged 15 to 49 years old in sub-Saharan Africa (UNAIDS, 2012).

The impact of HIV is felt at all levels within countries--it shortens life expectancy, changes population demographics, and overloads health and social systems (UNAIDS and WHO, 2009). The epidemic has had a drastic socioeconomic effect on countries that are already under-resourced, and has required significant political and financial commitment from both the national governments of affected countries and the international community (OGAC, 2009a).

HISTORY OF U.S. INVESTMENT TO RESPOND TO GLOBAL HIV/AIDS

The U.S. government (USG) first began addressing HIV in low-income countries in the 1980s. HIV/AIDS funding through the United States Agency for International Development (USAID) grew from $1.1 million in fiscal year (FY) 1986 to $433 million in FY 2001 (USAID, 2009). A Kaiser Family Foundation report found that the U.S. was the largest donor of HIV/AIDS assistance funds in the world in 1996 and 1997, accounting for 49 percent of total contributions (Alagiri, 2001). In 1999, the Clinton Administration initiated the $100 million Leadership and Investment in Fighting an Epidemic initiative, which supported funding increases that would be directed to prevention, care and treatment, and capacity and infrastructure development (USAID, 2000). Continuing the trend, in 2002 President Bush launched a $500 million program to reduce mother-to-child transmission by as much as 40 percent, called the International Mother and Child HIV Prevention Initiative. This program aimed to reach up to 1 million women each year in 12 African countries, the Caribbean region, and 2 focus Caribbean countries. The program expanded national prevention of mother-to-child transmission (PMTCT) programs and facilitated linkages between PMTCT services and care and treatment for infants, mothers, and family members. The activities in this program were managed by various USG agencies such as USAID and the Centers for Disease Control and Prevention (CDC) (CRS, 2003; Kaiser Family Foundation, 2009; Shaffer et al., 2004; White House, 2002).

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The U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003

In his 2003 State of the Union address, President Bush asked the U.S. Congress to authorize $15 billion over 5 years to address the urgent and severe crisis of HIV/AIDS globally (Bush, 2003). Congress authorized this initiative just a few months later through the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (henceforth, the Leadership Act),[2] and it became the largest investment that any donor had made for combating a single disease. The authorizing legislation clearly articulated the urgent need to scale-up and rapidly implement HIV services and interventions in the countries most affected.

The funding was directed toward the establishment and scale-up of prevention, care, and treatment programs with the aim of reaching the following performance targets: preventing 7 million new HIV infections by 2010, treating 2 million HIV-infected people with antiretroviral (ARV) drugs by 2008, and providing care for 10 million people infected with and affected by HIV/AIDS (including orphans and vulnerable children) by 2008. Two-thirds of the $15 billion budget, the bulk of this initial, intense PEPFAR investment, was to be specifically directed toward the same countries targeted in the International Mother and Child HIV Prevention Initiative; together the burden of HIV in these countries accounted for more than 50 percent of the global HIV prevalence. These were countries with limited resources and infrastructure with which to address the epidemic. They later became known, with the addition of Vietnam, as the "focus countries."[3]

Even with the sense of urgency and the focus on scale up of services, the authorizing legislation also acknowledged the need for sustainability. Many of the programs and activities that had already been initiated by prior USG efforts, such as the operation and management of supply chains for essential medicines, HIV counseling and testing, PMTCT, and care and treatment services for HIV-positive parents and their children, would need to not only continue in the future but also be expanded to national level programs in a coherent manner. The Leadership Act also emphasized programs that specifically address the vulnerabilities of women and children, the development and strengthening of health care systems and human resources, and the necessity of periodic monitoring and evaluation (M&E).

The legislation stipulated that an effective distribution of funds would be 55 percent for treatment, 15 percent for palliative care, 20 percent for HIV/AIDS prevention, and 10 percent for orphans and vulnerable children.[4] It further specified the following budgetary allocation requirements:

- "not less than 55 percent…shall be expended for therapeutic medical care" for those with HIV, of which "at least 75 percent should be expended for the

[2] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong., 1st Sess. (May 27, 2003).

[3] The 15 focus countries are Republic of Botswana, the Republic of Côte d'Ivoire, the Federal Democratic Republic of Ethiopia, the Cooperative Republic of Guyana, the Republic of Haiti, the Republic of Kenya, the Republic of Mozambique, the Republic of Namibia, the Federal Republic of Nigeria, the Republic of Rwanda, the Republic of South Africa, the United Republic of Tanzania, the Republic of Uganda, the Socialist Republic of Vietnam, and the Republic of Zambia. These countries are named in the Leadership Act, with the exception of Vietnam, which was added later.

[4] *Supra*, note 2at § 402(b).

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purchase and distribution of antiretroviral pharmaceuticals" and "at least 25 percent should be expended for related care";[5]

- "not less than 33 percent" of funds allocated for prevention "shall be expended for abstinence-until-marriage" programs;[6,7] and
- "not less than 10 percent…shall be expended for assistance for orphans and vulnerable children affected by HIV/AIDS."[8]

PEPFAR's goals, budgetary allocations, and targets are summarized later in this chapter in Table 1-2.

The authorizing legislation also imposed the restrictions that "no funds made available to carry out this Act, or any amendment made by this Act, may be used to promote or advocate the legalization or practice of prostitution or sex trafficking"[9] nor "to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking."[10] The authorizing legislation also noted that nothing in this restriction should "be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides."[11] The history of these budgetary requirements and of the funding restrictions on implementation of programs are discussed in subsequent chapters of this report.

The Leadership Act described the essential elements for program implementation. It mandated that: (1) the President institute a comprehensive and integrated 5-year strategy to control HIV/AIDS globally by focusing on prevention, care, and treatment; (2) priorities be assigned to pertinent executive branches; (3) agencies improve coordination and cooperation; (4) resources be used to accomplish the projected goals; and (5) resources be coordinated with relevant assistance from multilateral organizations, foreign country governments, international organizations, and governmental and non-governmental organizations.

The legislation also created the position of the U.S. Global AIDS Coordinator (the Coordinator), which sits within the U.S. Department of State (DoS) and holds the rank of ambassador.[12] The President, with the advice and approval of the Senate, appoints the Coordinator, who then is accountable for overseeing and coordinating all U.S. resources and programs used to combat HIV/AIDS globally. The first Coordinator was Ambassador Randall Tobias (2003-2006), who presented the first Five-Year Global HIV/AIDS Strategy to Congress in 2004. Ambassador Mark R. Dybul followed Tobias (2006-2009), and the current Coordinator is Ambassador Eric Goosby.

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[5] *Supra*, note 2at § 403(a).
[6] *Ibid*., § 403(a).
[7] "Abstinence-until-marriage" programs were later referred to using the term "abstinence and be faithful" or "AB." USG-supported HIV prevention programs are discussed in depth in Chapter 5.
[8] *Supra*, note 2 at § 403(b).
[9] *Ibid*., § 301(e).
[10] *Ibid*., § 301(f).
[11] *Ibid*., § 301(e).
[12] *Ibid*., § 102.

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The President's Emergency Plan for AIDS Relief: First Five-Year Strategy

The first U.S. Five-Year Global HIV/AIDS Strategy, instituted in response to the legislation's mandate, was titled "The U.S. President's Emergency Plan for AIDS Relief." This generated the acronym PEPFAR, which has become the common name for the program.[13] As described above, the initiation of PEPFAR did not represent a zero baseline for USG investment in global HIV programs — rather, it was a major scale up and expansion of programs with an articulated central mission and reorganization with a new coordinating mechanism, as detailed in the Five-Year Strategy. The organizational infrastructure used to implement PEPFAR is described in detail in Chapters 3 and 4.

The Five-Year Strategy laid out three overarching goals to guide program development: (1) to promote strong leadership at all levels to combat HIV/AIDS; (2) to utilize best practices within bilateral HIV/AIDS prevention, care, and treatment programs, in harmony with the policies and goals of national HIV/AIDS strategies employed by partner governments; and (3) to work with multilateral organizations, partner governments, and other partners to ensure coordination at all levels, to apply best practices, to adhere to sound management practices, and to harmonize M&E between partners to ensure efficiency and effectiveness (IOM, 2007). The initial strategy also specified several principals to guide these goals, including: respond urgently to the HIV/AIDS crisis; seek novel approaches; devise ways in which to measure goals and ensure accountability; develop and implement programs that align with the objectives of partner countries; integrate prevention, care, and treatment programs; and build and strengthen national capacity (OGAC, 2004).

As described in the Five-Year Strategy, the initiation of PEPFAR not only included significant new resources in the focus countries, but also renewed commitment and consolidation of policy and leadership for all bilateral USG HIV/AIDS programs. This encompassed programs through USAID, the Department of Health and Human Services, the Department of Defense, the Department of Labor, and the Peace Corps in more than 100 countries in diverse geographical regions (Table 1-1), as well as State Department public diplomacy and small-scale HIV/AIDS prevention programs in many countries (OGAC, 2004).

[13] Hereinafter in this report, the program across its entire history will be referred to as PEPFAR. When a distinction is made between phases of the program, the program during the years covered in the first legislation and Five-Year Strategy (2004-2008) will be referred to as PEPFAR I while the program during the years since the reauthorization legislation and second Five-Year Strategy (2009-2013) will be referred to as PEPFAR II.

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TABLE 1-1 PEPFAR HIV/AIDS Programs in 2004

Region/Country	USAID	HHS	DOD	DOL	Peace Corps
Sub-Saharan Africa					
1 Angola	B	B	B		
2 Benin	B		B	B	V
3 **Botswana**	R	B	B	B	V
4 Burkina Faso	R		B		V
5 Burundi	R		B		
6 Cameroon	R		B		V
7 Cape Verde	R				
8 Chad	R		B		V
9 Congo, D.R. of	B	B	B		
10 **Côte d'Ivoire**	R	B			
11 Djibouti	R				
12 Eritrea	B		B		
13 **Ethiopia**	B	B	B	B	
14 Gabon			B		V
15 Gambia, The	R				
16 Ghana	B		B	B	V
17 Guinea Bissau	R				
18 **Kenya**	B	B	B	B	V
19 Lesotho	R		B	B	V
20 Liberia	R				
21 Madagascar	B		B		V
22 Malawi	B	B	B	B	V
23 Mali	B		B		V
24 Mauritania	B				
25 **Mozambique**	B	B	B	B	V
26 **Namibia**	B	B	B	B	V
27 Niger	R				V
28 **Nigeria**	B	B	B	B	
29 **Rwanda**	B	B			
30 Senegal	B	B	B		V
31 Sierra Leone	R		B		
32 Somalia	R				
33 **South Africa**	B	B	B	B	V
34 Sudan	R				
35 Swaziland	R		B	B	V
36 **Tanzania**	B	B	B	B	V
37 Togo	R		B	B	V
38 **Uganda**	B	B	B	B	V
39 **Zambia**	B	B	B	B	V
40 Zimbabwe	B	B	B	B	
Asia and Near East:					
41 Bangladesh	B				
42 Burma	R				
43 Cambodia	B	B	B	B	
44 China	R	B			
45 East Timor	R				
46 Egypt	B		B		
47 India	B	B	B	B	
48 Indonesia	B		B	B	
49 Jordan	B				
50 Laos	R			B	
51 Nepal	B			B	V
52 Papua New Guinea	R				
53 Philippines	B				
54 Thailand	R	B	B		
55 Vietnam	R	B	B	B	
56 West Bank/Gaza	B				

NOTE: B = bilateral program; R = regional program; V = volunteers. The 14 focus countries named in the original authorizing legislation are in bold.
SOURCE: Appendix F from PEPFAR's First Five Year Strategy (OGAC, 2004).

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TABLE 1-1 Continued

Region/Country	USAID	HHS	DOD	DOL	Peace Corps
Europe and Eurasia:					
57 Albania	B				V
58 Armenia	B				
59 Azerbaijan	B				
60 Belarus	B				
61 Bosnia	R				
62 Bulgaria	R				
63 Croatia	R				
64 Estonia	R				
65 Georgia	B		B		
66 Kazakhstan	B		B		V
67 Kosovo	B				
68 Kyrgyzstan	R		B		
69 Latvia	R				
70 Lithuania	R				
71 Macedonia	R				
72 Moldova	B				
73 Romania	B	B		B	V
74 Russia	B		B		
75 Serbia	R				
76 Tajikistan	R		B		
77 Turkmenistan	R				V
78 Ukraine	B		B	B	V
79 Uzbekistan	R		B		V
Latin America and the Caribbean					
80 Antigua & Barbuda	R				V
81 Argentina			B		
82 Bahamas		B			
83 Barbados	R				
84 Belize	R		B	B	V
85 Bolivia	B		B		V
86 Brazil	B	B	B		
87 Chile			B		
88 Colombia			B		
89 Costa Rica		B	B		
90 Dominica	R				V
91 Dominican Republic	B	B		B	V
92 Ecuador			B		V
93 El Salvador	B				V
94 Grenada					V
95 Guatemala	B				V
96 Guyana	B	B		B	V
97 Haiti	B	B		B	V
98 Honduras	B	B	B		V
99 Jamaica	B	B			V
100 Mexico	B				
101 Nicaragua	B				V
102 Panama	R		B		V
103 Paraguay			B		V
104 Peru	B	B	B		V
105 St. Lucia	R				V
106 St. Kitts and Nevis	R				V
107 St. Vincent & Grenadines	R				V
108 Suriname	R				V
109 Trinidad and Tobago	R	B			
110 Uruguay			B		
111 Venezuela			B		

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IOM Prior Evaluation of PEPFAR: "PEPFAR Implementation: Progress and Promise"

Three years after PEPFAR's authorization, the Institute of Medicine (IOM) evaluated its implementation in a study that was mandated by the Leadership Act. The IOM convened an independent committee of experts, 3 subcommittees, and several consultants to design and conduct the study, and provided Congress with a report in 2007 for use as it considered reauthorization of the program (IOM, 2007). The IOM evaluation focused on PEPFAR implementation in the 15 focus countries and was primarily a process evaluation. The evaluation did not cover the contributions of the United States to the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) (IOM, 2005).

The first IOM evaluation centered on the idea of "harmonization" and focused on PEPFAR's contribution to capacity building in partner countries to address HIV/AIDS. The evaluation was based in part on the "Three Ones" principles that UNAIDS, host countries, donor countries, and international organizations endorsed as guiding principles of harmonization. According to these principles, countries are encouraged to have one agreed upon HIV/AIDS Action Framework, one National HIV/AIDS Coordinating Authority, and one HIV/AIDS country-level M&E system in order to strengthen the country-level response to HIV/AIDS as well as reduce transactional business costs between countries and donors (UNAIDS, 2004).

The evaluation employed a wide range of methods, including six meetings for information-gathering and deliberations; reviews of scientific and other literature as well as PEPFAR documents; and discussions with a range of stakeholders, including PEPFAR staff, in-country implementation partners, and other donors and stakeholders. The committee also analyzed budget and program performance from PEPFAR I (IOM, 2007). Between October 2005 and February 2006, the committee visited 13 of the 15 focus countries to directly observe implementation activities. The committee was not able to visit Côte d'Ivoire or Haiti due to security concerns, but it did hold conference calls with country teams and implementing partners in these countries (IOM, 2007). The committee synthesized the observations, findings and conclusions that emerged as common across the country visits and triangulated these syntheses with information from other documents and interviews in order to make conclusions about significant components of PEPFAR I implementation (IOM, 2007).

The first IOM evaluation concluded that PEPFAR had made good strides toward meeting its performance targets in the first 2 years, and that it had laid a foundation for reaching the longer-term goals of the Leadership Act. The committee also recognized PEPFAR's contribution to the research, communication, dissemination, and global evidence base of HIV/AIDS information. The evaluation emphasized the need for PEPFAR to transition from an emergency response to a program that fosters the sustainability that will be needed to achieve long-term goals while still expanding HIV/AIDS services, and noted that PEPFAR had significantly improved capacity-building efforts to support this transition (IOM, 2007).

The 2007 IOM evaluation's recommendations can be summarized in the following main messages. PEPFAR should (1) address long-term factors by expanding prevention strategies including for key populations, improving the status of women and girls, and strengthening workforce capacity; (2) develop a strategy to institutionalize its role as a learning organization and to expand the knowledge base by conducting and publishing research; (3) harmonize its policies and activities with international and national stakeholders, particularly for strategic planning and monitoring and evaluation; (4) remove budget allocation requirements, which the evaluation report concluded had limited PEPFAR's ability to tailor its activities to the specific needs of each country and to coordinate with national plans; (5) establish performance targets for

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the care of orphans and vulnerable children; and (6) expand, improve, and integrate services using evidence-based strategies and supporting adequate availability of antiretrovirals, the use of local capacity, and provision of community-based, family-centered services (IOM, 2007).

Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008

The U.S. Congress passed the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (the Lantos-Hyde Act of 2008) on July 30, 2008.[14] This reauthorization legislation extended the USG's commitment to global HIV/AIDS programs for another 5 years, from 2009 to 2013 (PEPFAR II)[15] and provided continuity of support in the core program areas that had been initiated by PEPFAR I. The legislation authorized up to $39 billion for PEPFAR bilateral HIV/AIDS programs as well as U.S. contributions to the Global Fund. The major contrast in the reauthorization from the original legislation was a focus on a transition to activities and goals that would use different tools and processes for the USG to contribute to a more independent and sustainable response in and by partner countries to their HIV epidemics. The act called for a new 5-year global strategy to maintain the gains made to date in the program areas supported by PEPFAR; ensure the role of civil society in the response; to provide capacity-building assistance to countries; and identify appropriate criteria, methods, and measures to encourage transparency and benchmarks for success for the framework agreements between partner countries and external donors for sustainability and accountability.

The Lantos-Hyde Act of 2008 set performance targets that included the prevention of 12 million new infections worldwide (no proportional goal was stated for women or children), the provision of care for 12 million people living with or affected by HIV/AIDS including 5 million orphans and other children made vulnerable by HIV/AIDS, and the training and retention of 140,000 new health care workers.[16] The reauthorization legislation also established the goal of supporting the provision of antiretroviral therapy (ART) to people with HIV/AIDS, beyond the initial goal of 2 million under the Leadership Act of 2003, and set new programmatic requirements, many of which were related to prevention activities. In addition, it removed almost all of the highly specific fiscal benchmarks that were instituted in the original legislation. The benchmarks remaining were the target that set aside 10 percent of funding for orphans and vulnerable children, and an earmark that required at least half of the funds to be spent on ART and other treatment services. For prevention, the Lantos-Hyde Act of 2008 now requires the Coordinator to establish a balanced HIV sexual transmission prevention strategy to govern expenditures for prevention activities in countries with generalized epidemics. This "balanced funding" directive replaced the 20 percent earmark for prevention, with one-third earmarked for abstinence programs, from the original 2003 legislation. Instead of identifying a specific requirement for the distribution of funds for prevention of sexual transmission, programs in

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[14] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

[15] In this report the program across its entire history is referred to as PEPFAR. When a distinction is made between phases of the program, the program during the years covered in the first legislation and Five-Year Strategy (2004-2008) is referred to as PEPFAR I while the program during the years since the reauthorization legislation and second Five-Year Strategy (2009-2013) is referred to as PEPFAR II.

[16] *Supra.*, note 14 at § 101(a), 22 U.S.C. 7611(a)(4)(J).

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countries with generalized epidemics are now required to provide a compelling explanation, justified by the Coordinator, if less than 50 percent of prevention funding is directed toward activities promoting (a) abstinence, (b) delay of sexual debut, (c) monogamy, (d) fidelity, and (e) partner reduction. These programs are to be "implemented and funded in a meaningful and equitable way … based on objective epidemiological evidence as to the source of infections and in consultation with the government of each host county involved in HIV/AIDS prevention activities."[17]

Second PEPFAR Five-Year Strategy

In December 2009, Ambassador Goosby released a new legislatively required PEPFAR Five-Year Strategy, which included the targets written into the reauthorization legislation, but specified that the treatment target should provide direct support for over 4 million people (OGAC, 2009a). Unlike the legislation, this Five-Year Strategy extended the timeframe of these performance targets through FY 2014, rather than FY 2013 (OGAC, 2009a). The new strategic plan established the future direction of PEPFAR II and, based on the areas of emphasis in the reauthorization legislation, identified the need to "(1) transition from an emergency response to promotion of sustainable country programs; (2) strengthen partner government capacity to lead the response to this epidemic and other health; (3) expand prevention, care, and treatment in both concentrated and generalized epidemics; (4) integrate and coordinate HIV/AIDS programs with broader global health and development programs to maximize impact on health systems; and (5) invest in innovation and operations research to evaluate impact, improve service delivery, and maximize outcomes" (OGAC, 2009a).

The evolution of PEPFAR's goals, budgetary allocations, and targets over time is summarized in Table 1-2.

[17] *Supra.*, note 14 at § 403(1), 22 U.S.C. 7673(a)(1)(B).

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TABLE 1-2 Summary of PEPFAR's goals, budgetary requirements, and targets.

Goals from PEPFAR Five-Year Strategies	
PEPFAR I	**PEPFAR II**
1. Encourage bold leadership at every level to fight HIV/AIDS 2. Apply best practices within bilateral HIV/AIDS prevention, treatment, and care programs, in concert with the objectives and policies of host governments' national HIV/AIDS strategies 3. Encourage partners, including multilateral organizations and other host governments, to coordinate at all levels to strengthen response efforts, to embrace best practices, to adhere to principles of sound management, and to harmonize monitoring and evaluation efforts to ensure the most effective and efficient use of resources	1. Transition from an emergency response to promotion of sustainable country programs 2. Strengthen partner government capacity to lead the response to the HIV epidemic and other health demands 3. Expand prevention, care, and treatment in both concentrated and generalized epidemics 4. Integrate and coordinate HIV/AIDS programs with broader global health and development programs to maximize impact on health systems 5. Invest in innovation and operations research to evaluate impact, improve service delivery and maximize outcomes

PEPFAR Budgetary Allocation Requirements	
Authorizing Legislation 2003	**Reauthorization Legislation 2008**
Therapeutic medical care: Not less than 55 percent, of which at least 75 percent for the purchase and distribution of antiretrovirals and at least 25 percent for related care	Care and Treatment: More than 50 percent for antiretroviral treatment for HIV/AIDS; clinical monitoring of HIV-seropositive people not in need of antiretroviral treatment; care for associated opportunistic infections; nutrition and food support for people living with HIV/AIDS; and other essential HIV/AIDS-related medical care for people living with HIV/AIDS
Palliative care: 15 percent	
Prevention: 20 percent, of which not less than 33 percent for abstinence-until-marriage programs	Prevention: Balanced funding for prevention activities for sexual transmission of HIV/AIDS, based on objective epidemiological evidence and in consultation with the governments of partner countries involved in HIV/AIDS prevention activities. For countries with a generalized epidemic, justification is required if less than 50 percent of this funding is allocated for promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction [a]
Orphans and vulnerable children: Not less than 10 percent	Orphans and vulnerable children: Not less than 10 percent

[a] New prevention technologies or modalities (e.g. male circumcision) are not included when calculating this funding breakdown.

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PEPFAR Targets			
Leadership Act of 2004 and First Five-Year Strategy (FY 2004–2008)	**Lantos-Hyde Reauthorization Act (Through FY 2013)**	**PEPFAR Strategy (Through FY 2014)**	**Presidential Declaration, World AIDS Day, 2011 (Through 2013)**
Treatment for 2 million	Treatment for at least 3 million	Treatment for more than 4 million	Treatment for more than 6 million
Prevention of 7 million new infections	Prevention of 12 million new infections		
Reduce the rate of maternal-to-child transmission by 20 percent by 2005 and 50 percent by 2010	80 percent access to counseling, testing, and treatment to prevent the transmission of HIV from mother to child	80 percent coverage of testing for pregnant women; 85 percent coverage of antiretroviral prophylaxis, and treatment as indicated, for HIV-positive pregnant women; 480,000 babies of HIV-positive mothers born HIV-negative	
		65 percent coverage of early infant diagnosis and 80 percent coverage of testing for older children of HIV-positive mothers	
Provision of care to 10 million, including orphans and vulnerable children	Provision of care to 12 million, including 5 million orphans and vulnerable children		
	Care and treatment services to children with HIV in proportion to their percentage within the HIV-infected population		
	Training and retention of 140,000 new health care workers	Training and retention of more than 140,000 new health care workers	
		Ensure that in countries with a major PEPFAR investment (greater than $5 million), the partner government leads efforts to evaluate and define needs and roles in the national response	
		Ensure that every partner country with a Partnership Framework will change policies to address larger structural conditions, such as gender-based violence, stigma, or low male partner involvement that contribute to the epidemic	

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Changes in PEPFAR Since the Lantos-Hyde Act and the Second Five-Year Strategy

Since the reauthorization of PEPFAR, as the implementation of the second five-year strategy has progressed, some additional key developments have taken place. The number of partner countries in which the intensity of PEPFAR implementation warrants management through the annual Country Operational Plan (COP) process has expanded from the original fifteen focus countries. In 2009, when the scope of this evaluation was established, an additional 16 countries were preparing COPs for a total of 31 countries; by FY 2011, this had increased to 33. There are also 3 regions for which one COP is submitted for operations in multiple countries[18] (GAO, 2011).

Several new initiatives have been instituted that are targeted at aims articulated in the reauthorization legislation and the second Five-Year Strategy. As part of the effort to meet the goals of training new health care workforce, PEPFAR established the Medical Education Partnership Initiative and the Nursing Education Partnership Initiative (described further in Chapter 9). In addition, a "New Partners Initiative/Local Capacity Initiative" was launched to encourage a greater emphasis on capacity building for partner organizations in partner countries (described further in Chapter 10).

New scientific evidence has emerged that has affected or will affect decisions about the programs supported and implemented through PEPFAR, such as evidence on voluntary male circumcision and the use of antiretrovirals as prevention in serodiscordant couples. Building on the evolving implementation of PEPFAR and the evolving evidence base, Secretary Clinton articulated PEPFAR's commitment to the goal of achieving an "AIDS-free generation" by focusing on combination prevention, treatment as prevention, voluntary medical male circumcision, and ending the transmission of HIV from mothers to children (Clinton, 2011). Furthermore, in December 2011, on World AIDS Day, President Obama announced the expansion of the treatment target to providing treatment to more than 6 million people by the end of 2013 (Obama, 2011).

At the meeting of the International AIDS Society in July 2012, PEPFAR announced several new investments, including "$80 million to support innovative approaches that ensure HIV-positive pregnant women get the treatment they need to protect themselves, their babies, and their partners; $40 million to support South Africa's plans to provide voluntary medical male circumcisions for almost half a million boys and men in the coming year; $15 million for implementation research to identify the specific interventions that are most effective for reaching key populations; $20 million to launch a challenge fund that will support country-led plans to expand services for their key populations; and $2 million for the Robert Carr Civil Society

[18] The original 15 focus countries are Botswana, Republic of Côte d'Ivoire, Federal Democratic Republic of Ethiopia, Cooperative Republic of Guyana, Republic of Haiti, Republic of Kenya, Republic of Mozambique, Republic of Namibia, Federal Republic of Nigeria, Republic of Rwanda, Republic of South Africa, United Republic of Tanzania, Republic of Uganda, Socialist Republic of Vietnam, and Republic of Zambia. The following additional countries began submitting country operational plans in time to be considered part of the emphasis of this evaluation: Republic of Angola, Kingdom of Cambodia, People's Republic of China, Democratic Republic of the Congo, Dominican Republic, Republic of Ghana, Republic of India, Republic of Indonesia, Kingdom of Lesotho, Republic of Malawi, Russian Federation, Republic of the Sudan, Kingdom of Swaziland, Kingdom of Thailand, the Ukraine, and the Republic of Zimbabwe. The following two countries were added more recently: Cameroon and Burundi. The regional COPs are in the Caribbean, Central America, and Central Asia.

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Networks Fund to bolster the efforts of civil society groups in addressing key populations" (Clinton, 2012).

In November 2012, PEPFAR released a "blueprint" that is intended to provide "a road map that clearly outlines PEPFAR's contribution to achieving an AIDS-free generation" which it defines as a generation in which "virtually no children are born with the virus. As these children become teenagers and adults, they are at far lower risk of becoming infected than they would be today thanks to a wide range of prevention tools, and if they do acquire HIV, they have access to treatment that helps prevent them from developing AIDS and passing the virus on to others." (OGAC, 2012, p. 4). The blueprint emphasizes the principles of scaling up services, shared responsibility among the full range of stakeholders in the HIV response, focusing on women and girls to increase gender equality in HIV services, ending stigma and discrimination that contribute to the HIV epidemic, and adapting to and adopting new science and evidence for both effective implementation of interventions and capturing cost-saving efficiencies (OGAC, 2012).

In addition to these PEPFAR-specific developments since the reauthorization legislation, in May 2009 the Obama Administration announced a new 6-year Global Health Initiative (GHI) as an approach to institute "integrated, coordinated and results-driven global health investments" (GHI, 2012a). The GHI's initial consultation document described how it would incorporate PEPFAR's strategic cumulative goals within a comprehensive U.S. global health policy (DOS, 2010), and PEPFAR's second Five Year strategy indicated how PEPFAR can help leverage current USG investments in global health as a part of the GHI (OGAC, 2009b). Initially, a new GHI office, with an Executive Director, was created at the State Department to coordinate efforts among the three agencies that oversee most U.S. global health programs, USAID, CDC, and OGAC. In July 2012, this office was closed, with the three core agencies to continue a collaborative leadership structure directed by the ongoing mandate to ensure implementation of GHI principles in the field. At the same time, a new Office of Global Health Diplomacy was created at the State Department with a mandate not for coordination but for advancing GHI priorities and policies as a component of U.S. foreign relations (GHI, 2012b; Kaiser Family Foundation, 2012). In December 2012, the current U.S. Global AIDS Coordinator, Ambassador Eric Goosby, was named to also lead the Office of Global Health Diplomacy (Goosby, 2012; McNeil Jr., 2012).

Finally, it is also important to note that in addition to bilateral HIV programs in partner countries, the scope of the U.S. response to global HIV/AIDS has also included major investments in funding to the Global Fund and in support for basic research related to HIV, primarily through the U.S. National Institutes of Health.

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———. 2009. *USAID's HIV/AIDS annual budget*. http://www.usaid.gov/our_work/global_health/aids/Funding/index.html (accessed May 6, 2010).

White House. 2002. *Fact Sheet: President Bush's International Mother and Child HIV Prevention Initiative*. http://georgewbush-whitehouse.archives.gov/news/releases/2002/06/20020619-1.html (accessed January 28, 2013).

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2

Evaluation Scope and Approach

CONGRESSIONAL CHARGE

As described in Chapter 1, the United States government currently supports programs to combat global HIV/AIDS through an initiative known as the President's Emergency Plan for AIDS Relief (PEPFAR). This initiative was originally authorized in the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003[1] and subsequently reauthorized in the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (hereinafter, the Lantos-Hyde Act of 2008).[2] A description of the history and evolution of the PEPFAR initiative can be found in Chapter 1.

In the Lantos-Hyde Act of 2008 which reauthorized PEPFAR, the U.S. Congress mandated that the Institute of Medicine (IOM) conduct a study that includes "an assessment of the performance of United States-assisted global HIV/AIDS programs" and "an evaluation of the impact on health of prevention, treatment, and care efforts that are supported by United States funding, including multilateral and bilateral programs involving joint operations."[3] The legislation further specified that the study include the following:

> (i) an assessment of progress toward prevention, treatment, and care targets;
> (ii) an assessment of the effects on health systems, including on the financing and management of health systems and the quality of service delivery and staffing;
> (iii) an assessment of efforts to address gender-specific aspects of HIV/AIDS, including gender-related constraints to accessing services and addressing underlying social and economic vulnerabilities of women and men;
> (iv) an evaluation of the impact of treatment and care programs on 5-year survival rates, drug adherence, and the emergence of drug resistance;
> (v) an evaluation of the impact of prevention programs on HIV incidence in relevant population groups;

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[1] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong., 1st Sess. (May 27, 2003).
[2] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).
[3] *Ibid*., at § 101(c), 22 U.S.C. 7611(c).

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(vi) an evaluation of the impact on child health and welfare of interventions authorized under the Act on behalf of orphans and vulnerable children;
(vii) an evaluation of the impact of programs and activities authorized in the Act on child mortality; and
(viii) recommendations for improving [*United States-assisted global HIV/AIDS*] programs. [4]

PLANNING PHASE FOR THE EVALUATION

In the first phase of the study, the IOM formed a multidisciplinary ad hoc committee to develop a strategic plan for the assessment and evaluation of U.S.-supported global HIV/AIDS programs as requested in the Lantos-Hyde Act of 2008. In developing the plan, the planning committee engaged in deliberations through 3 in person meetings, 2 committee teleconferences, and telephonic and electronic communications as needed among working groups composed of subsets of the committee. To inform these deliberations, the planning committee held public sessions to solicit input and gather information from a broad range of stakeholders involved in and affected by PEPFAR. Delegations from the planning committee and IOM project staff also held information-gathering meetings with a range of global stakeholders, including the Global Fund, the Joint United Nations Progamme on HIV and AIDS (UNAIDS), the World Health Organization (WHO), and the United Nations Children's Fund (UNICEF) to discuss potential data sources, methodologies, and lessons learned from experiences with large-scale evaluations. The planning committee and staff also explored potential data sources for the evaluation by consulting and reviewing a range of resources, including documents from and the Office of the U.S. Global AIDS Coordinator (OGAC) and other bilateral and multilateral agencies, relevant published literature on PEPFAR and global HIV/AIDS, available literature on large-scale program evaluation, and communications with staff from OGAC, implementing partners, and multilateral stakeholders.

The planning committee used the information gathered to assess the methods and anticipated data sources that could potentially be employed to respond, to the extent possible, to the charge in the statement of task. The planning committee focused on identifying data and methodology that would be robust, available, feasible, and appropriate. This was a preliminary exploration of the identified data sources, carried out within the time and resources available for the planning phase. The planning committee could not make conclusive determinations about the suitability of some data sources and therefore, the feasibility of some methodological approaches. Therefore, as described in the sections that follow and throughout the report, a more thorough examination and assessment to make these determinations was carried out as data were requested, reviewed, and collected in the subsequent phases of the evaluation.

Through this information gathering and deliberation, the planning committee developed a conceptual framework for the evaluation that was based on both the committee's expertise and current standards in evaluation methodologies for large-scale programs. The planning phase culminated with the publication of a report describing this conceptual framework and the proposed strategic approach to the evaluation, taking into consideration the requirements for the congressional mandate (IOM and NRC, 2010).

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[4] *Supra*., note 2 at § 101(c), 22 U.S.C. 7611(c)(2)(B).

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The following sections of this chapter describe how the evaluation itself was subsequently implemented. To conduct the evaluation, the IOM convened an evaluation committee whose members represented the appropriate expertise for the evaluation scope and approach as defined and articulated in the planning phase. There was significant overlapping membership between the planning committee and the evaluation committee. More information about the members of the evaluation committee can be found in Appendix D.

INTERPRETATION OF THE CHARGE

Scope of the Evaluation

As part of the planning phase, the scope of the evaluation was determined based on the planning committee's interpretation of the legislatively mandated statement of task. The primary content areas for the evaluation were specified in the Lantos-Hyde Act of 2008.[5] As described above, this legislative mandate requested an assessment of the performance of PEPFAR and an evaluation of the impact on health of PEPFAR's prevention, treatment, and care efforts. More specifically, the mandate requested that the evaluation include an assessment of progress toward meeting PEPFAR's performance goals and targets, which are laid out in the legislation and the PEPFAR Five-Year Strategies (OGAC, 2004, 2009b). The mandate also specifically requested that the evaluation of PEPFAR include the impact of HIV treatment, care, and prevention programs; the effects on health systems; the efforts to address gender-specific aspects of HIV/AIDS; and the impact of programs on child health and wellbeing.

In the *Strategic Approach*, the planning committee identified three additional content areas that were not explicitly identified in the legislation but were determined to be critical elements underlying the assessment of the specific content areas requested by Congress. First, the committee deemed it important to review PEPFAR funding in order to determine the level of PEPFAR's investment and to gain insight into how financial support for programs and activities has been determined and distributed over time. Second, it found it essential to assess PEPFAR's progress in transitioning to a more sustainable response in partner countries, given that this was a major goal set forth in the Lantos-Hyde Act of 2008 and the second PEPFAR Five-Year Strategy. Finally, the committee determined that assessing the performance of PEPFAR's activities to collect, manage, use, and share data, information, and knowledge was an important evaluation component because it is not only critical to the IOM's evaluation process but also to PEPFAR's own ability to successfully monitor and evaluate the activities and effects of its programs as well as to guide policies, priorities, and programmatic decisions (IOM and NRC, 2010).

The legislative mandate also requested recommendations for improving the U.S. government's bilateral programs as part of the U.S. response to the global HIV epidemic. Informed by its findings with regard to PEPFAR's progress toward its stated goals and the effects of the supported programs on health, the overall aim of the evaluation committee in its major conclusions and recommendations was to be forward-looking and anticipate the evolution of the U.S. response to global HIV and therefore, to be positioned to inform the U.S. government response to key issues under consideration at the time of the report release.

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[5] *Supra*., note 2 at § 101(c), 22 U.S.C. 7611(c).

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Further parameters for the scope of the evaluation were interpreted by the planning committee, informed where needed by clarifications discussed with congressional staff and OGAC.[6] The evaluation was defined as an assessment of the performance of PEPFAR and of the contribution of PEPFAR to changes in health outcomes and health impact. As described in more detail below, it is not feasible or appropriate to determine the direct attribution of PEPFAR funds to effects on health outcomes because PEPFAR is implemented in partner countries within the complex and diverse context of other funding sources, other HIV and health programs, and other factors that affect health outcomes.

As an assessment across the whole of PEPFAR, the evaluation was not intended to be an assessment of nor a comparison among specific countries, agencies, programs, or partners. It was also not intended to be an assessment of the organizational infrastructure and management of PEPFAR, nor a financial audit or assessment; these areas fall under the scope and mandate of other organizations external to PEPFAR that have issued reports of their assessments, including the U.S. Government Accountability Office and the Inspectors General of the Department of Health and Human Services, the U.S. Agency for International Development, and the Department of State.

As described in Chapter 1, PEPFAR has provided support to more than 100 countries over time. However, in order to represent the greatest intensity of PEPFAR's investment, the scope of this evaluation was defined to focus on the 31 partner countries submitting an annual Country Operational Plan (COP) at the time of the initiation of the planning phase for this evaluation in 2009.[7] In FY 2011, these 31 countries represented 96 percent of PEPFAR's planned funding (OGAC, 2011).[8] As specified in the chapters that follow, in some cases, the data presented in this report represent only a subset of these COP countries.

The legislative mandate describes an assessment of programs and efforts "that are supported by United States funding, including multilateral and bilateral programs involving joint operations."[9] This was clarified by congressional staff as a request to focus on the performance and impact of bilaterally funded PEPFAR programs, including those activities that are operated jointly with both bilateral funding through PEPFAR and funding through the Global Fund, which also receives a substantial proportion of its funding from the U.S. government. As described in the *Strategic Approach*, "Consistent with the clarified congressional intent, U.S. contributions to the Global Fund that are not a part of activities *jointly* funded or implemented by PEPFAR will not be the focus of the evaluation, and the evaluation will not compare the performance of

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[6] Personal communications from Congressional Staff of the U.S. House Committee on Foreign Affairs and U.S. Senate Committee on Foreign Relations and OGAC, 2009.

[7] The 31 PEPFAR countries submitting Country Operational Plans at the time of the planning phase include the original 15 focus countries (Botswana, Republic of Côte d'Ivoire, Federal Democratic Republic of Ethiopia, Cooperative Republic of Guyana, Republic of Haiti, Republic of Kenya, Republic of Mozambique, Republic of Namibia, Federal Republic of Nigeria, Republic of Rwanda, Republic of South Africa, United Republic of Tanzania, Republic of Uganda, Socialist Republic of Vietnam, and Republic of Zambia) as well as the following additional countries: Republic of Angola, Kingdom of Cambodia, People's Republic of China, Democratic Republic of the Congo, Dominican Republic, Republic of Ghana, Republic of India, Republic of Indonesia, Kingdom of Lesotho, Republic of Malawi, Russian Federation, Republic of the Sudan, Kingdom of Swaziland, Kingdom of Thailand, the Ukraine, and the Republic of Zimbabwe. (personal communication from OGAC, June 16, 2009).

[8] Planned/approved funding as reported in the FY 2011 PEPFAR Operational Plan. See Chapter 4 for more information on PEPFAR funding.

[9] *Supra*., note 2 at § 101(c), 22 U.S.C. 7611(c)(2)(A)(ii).

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bilateral PEPFAR programs to that of Global Fund programs" (Bressler, 2009; IOM and NRC, 2010, p. 19; Marsh, 2009).

The new U.S. Global Health Initiative (GHI) was launched subsequent to the Lantos-Hyde Act which mandated this evaluation (OGAC, 2009c). The scope of this evalaution does not include an evaluation of the GHI itself nor an assessment of the incorporation of PEPFAR's strategic cumulative goals within the GHI as a comprehensive U.S. global health policy approach (DOS, 2010).

Time Frame of the Evaluation

The evaluation encompasses PEPFAR's efforts since PEPFAR funding first became available in 2004. The time frame of the data collected and assessed by the evaluation committee varies by data type and data source. This is described in brief in the methods section of this chapter and in Appendix C, and details are also given at points throughout the report where the analysis and interpretation of the data are presented. The majority of data collection was completed before June 2012; however, some primary data collection through interviews was conducted as late as September 2012. Data requested from OGAC, implementing agencies, and implementing partners were received as late as October 2012. Recent developments in PEPFAR that were introduced since the main data collection period could not feasibly be assessed by the committee, although key recent developments are noted for context in Chapter 1 and in relevant content areas of subsequent chapters of this report.

OPERATIONAL PLANNING PHASE

The Department of State, as the study sponsor, agreed contractually that a transitional period for operational planning should take place between the delivery of the report describing the strategic plan and the implementation of the evaluation itself, which began in the fall of 2010. During this operation planning phase, OGAC partnered with the IOM to disseminate information about the purpose and process of the evaluation and to facilitate introductions to field, headquarters, and agency staff. The primary purpose of the operational planning phase was for IOM staff, planning committee members, and consultants to carry out activities to inform and prepare for the implementation of the evaluation. The operational planning activities focused on data mapping (to continue to identify and assess sources and availability of relevant data); mapping of methods and data sources, including key indicators, to the mandated evaluation tasks; developing procedures for data requests; initiating data requests; designing and initiating data quality review methods for data collected directly or received from outside sources; preparing background materials; and continued relationship building with relevant stakeholders such as contacts in PEPFAR countries and at implementing partner organizations. In addition, a major focus of the operational planning phase was to develop and refine processes, frameworks, methods, and instruments for qualitative data collection. This also included early planning of logistics for field work and training for IOM staff by expert consultants in qualitative methods and the use of qualitative analytical software. Additional pilot testing and refinement of field research methods and data collection instruments occurred during pilot visits to two PEPFAR countries, which took place in late 2010 and early 2011.

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CONCEPTUAL FRAMEWORK FOR THE EVALUATION

The following section describes the conceptual and methodological approach taken for evaluating the performance and impact of PEPFAR, while reiterating the context for reasonable and appropriate expectations for an evaluation of this kind as originally articulated in the report of the strategic approach to the evaluation (IOM and NRC, 2010).

Program Impact Pathway

The planning committee developed an overall conceptual framework that was subsequently used to carry out the evaluation. In this framework, a program impact pathway guided the assessment of the contribution of PEPFAR. The program impact pathway illustrates how PEPFAR-supported programs are intended to ultimately translate into health impact. It represents the theory of change that underlies PEPFAR—in other words, the rationale for how the combination of activities supported by PEPFAR are logically expected to produce intermediate outcomes, which are then expected to collectively contribute, along with programs funded by other sources, to the desired individual and population health impact. The use of a program impact pathway, which is also referred to as a logic model or results chain, is a well-established method for evaluating complex, large-scale development assistance programs and is becoming widely accepted as a standard in the global HIV/AIDS community (IOM and NRC, 2010; Leeuw and Vaessen, 2009; Monitoring and Evaluation Reference Group (MERG), 2010).

Figure 2-1 shows the program impact pathway developed to guide the assessment of PEPFAR. The pathway begins with the investments and other inputs to the program. For PEPFAR, inputs include not only funding and other resources but also strategic planning, programmatic and policy guidance, and technical assistance. These inputs support activities to provide services and support to children, adolescents, and adults in need. Although services are described by PEPFAR in categories like prevention, treatment, and care and support, the conceptual framework acknowledges that they are part of an interrelated and overlapping approach, which also includes activities around gender issues and capacity building. These activities result in outputs that are measureable proximal effects. When PEPFAR-supported programs are implemented well, these outputs are expected to produce outcomes as intermediate effects on the pathway to the ultimate goal of health impact. These intermediate outcomes include, for example, the delivery of high quality, efficient services that are available and accessible to the targeted populations and that are achieving the intended and appropriate coverage. Other target outcomes include, for example, health systems strengthening; changes in individual risk behavior; and changes in knowledge, norms, and attitudes that affect sexual behavior, stigma, and gender issues. Ultimately, PEPFAR-supported programs are intended, through this pathway, to contribute to an impact on individual and population health and well-being, including HIV incidence, HIV prevalence, morbidity, and mortality (IOM and NRC, 2010)). Among the inputs to this program impact pathway is the evolving evidence base. This is derived from evidence generated outside of PEPFAR and used to inform PEPFAR-supported programs as well as from data, information, and other forms of knowledge that are generated through PEPFAR-supported activities in monitoring, evaluation, epidemiological data collection, and research, and through the experiences of those implementing PEPFAR-supported programs. Although not directly represented in the pathway shown in Figure 2-1, this knowledge is also an

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output of PEPFAR-supported activities that underlies the rest of the pathway by serving to monitor, inform, and improve the supported programs.

By identifying intermediate steps, the program impact pathway allowed for the evaluation to consider more than the starting point of the PEPFAR investment and the ultimate endpoint of impact on health. Rather, this framework supported an assessment of the performance of PEPFAR along the full range of its implementation and its intended effects. Although it was a major challenge to directly assess health impact, the evaluation committee was able to use the framework of the program impact pathway to state credible findings about the effects of PEPFAR-supported programs.

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Evaluation of PEPFAR

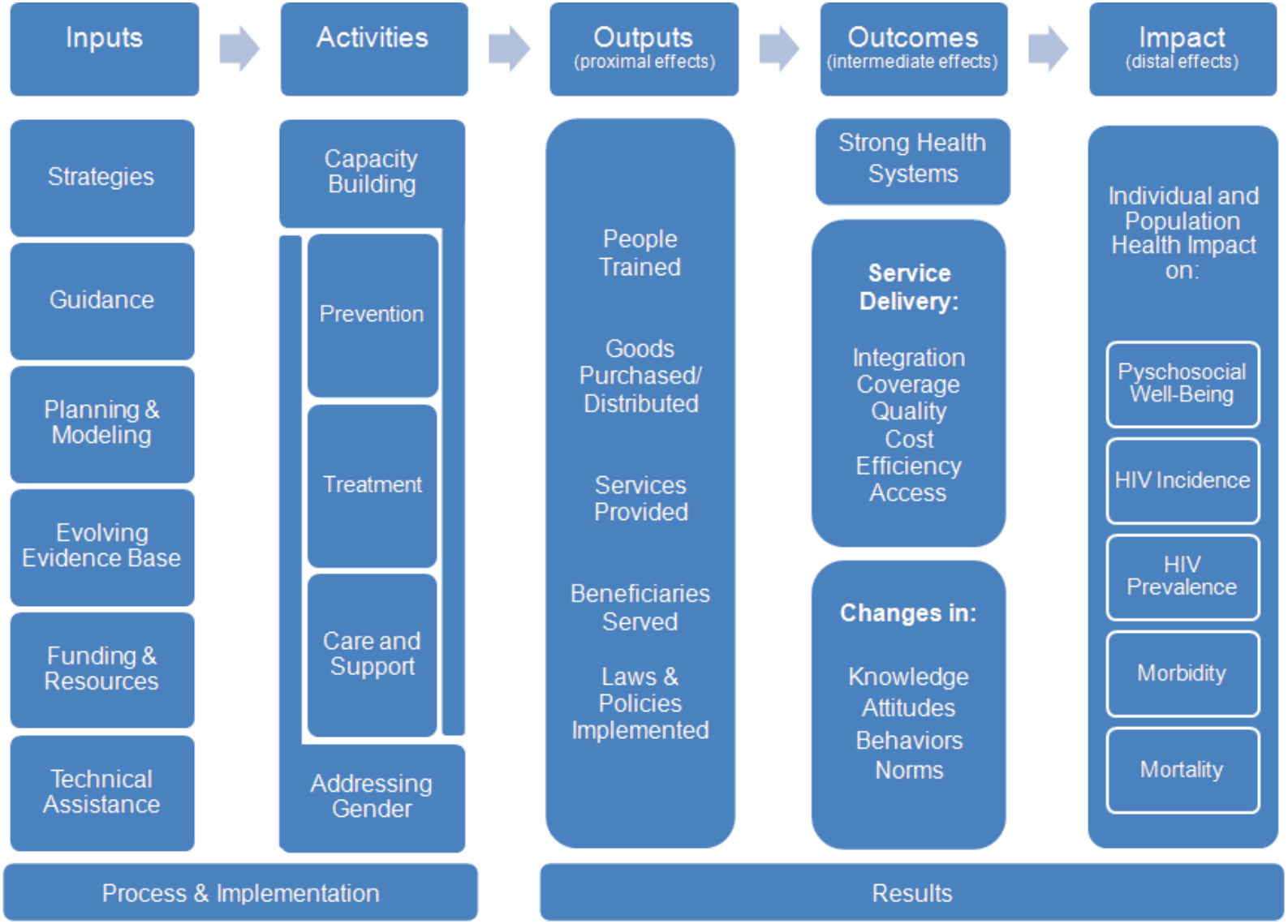

FIGURE 2-1 Program impact pathway for evaluation of PEPFAR's effects on HIV-related health impact for children and adults.
SOURCE: (IOM and NRC, 2010).

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Assessment of Contribution

Although it provides a critical guide for the evaluation, the program impact pathway is of course a simplified view of the implementation of PEPFAR-supported programs. Of particular importance is the reality that PEPFAR-supported programs in partner countries operate within the context of a wide range of other factors that affect implementation as well as health outcomes (see Figure 2-2). These other factors include the presence of HIV programs supported through the Global Fund and other external and partner country funding sources, as well as other health and development programs funded through both the USG and other sources. As described in the strategic approach to the evaluation, "Investments from a range of other sources support programs that are aimed at the same desired outcomes [as PEPFAR], and the proportion of total HIV/AIDS support that is provided by PEPFAR varies from country to country. In some cases, multiple funding sources may be co-mingled to support the same programs. Therefore, changes in population health that can be used to reflect program impact cannot be separated by specific programs or investments. Even individual measures can be difficult to attribute directly, as an individual or household may be receiving different services from different programs funded through different sources, all of which have an impact on the health outcomes of the beneficiary" (IOM and NRC, 2010), p. 25). In addition to the influence of other health and development programs, health outcomes are also influenced by cultural, societal, geographical, and political factors that vary by country and are not within the control of PEPFAR-supported programs. In addition, as noted in the *Strategic Approach*, "As PEPFAR programs increasingly operate with an emphasis on country ownership and harmonization with national plans, the extent to which central USG guidance and authority can influence all levels of priority setting, decision making, and implementation can be quite limited" (IOM and NRC, 2010), p. 25). Ultimately, with a foreign assistance program that is implemented as broadly as and on the scale of PEPFAR, there is not an appropriate comparison available to allow direct attribution of outcomes based on what would have happened in the absence of the investment.

Therefore, the aim of this evaluation approach was not to determine the direct attribution of PEPFAR funds to effects on health outcomes. Rather, the aim was to reasonably assess the contribution of PEPFAR to changes in health outcomes and health impact within the landscape of other funding sources, other HIV programs, and other factors that affect health. This contribution analysis is accepted as an appropriate standard for large-scale development assistance programs (Leeuw and Vaessen, 2009) and is consistent with the guidance about expectations for the evaluation provided by congressional staff during the planning phase for this evaluation (Bressler, 2009; Marsh, 2009).

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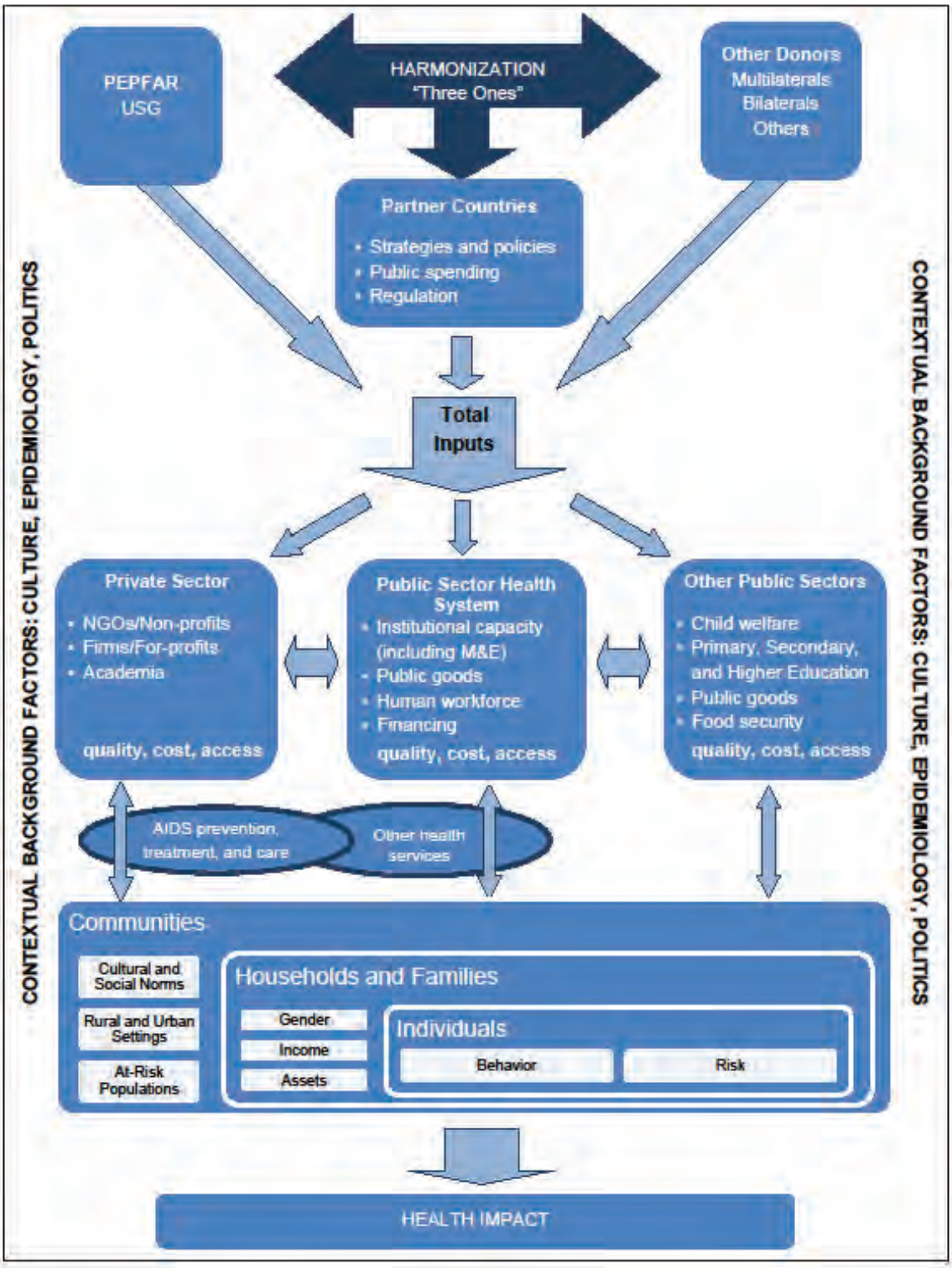

FIGURE 2-2 Context for PEPFAR contribution in partner countries.
NOTES: M&E = monitoring and evaluation; NGOs = nongovernmental organizations; USG = U.S. government.
SOURCE: (IOM and NRC, 2010).

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EVALUATION METHODS

This section provides a brief overview of the methodological approach for the evaluation; more detailed descriptions of the methods can be found in Appendix C. The evaluation utilized a mix of methods and data sources, including the mapping of investment using financial data, assessing trends over time using program monitoring indicators and clinical data, benchmarking of progress against stated programmatic targets and goals, document review, and analysis of primary data collected through site visits and semi-structured interviews.

Interview Data

As the largest component of the data gathering effort for the evaluation, committee members, IOM staff, and consultants conducted primary data collection through semi-structured interviews. The scope of these interviews is summarized in brief here; the design and methods for data collection and data analysis are described in full detail in Appendix C.

Country Visit Interview Data

From November 2010 to February 2012 the evaluation committee, IOM staff, and consultants conducted 13 country visits. These countries were selected by the evaluation committee through purposeful sampling based on a review of background data for each of the 31 PEPFAR countries covered by the evaluation. Background data covered a range of variables including: country income level, geographic location, HIV epidemic type, HIV prevalence, status as a focus country, population size, PEPFAR funding per capita and per person living with HIV, and relative contribution of PEPFAR to the national response compared with the Global Fund. Committee members iteratively grouped countries by different variables and ultimately selected a sample of countries representing a cross-section of attributes.

During each country visit, qualitative interviews were conducted with key stakeholders involved in the HIV/AIDS response. Requests for in-country interviews were made using a purposeful sampling methodology in order to develop a sample, both within and across countries, of interviewees that represented a range in types and levels of key stakeholders involved in the implementation of PEPFAR-supported programs and in the country's HIV/AIDS response. Interviewees also represented a range of direct experiences relevant to the multiple content areas that were the focus of the evaluation. The initial selection in advance of each country visit process was based on systematic information gathering from country background research completed by the IOM staff team; input from the PEPFAR mission team and other country stakeholders; and input from committee members. Once in-country, the country visit teams also employed a process of additional snowball sampling by querying scheduled interviewees to identify individuals or organizations who could provide additional information in particular content areas or additional stakeholder perspectives; country visit schedules were structured to allow time for additional interviews to be scheduled to enrich the data collection sample. The selection process and sampling methods are described in detail in Appendix C.

Over the 13 country visits, the IOM delegations conducted a total of 383 interviews; 68 of these included a visit to a service delivery facility or program site. The interviewees included individuals or, more commonly, groups of interviewees representing partner country government; U.S. government mission staff from the Department of State and the PEPFAR implementing agencies, including both U.S. and local partner country hires; multilateral

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organizations; international and local nongovernmental organizations (NGOs); academia; the private sector; and civil society organizations in partner countries, including organizations representing beneficiaries of PEPFAR-supported programs and people living with HIV or affected by the HIV epidemic.

Table 2-1 summarizes the completed interviews by stakeholder type and sub-type.

TABLE 2-1 Country Visit Interviews by Stakeholder Type

Stakeholder Type and Sub-Type	Number of Interviews	
U.S. Government Stakeholders		**147**
Mission Leadership In-Briefings and Exit Meetings	26	
PEPFAR All-Staff Mission Team Briefings	16	
PEPFAR Country Coordinator	13	
Agency Leadership	25	
Technical Staff and Working Groups	67	
U.S.-Based Stakeholders with Operations in Partner Country		**62**
NGO	41	
Academia	11	
Private Sector (for-Profit)	10	
Partner Country Stakeholders		**156**
Government, National	53	
Government, Subnational (Province, District, Facility)	40	
NGO	51	
Academia	6	
Global Fund CCM	4	
Private Sector (for-Profit)	2	
Other Stakeholders		**16**
NGO (Other Country-Based)	4	
Other Bilateral Government Donors	1	
Multilateral	11	
Mixed (Stakeholders from USG, Mutilateral Organizations, Other Bilateral Donors, Partner Country Government, US Private Sector)		**2**
TOTAL	**383**	

NOTE: This does not represent the total number of interviewees, as the majority of interviews were with groups of interviewees. In some cases, the same interviewees participated in multiple interviews. For example, there was usually participant duplication between the PEPFAR all-hands interview and subsequent USG interviews. Repeat participation also happened occasionally across multiple interviews with partner country governments.

Non-Country Visit Interview Data

IOM staff and consultants also conducted 32 non-country visit individual or group interviews with key stakeholders. These interviewees included members of the U.S. government at PEPFAR headquarters level (including OGAC, the U.S. Centers for Disease Control and Prevention (CDC), and the U.S. Agency for International Development (USAID)) and U.S.-based implementing partners at headquarters level, as well as other organizations that work in the global response to HIV, such as multilateral organizations, nongovernmental organizations, and

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another bilateral donor. As with the country visit interviews, non-country visit interviewees were selected through purposeful sampling, prioritized based on targeted focus areas within the evaluation and on the process of mapping data sources for evaluation questions. Interviews were conducted using the same methodology as for country visit interviews, utilizing semi-structured interview guides with questions and prompts appropriate to the interviewee(s).

Secondary Data Sources

The secondary data sources used in this evaluation included financial data, programmatic monitoring data, clinical data, global indicator data, and publicly available documents. These are described briefly here, with additional information provided where data are presented in the subsequent chapters as well as in Appendix C. Financial data were received from OGAC, extracted from publicly available PEPFAR documents, and gathered from other external sources including the Organisation for Economic Cooperation and Development and the Center for Global Development. PEPFAR's program monitoring indicators were received from OGAC, and additional clinical data representing programs implemented by Track 1.0 partners were received from the CDC. Some additional data analyses were provided directly by one Track 1.0 partner. Another source of information was global indicator data, primarily from UNAIDS. Finally, document review drew upon a wide range of publicly available sources, including PEPFAR documents, reports from PEPFAR-supported activities and evaluations, reports from organizations external to PEPFAR, and published literature.

Data Analysis and Interpretation

As described in more detail in Appendix C, primary and secondary data were analyzed, using appropriate methodologies, by the members of the evaluation committee, the study staff team, and consultants with specialized knowledge in both qualitative and quantitative methodologies. The committee, staff, and consultants took steps to assess and ensure the quality and completeness of the data used for the evaluation, and took into account these factors in the interpretation of the data. The methods used to assure the quality of the primary data collected by the committee and the secondary data received through data requests are described in Appendix C. When existing data analyses were used, the committee and consultants reviewed and assessed the methodology and quality of the data in the original analyses.

The mandate of the committee was to draw conclusions and to make recommendations across the whole of the program. Wherever possible, data presentations, analyses and interpretation are presented in this report across all of the 31 PEPFAR partner countries defined as the focus of the evaluation. However, data sources with comparable and comprehensive data across all of these countries were very limited. To ensure that this constraint would not overly limit the scope of the evaluation findings, the committee also identified subsets of countries and components within programmatic areas for which more robust data could be gathered to contribute to the assessment. Therefore, some of the data presentations and analyses in this report represent only a subset of countries and were interpreted with care to inform conclusions about the whole of the program. For example, analysis of country visit interview data was limited to the countries selected for visits by the committee. In addition, some analyses drew on existing data sources that were available only for some countries, programs, or partners. Some evaluation questions were most applicable only for a subset of countries, such as countries with concentrated epidemics driven by injection drug use. Finally, the time and resources available

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limited the scope of some analyses, such as those involving review of Country Operational Plans for which the sheer volume of the documents over all countries and years limited the feasibility of comprehensive review across all countries. Throughout the report, where data analyses that do not represent the whole of the program are presented, the scope of these data is described. Because the committee was not charged to draw conclusions or to make recommendations at the level of specific countries, partners, or programs, analyses of data from subsets of countries or partners are presented in a manner designed to maintain anonymity.

In summary, the committee applied a mix of methods and layers of investigation and analysis using a range of available primary and secondary data sources, summarized in Figure 2-3. Using this approach, the committee was able to arrive at findings that could be triangulated to draw conclusions about the performance and impact of PEPFAR even when any one data source was not sufficient or any one methodological approach was not feasible. Building on the interpretation of the available data, the conclusions and recommendations presented in this report represent the consensus reached through the deliberations of the evaluation committee.

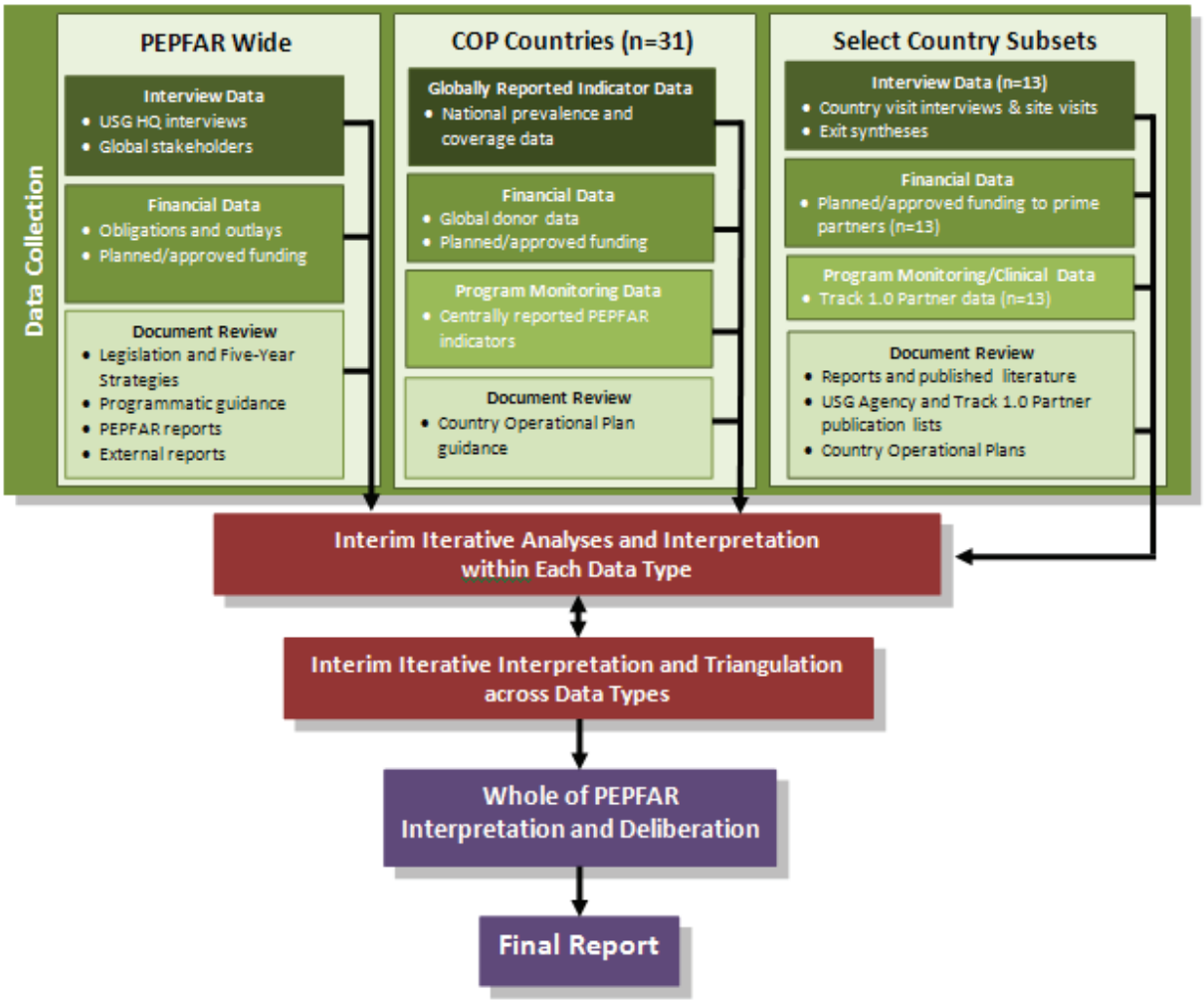

FIGURE 2-3 Overall data collection and analysis process.

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OVERARCHING EVALUATION CHALLENGES AND LIMITATIONS

There were a number of challenges to carrying out this evaluation. The overarching challenges and limitations are described here, while more specific challenges and limitations are described in Appendix C, and in the subsequent chapters of this report.

Limitations to Evaluation Design

The *Strategic Approach* included a robust discussion of different evaluation designs and the limitations to applying these designs to this study (IOM and NRC, 2010). In summary, one major limitation for the design of this evaluation of PEPFAR is that it was not feasible to identify an appropriate comparison or control, which would typically be the approach used to answer the underlying question of what would have happened if the program had not existed or if it had been implemented differently. A main reason for the lack of an appropriate comparison is that PEPFAR is widely implemented across many partner countries, which were not selected at random but rather for specific strategic reasons.

In addition, an ideal evaluation would use a prospective design, in which data for both intervention and comparison groups would be collected from the beginning of the evaluation. When it is not possible for ethical reasons or practical considerations to have a comparison group, a prospective design can at least allow for the planning of a before-and-after comparison of the intervention group. However, the timeframe of this mandated evaluation begins with the initiation of PEPFAR-supported programs, which took place before the evaluation was mandated, planned, and carried out. It was not feasible to carry out complex intervention and evaluation designs or new data collection in order to make prospective comparisons within the time period and resources for this evaluation. Therefore, the questions asked in this evaluation can only be answered retrospectively.

Limitations on Data Availability

A primary and very concrete challenge to the evaluation was the limited availability of data to address health outcomes and impact across the whole of PEPFAR, a limitation that was revealed by the data mapping and data collection process for this evaluation. The lack of relevant available measures made it difficult, and in some cases impossible, for the evaluation committee to respond directly to aspects of the evaluation as requested in the Lantos-Hyde Act of 2008.

The programmatic indicators that are reported centrally to OGAC across the entire PEPFAR program provide only limited answers to the evaluation charge. There are only nine indicators that are routinely reported centrally to OGAC and that have had stable, consistent indicator definitions since the inception of PEPFAR (see Table 2-2). Therefore, these are the indicators that are available across the whole scope of countries and duration of PEPFAR. These indicators represent limited aspects of PEPFAR's programmatic areas. They also primarily represent outputs, which can serve to assess program implementation through the volume of services provided, but are limited in terms of outcomes and impact to assess those services in the context of the population in need, to assess the quality of the services provided, and to assess PEPFAR's effectiveness in achieving measurable effects on health.

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TABLE 2-2 PEPFAR Indicators

Indicator	Program Impact Pathway Level
Care	
Percent of HIV-positive patients in HIV care or treatment (pre-ART or ART) who started tuberculosis treatment	PEPFAR Output
Health Systems Strengthening	
Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests	PEPFAR Output
Prevention	
Number of HIV-positive pregnant women who received antiretrovirals to reduce risk of mother-to-child-transmission	PEPFAR Output
Percent of HIV-positive pregnant women who received antiretrovirals to reduce the risk of mother-to-child-transmission	National Outcome
Number of individuals who received testing and counseling services for HIV and received their test results	PEPFAR Output
Treatment	
Number of adults and children with advanced HIV infection newly enrolled on ART	PEPFAR Output
Number of adults and children with advanced HIV infection receiving antiretroviral therapy	PEPFAR Output
Percent of adults and children with advanced HIV infection receiving antiretroviral therapy	National Outcome
Percent of adults and children known to be alive and on treatment 12 months after initiation of antiretroviral therapy	PEPFAR Outcome

NOTE: ART = antiretroviral therapy
SOURCES: (OGAC, 2005, 2007, 2009a)

Most evaluation questions required the evaluation committee to draw on data that went beyond the indicators that are routinely reported OGAC. Data from PEPFAR beyond the centrally-reported indicators, such as recommended indicators collected by country programs but not reported to OGAC, data collected independently by the major USG implementing agencies and other implementation partners, financial data by type of partner and expenditures by program activity, results of PEPFAR-supported evaluations, and publications from PEPFAR-supported programs are not managed through processes that allow for ready cataloguing or ready access to what is available. Accessing these data comprehensively would have required a more intensive and significant data-mapping, data-gathering, and data-analysis effort than was possible given the time and resources available for the IOM evaluation. The necessary requests from the IOM also would have imposed a significant burden of time and resources on staff at OGAC and other

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implementing agencies as well as on mission teams and implementing partners while they simultaneously continued to oversee and implement the program. Therefore, data requests and data gathering were done strategically within the limitations of what could be responded to and completed in a timely manner. In addition to challenges related to feasibility, for some implementing partners, concerns about sacrificing the right to first publication also represented a barrier to data sharing for the evaluation. More information about the PEPFAR-specific data considered, requested, and used by the committee can be found in the more detailed description of the methods in Appendix C. The PEPFAR indicators are also discussed in Chapter 11 on PEPFAR's knowledge management.

Some global data sources available through multilateral organizations, such as UNAIDS, contributed to the committee's assessment, but these data are not PEPFAR-specific, which limited their utility in evaluating PEPFAR's effects. In general, for efforts to collect similar data across multiple countries there remains variability by country in the quality and availability of data. Also, in some critical areas that are increasingly a part of PEPFAR-supported programs, such as gender-related efforts, policy efforts, health systems strengthening, capacity building, technical assistance, and benchmarks for sustainability and country ownership, consensus measures have not been developed or implemented either globally or within PEPFAR, and therefore are not available systematically across countries. Challenges with assessing effects in these areas are discussed in more depth in the relevant subsequent chapters of this report.

As described above, several sources of data were available for only a subset of countries. The data collected for this evaluation through semi-structured interviews were extensive and systematic, yet the country-level data from these interviews were limited to a subset of 13 PEPFAR partner countries. Available publications provided some useful data for the assessment; however, they did not capture information across the whole of PEPFAR but instead represented different subsets of countries and programmatic areas. Given the considerable heterogeneity in PEPFAR implementation across various countries and programs, using data not collected systematically to represent all PEPFAR countries limited the evaluation committee's ability to generalize findings to the whole of the program and required careful analysis and interpretation, especially since the committee was not charged to draw conclusions at the level of countries, partners, or programs.

In summary, the extent to which the goals of this evaluation were met depended on the timely availability of relevant data. As a result, the data used in this evaluation came from a range of disparate sources, and the availability depended in part on the feasibility of access within the evaluation's timeframe. There were, therefore, challenges of interpretation due to heterogeneous data sources with different sampling frames and different data collection systems and criteria, as well as the potential for reporting bias in the responsiveness to data requests from the committee.

Chapter 11 presents a discussion of the collection and use of data and information to assess and improve PEPFAR programs and activities, including a forward-looking framework for knowledge management and suggestions for how to develop the means to answer questions posed in the mandate for this evaluation if they are found to be important for future ongoing evaluation.

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Timing of the Evaluation

This evaluation was conducted early in the implementation of changes to the program in response to the reauthorization legislation[10] and the new PEPFAR Five-Year Strategy (OGAC, 2009b). "These changes reflect a progressive transition to a new era of challenges and goals for the program, which include efforts to improve sustainability of the response over time, to enhance coordination with partner governments and other global funding partners, and to support accountable ownership of HIV program delivery by countries themselves. They also reflect efforts to give greater consideration to the relationship of PEPFAR to broader health and development needs in partner countries" (IOM and NRC, 2010), p. 21). The timing of this evaluation made it difficult to assess the outcomes or impact of these recently implemented changes. For example, the full effect from some efforts to strengthen health systems might not be realized for several years or even decades, such as the training and retention of new health care workers or the strengthening of health information systems. There will be a similarly long timeframe required to assess the effects of recently instituted processes being implemented by PEPFAR, in partnership with partner countries, to increase sustainability and country ownership. Nonetheless, the evaluation assessed efforts in these areas in order to understand whether PEPFAR is making reasonable progress toward these new goals and to lead to recommendations for how the program can be improved to ensure that these evolving goals can be met.

PEPFAR is dynamic, and even as the evaluation was being carried out, it continued to evolve with new goals, new guidance, new efforts and activities, within the context of newly available evidence. This change in the program over time is a beneficial necessity, but makes evaluation difficult as it presents a "moving target" during the timeframe of the evaluation. Recent changes and new initiatives are not a part of the core content and scope of the evaluation, which was focused on PEPFAR as implemented under the Lantos-Hyde Act of 2008 and the second Five-Year Strategy, but are acknowledged where relevant throughout the report and serve as context for the ultimate major messages and recommendations.

SUMMATION

PEPFAR is large, multifaceted, and complex and it supports a wide range of activities that are carried out by many different partners in a diverse group of countries alongside programs supported by other funders that share the same ultimate aim. Through the conceptual framework of the program impact pathway and contribution analysis described above, the IOM endeavored to conduct a rigorous assessment of PEPFAR that took into account the complexities of implementation and that maintained the flexibility necessary to adapt to the information gathered as the evaluation proceeded and to the programmatic evolution occurring within the evaluation timeframe. To conduct a rigorous and thorough assessment, given the limitations, the evaluation committee used a mixed methods approach guided by the program impact pathway framework, drawing on a range of available quantitative and qualitative data sources and using a combination of analytical techniques appropriate to each type of data. By assessing convergence and consistency among different yet complementary data sources and methods, each with different strengths and limitations, the evaluation committee was able to triangulate or cross examine

[10] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

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findings to support reasonable conclusions. When taken together, the totality of evidence allowed the evaluation committee to make recommendations for the program as a whole.

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PART II

PEPFAR Organization and Investment

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3

PEPFAR Organization and Implementation

This chapter presents the organization and management of PEPFAR and briefly places the role of PEPFAR and the implementation of PEPFAR-supported programs in the broader contexts of the HIV epidemic in partner countries and the policy environment at the domestic, partner country, and global levels.

As described in Chapter 1, PEPFAR focuses primarily on activities that facilitate the delivery of HIV prevention, care, and treatment services to beneficiaries in partner countries. These include directly supporting service provision as well as supporting activities that promote or facilitate the delivery of services, such as strengthening health care and other systems, building capacity, providing technical assistance, and engaging with governments and other stakeholders to encourage a policy environment that supports an effective response to HIV.

To support these activities, PEPFAR operates through a coordination, management, and implementation structure that follows a whole-of-government approach involving multiple USG agencies. In a manner that inextricably links PEPFAR to foreign relations and health diplomacy, central coordination is based in the State Department through the Office of the U.S. Global AIDS Coordinator while in partner countries PEPFAR is housed in U.S. diplomatic missions under the oversight of the U.S. ambassador to the country. From this home base in the Department of State, the implementation of PEPFAR involves multiple U.S. government agencies that oversee and manage PEPFAR-supported programs at both headquarters level and in partner countries. PEPFAR also engages implementing partners, which may be based in the United States, in partner countries, or in other countries. Figure 3-1 shows a schematic overview of how PEPFAR is implemented, from Congressional appropriations through service delivery to beneficiaries. The sections that follow describe the core components and levels of PEPFAR's organization and implementation. This chapter is complemented by a more detailed discussion in Chapter 4 of the flow of PEPFAR funding through these levels, described in brief in Figure 3-1. This chapter focuses on organization and implementation within and among the levels of PEPFAR. Chapter 11 provides an in-depth discussion of PEPFAR's knowledge management, including systems for monitoring, evaluation, research, and information transfer.

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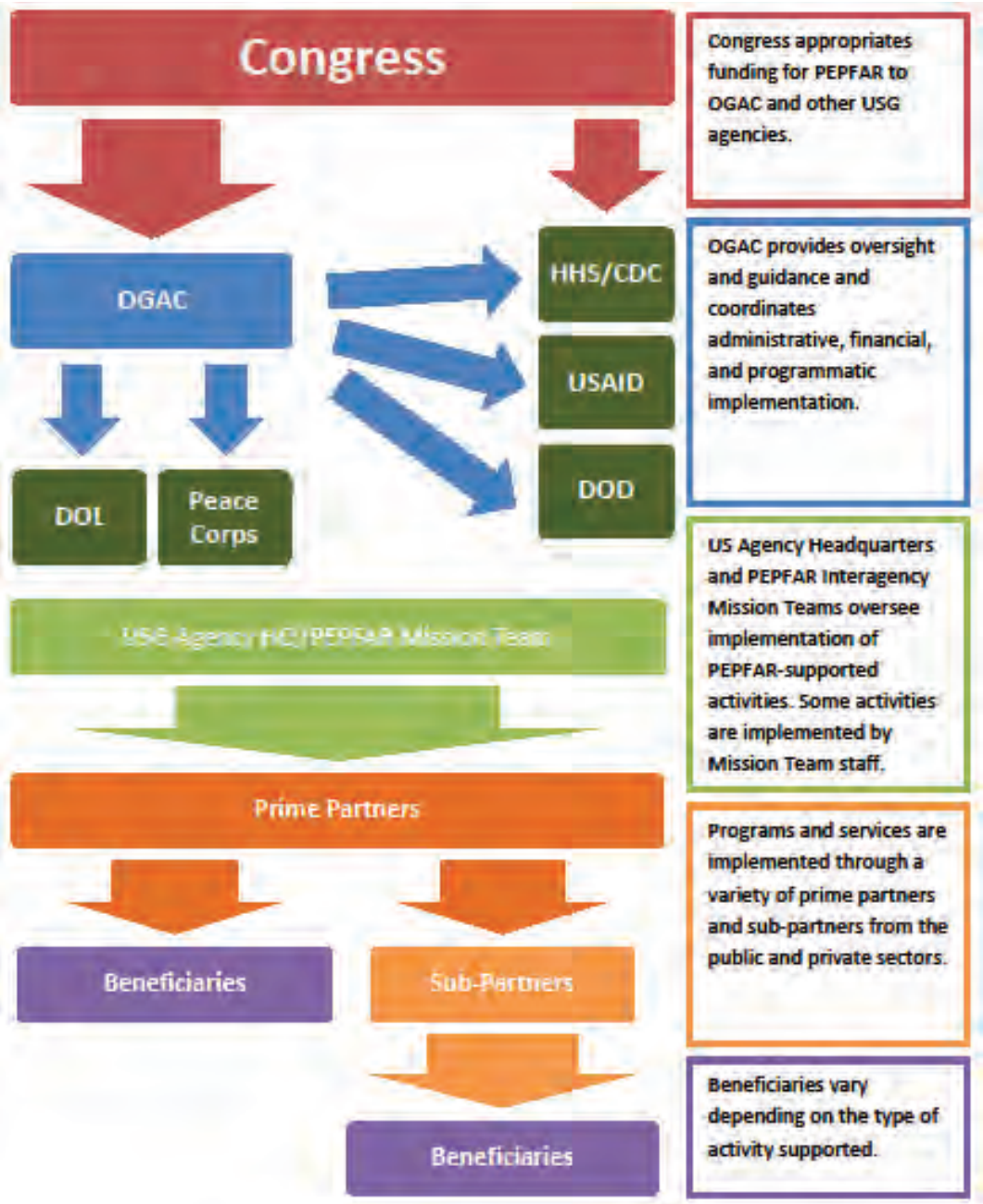

FIGURE 3-1 PEPFAR overall organization and implementation.
SOURCE: Developed by IOM after document review and consultations with OGAC.

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ORGANIZATION OF PEPFAR AT THE CENTRAL/HEADQUARTERS LEVEL

Office of the U.S. Global AIDS Coordinator

The formal organizational unit for PEPFAR is the Office of the U.S. Global AIDS Coordinator (OGAC) at the Department of State. OGAC is overseen by the Coordinator, an appointed position at the level of Ambassador who reports directly to the U.S. Secretary of State. It serves as the administrative office for PEPFAR and directs and coordinates activities at both the headquarters level in Washington, DC, and at the country level, where PEPFAR operates under the additional oversight of the U.S. ambassador of the country. OGAC staff, including detailees from other USG agencies, coordinate administrative, financial, and programmatic implementation, oversight, and guidance. In addition, the ambassador and other OGAC staff represent the United States on global bodies responding to the HIV/AIDS pandemic and participate with multinational organizations, including UNAIDS, the Global Fund, WHO, and UNICEF, on a range of aspects of the global HIV response, such as developing normative technical guidelines and conferring with other donors and institutions with respect to global priorities and harmonizing elements of the global response.

The organizational structure of OGAC has changed over time; the current iteration at the time of this evaluation is shown in Figure 3-2. OGAC also has Country Support Team Leaders who serve as the principle point of contact and liaison to in-country PEPFAR mission teams.

U.S. Government Implementing Agencies

Although coordinated through OGAC, PEPFAR is implemented through a number of USG agencies.[1] At the headquarters levels, the leadership of these agencies are involved in overseeing the implementation of PEPFAR programs through their respective agencies, as well as participating in a number of coordination bodies and mechanisms, as described in the section that follows. The various agencies and departments involved in the USG response to the global HIV/AIDS include the following:

- The Department of State houses OGAC and provides its infrastructure, including information technology, human resources, and accounting. In partner countries, Department of State Chiefs of Mission provide overall leadership for interagency HIV/AIDS teams and engage in discussions of policy with partner country leaders. In addition, the Department of State's PEPFAR Small Grants Programs make funds available to Ambassadors for support of local projects, which typically involve local communities, non-governmental organizations, and municipalities. Through its embassies, the Department of State also implements diplomatic initiatives and other HIV/AIDS programs and uses public diplomacy tools to support local communications and engagement with PEPFAR (PEPFAR, 2012).

[1] In general in this report descriptions of activities carried out by and actions recommended to be taken by OGAC should be understood to mean by the U.S. government implementing agencies through PEPFAR's interagency coordination mechanism, which is led by OGAC.

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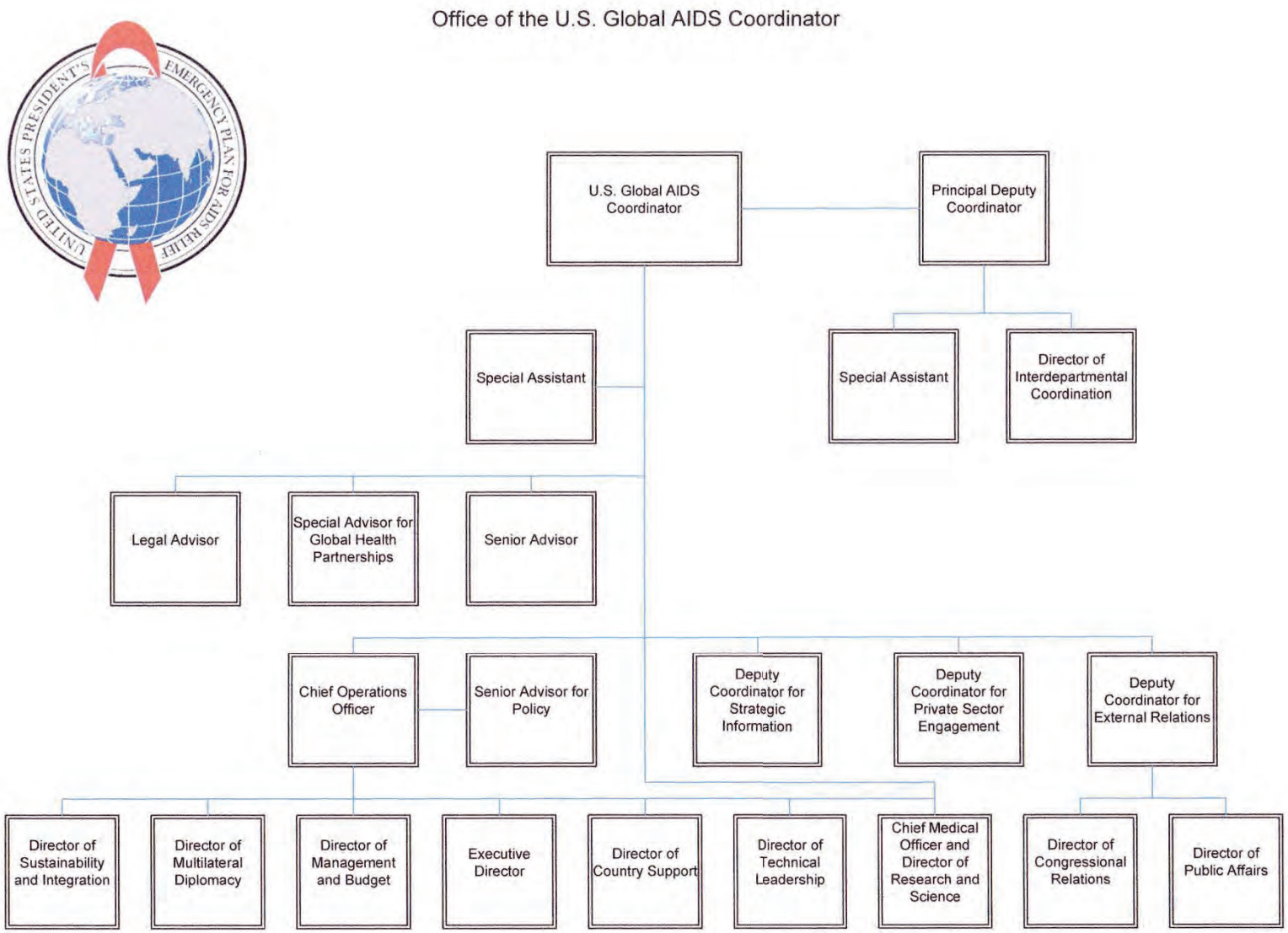

FIGURE 3-2 Current Organizational Structure of OGAC (last updated November 14, 2011).
SOURCE: (PEPFAR, 2011)

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- The U.S. Agency for International Development (USAID) supports the implementation of PEPFAR programs with a direct in-country presence in 50 countries as well as through seven regional programs. USAID's foreign service officers, including physicians, epidemiologists, and public health advisors, work with governments, NGOs, and the private sector to provide training, technical assistance, and commodities for HIV-related prevention, treatment, and care. USAID is also described as being "uniquely positioned to support multi-sectoral responses to HIV/AIDS that address the widespread impact of HIV/AIDS outside the health sector in high-prevalence countries." USAID supports programs in areas such as agriculture, education, democracy, and trade which mutually support the objective of reducing the impact of HIV/AIDS on nations, communities, families, and individuals. USAID also supports the New Partners Initiative (NPI) for capacity-building of community-level organizations and contributing to long term local ownership of HIV/AIDS responses. In addition, USAID supports a number of international partnerships (such as the International AIDS Vaccine Initiative and UNAIDS). Finally, USAID supports targeted research, development, and dissemination of new technologies as well as packaging and distribution mechanisms for ARVs through the Supply Chain Management System (PEPFAR, 2012).
- The Department of Health and Human Services (HHS) implements PEPFAR prevention, treatment, and care programs in developing countries and conducts or supports HIV/AIDS research. HHS contributes to the implementation of PEPFAR through several agencies, coordinated by the Office of Global Affairs:
- The CDC Division of Global HIV/AIDS (DGHA) provides technical assistance to 75 countries through its country and regional offices with approximately 1,300 staff overseas (over 1,000 of them locally employed nationals) and 380 at headquarters, including physicians, epidemiologists, public health advisors, behavioral scientists, and laboratory scientists. These staff provide "technical leadership and direct assistance to Ministries of Health to strengthen and build sustainable laboratory, epidemiology, surveillance, and health information systems; expand quality HIV/AIDS service delivery and transition these services to local host-government ownership; implement evidence-based HIV/AIDS prevention programs that build synergies between prevention and care and treatment programs; and conduct, translate, and operationalize research on program impact and cost effectiveness. Moreover, DGHA builds in-country capacity to design, implement, and evaluate these systems as well as provides the technical assistance needed to establish and maintain national laboratory networks." DGHA is also able to coordinate with other HHS global health programs, such as global disease detection, public health training, and prevention and control of other infectious diseases, as well as with domestic HIV/AIDS prevention programs in the U.S.
- The National Institutes of Health (NIH) is the lead federal agency for biomedical research on AIDS. Through an international research and training portfolio that includes work in more than 90 countries, NIH supports basic science, clinical, and behavioral research on HIV and its associated opportunistic infections, co-infections, and malignancies.
- The HRSA Global HIV/AIDS Program implements rapid roll-out of ARVs and other clinical services, training and technical assistance, and nursing leadership

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development. HRSA supports education and training in more than 25 countries for thousands of health care workers and provides HIV quality improvement models and software in order to improve the quality of care in PEPFAR countries.

- The Food and Drug Administration (FDA) "ensures the availability of safe and effective ARVs to meet the in-country treatment goals of global agencies and governments engaged in the treatment and care of patients living with HIV/AIDS. As of January 2007, using a process that combines focused engagement with companies prior to submitting authorization packages with a priority assessment of the submitted packages, the FDA has approved or tentatively approved 34 single-entity, fixed-dose combination, and co-packaged versions of previously-approved ARVs (most of which are still protected in the United States by patent and/or exclusivity) to increase the arsenal of low-cost, high-quality HIV/AIDS therapies available for purchase under PEPFAR."
- SAMHSA applies technical expertise and program experience in substance abuse and dependence prevention, treatment and recovery to PEPFAR's programs, with an emphasis on the use of medication-assisted treatment as an HIV prevention intervention (PEPFAR, 2012).
- "The Department of Defense (DoD) implements PEPFAR programs by supporting HIV/AIDS prevention, treatment, and care, strategic information, human capacity development, and program and policy development in host militaries and civilian communities of 73 countries around the world. These activities are accomplished through direct military-to-military assistance, support to nongovernmental organizations and universities, and collaboration with other U.S. Government agencies in country. The DoD supports a broad spectrum of military-specific HIV prevention programs, infrastructure development and support (including laboratory, clinic and hospital facility renovation, equipment, and training), and treatment and care activities. The DoD HIV/AIDS Prevention Program (DHAPP), based at the Naval Health Research Center (NHRC) in San Diego, California, is the DoD Executive Agent for the technical assistance, management, and administrative support of the global HIV/AIDS prevention, care, and treatment for foreign militaries. DHAPP administers funding, directly conducts training, and provides technical assistance for focus countries and other bilateral countries, and has staff actively serving on most of the Technical Working Groups and Core Teams through the Office of the U.S. Global AIDS Coordinator. DHAPP oversees the contributions to PEPFAR of a variety of DoD organizations, which fall under the various regional military commands, as well as specialized DoD institutions whose primary mission falls within the continental United States" (PEPFAR, 2012).
- The Peace Corps uses PEPFAR resources to extend its contribution to HIV work in 47 countries and one regional program. "Peace Corps posts in these countries use PEPFAR resources to enhance their HIV/AIDS programming and in-country training; field additional Peace Corps Response and two-year Peace Corps Volunteers specifically in support of Emergency Plan goals; and provide targeted support for community-initiated projects." Through its volunteers who have language and cultural training and who live in the communities where they work, the Peace Corps is described as "uniquely positioned to play an essential role in any country strategy aimed at combating HIV/AIDS. The Peace Corps' contributes to the PEPFAR

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transition to sustainable, country-led responses to HIV by providing long-term capacity development support to non-governmental, community-based, and faith-based organizations, with particular emphasis on ensuring that community-initiated projects and programs provide holistic support to people living with and affected by HIV/AIDS. Peace Corps volunteers also aim to develop the necessary management and programmatic expertise at recipient and beneficiary organizations to ensure long-lasting support, particularly in rural communities" (PEPFAR, 2012).

- The Department of Labor implements PEPFAR workplace-targeted projects that focus on prevention and on reducing stigma and discrimination related to HIV/AIDS-through workplace education, protective HIV/AIDS workplace policies, and engagement and capacity building with employer associations, government, and trade unions. The Department of Labor also contributes to an international technical assistance program focusing on child labor targeting HIV-affected children (PEPFAR, 2012).
- The Department of Commerce provides in-kind support to PEPFAR through engagement with companies, industry organizations, and multilateral organizations aimed at fostering private sector involvement in HIV interventions and public-private partnerships. The U.S. Census Bureau, within the Department of Commerce, is another important PEPFAR partner that assists with data management and analysis, survey support, estimating infections averted, and supporting mapping of country-level activities (PEPFAR, 2012).

OGAC Headquarters-Level Interagency Coordinating and Guidance Mechanisms

Interagency advisory bodies and processes support OGAC's coordination and the implementation of PEPFAR by sharing information and contributing to decision making for programmatic activities. For example, USG agency program directors make up the group of Deputy Principals who give policy and programmatic guidance to political appointees in the agency Principals groups as well as to the AIDS Coordinator. Input also comes from the country support teams who liaison with and share information from the country and region implementing teams. OGAC also coordinates interagency Technical Working Groups (TWGs) that focus on specific service areas and topics.[2]

One of the functions of the interagency coordination and advisory mechanisms is to develop and communicate operational guidance, technical considerations, and programmatic guidance to PEPFAR mission teams and implementing partners. Some overall aspects of the guidance process are discussed here, while the content of the guidance in specific program areas, including the timing and extent of changes over time, are discussed in the relevant chapters in this report.

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[2] OGAC operates the following TWGs (by program area): Prevention of Sexual Transmission in the General Population (Including Youth); Prevention of HIV in Persons Engaged in High-risk Behaviors; Medical Transmission; Counseling and Testing; Prevention with Positives Taskforce; Male Circumcision Taskforce; Care and Treatment Steering Committee; Adult Treatment; PMTCT/Pediatric AIDS; Tuberculosis (TB) and HIV/AIDS; Care and Support; Orphans and Vulnerable Children; Community/Faith Based Organizations, Food, Nutrition, and HIV/AIDS; Gender; Public-Private Partnerships; Health Systems Strengthening; Human Resources for Health; Laboratory; Finance and Economics; Strategic Information Steering Committee; Monitoring & Evaluation; Surveillance and Survey; Health Management Information Systems. Staff from USG agencies, USG-funded partners, and non-USG-funded partners may participate in each TWG (OGAC, 2012).

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In many technical areas related to HIV programs, PEPFAR does not issue programmatic guidance of its own, but instead defers when possible to the normative guidance of other authoritative technical bodies, primarily the World Health Organization (NCV-10-USG; NCV-13-ML).[3] Guidance for the implementation of such normative international guidance is often covered in PEPFAR's operational guidance or technical considerations. In other areas of the HIV response, PEPFAR issues its own programmatic guidance; for example, when there are programmatic needs not comprehensively addressed by existing normative guidance or when there are legislative directives and USG policies that may not align with international standards. The number and frequency of guidance documents issued varies by programmatic area, and in some areas PEPFAR's programmatic guidance has changed substantially since the beginning of the program. The use of evidence and the threshold for evidence required to instigate a change in guidance also seems to have varied by programmatic area. Guidance is discussed in more depth for each PEPFAR program area in the subsequent chapters of this report.

Interviewees at both headquarters and country level described several challenges with central guidance from OGAC. One is a lack of clarity around such things as appropriate service packages, allowable activities, and efforts in emerging areas of program emphasis, such as country ownership and transitioning to new models of implementation (396-ES; 272-ES). Another challenge noted by interviewees is the timeliness of guidance. The guidance document on prevention of sexual transmission was one notable example cited as suffering from a lengthy delay from OGAC headquarters to the field (166-26-USG; 587-23-USG; 166-26-USG). One reason noted for slow or delayed issuance of guidance was the iterative process for generating, reviewing, and approving the guidance, which usually requires information gathering, discussion, and agreement among multiple USG agencies and technical working groups. While this may ensure thorough vetting, it can also result in a lengthy period to get from the headquarters process to dissemination and implementation at the country level (NCV-11-USG; NCV-17-USG; NCV-18-USG; 587-23-USG; 166-26-USG; 587-23-USG; 166-26-USG). Another challenge interviewees noted was that guidance sometimes has taken a "one size fits all" approach that does not fit all country programs, whether because of limited applicability to special circumstances in smaller, more narrowly focused country programs or because of limited room for adaptation to local culture and standards (272-ES; 196-ES). Interviewees expressed a desire for more balance in guidance, and thus implementation of programs, among what is driven by USG headquarters and what is driven by the mission team in country through its planning and coordination with partner country stakeholders.

ORGANIZATION OF PEPFAR AT THE COUNTRY LEVEL

PEPFAR country programs that submit a country operational plan (COP) to OGAC typically have an interagency U.S. mission team that coordinates all of the program activities in

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[3] For citations of interview data:
Country Visit Exit Synthesis: Country # + ES
Country Visit Interview Citation: Country # + Interview # + Organization Type
Non-country Visit Interview Citation: "NCV" + Interview # + Organization Type
Organization Types Key: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO

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country. Mission teams are made of representatives of all implementing departments and agencies and are almost all anchored by a Country Coordinator working in the U.S. embassy (see Figure 3-3 for an illustration of a mission team).

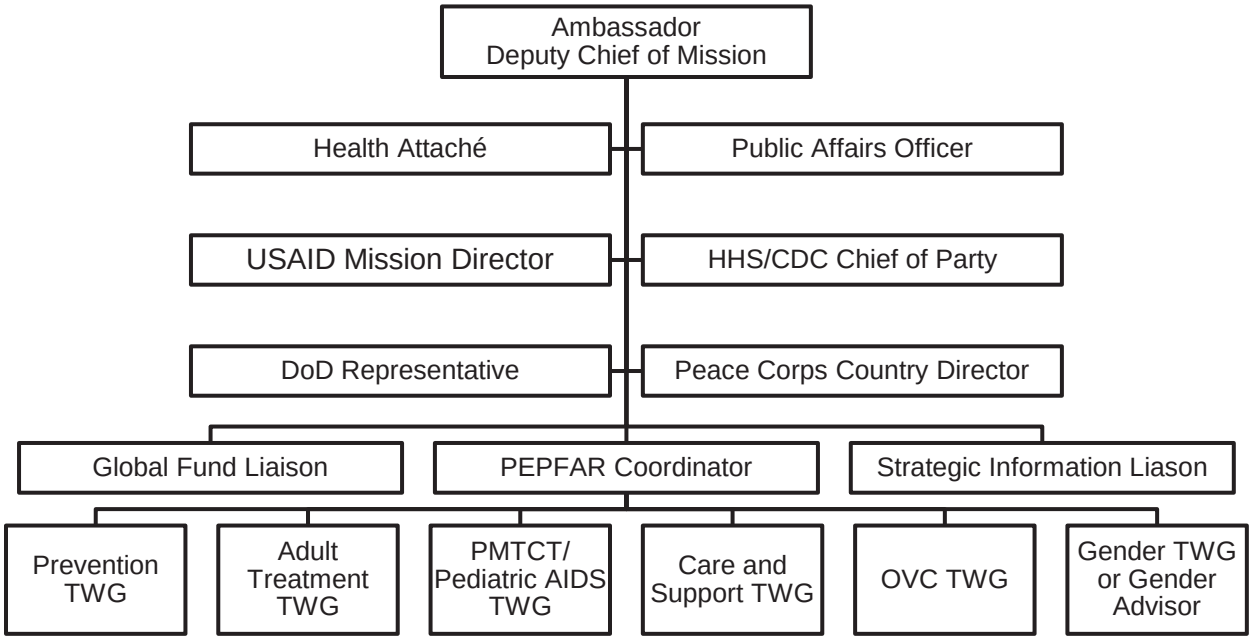

FIGURE 3-3 Example structure of PEPFAR mission team.
NOTE: The structure of each team will vary by country. Different TWGs are present in different countries; this figure includes an illustrative example. CDC = U.S. Centers for Disease Control and Prevention, DoD = U.S. Department of Defense, HHS = U.S. Department of Health and Human Services, OVC = orphans and vulnerable children, PMTCT = prevention of mother-to-child transmission, TWG = technical working groups, USAID = United States Agency for International Development.
SOURCE: Strategic Approach (IOM and NRC, 2010), adapted from personal communications from OGAC (June 16, 2009) and information gathered on country visits (November 2010-February 2012)

The mission teams work with implementing partners, other international organizations and donors, and partner country governments and nongovernmental entities to implement programs and services, develop partnerships, participate in coordination and planning processes, and support policies that contribute an effective response to HIV and ensure that more attention and resources are put toward HIV/AIDS. U.S. Ambassadors or Chiefs of Mission are the ultimate leaders of interagency HIV/AIDS teams, responsible for ensuring that policies and programs are coordinated at the highest levels, accounting for all plans and reports submitted to OGAC, and engaging with partner-country leadership. Mission team staff participate in joint planning committees or working groups organized by the partner country government or by multilateral organizations. Members of the interagency mission team also work with the Global Fund's local committee, known as the Country Coordinating Mechanism, to improve implementation of Global Fund grants programs and to facilitate coordination between Global Fund and USG programs. Some PEPFAR-supported activities are also implemented directly by members of the mission team.

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Most PEPFAR-supported programs and services within countries are implemented by a variety of different partners, including international and partner country nongovernmental organizations, academic institutions, partner country governments, private-sector entities, civil society organizations, and faith-based organizations. Prime partners are direct recipients of PEPFAR funding and may contract with sub-partners to implement services or activities. Most of the activities PEPFAR supports and implements in partner countries are determined and contracted through the in-country mission teams, although some programs and initiatives are funded and managed at the central, headquarters level. Chapter 4 describes in more detail the different ways in which programs are funded and implemented.

Although the general structure is similar across countries, the model of implementation varies depending on the needs and capacity of the country. Activities are expected to aim toward performance targets and goals in areas such as prevention, care, treatment, M&E, partnership framework development, capacity building, and health systems strengthening. The types of activities supported by PEPFAR also vary, ranging from direct support for service delivery to primary technical assistance. Specific activities supported and implemented by PEPFAR will be described in more detail throughout this report. While not a comprehensive list, the following describes the types of activities supported and implemented through PEPFAR. In supporting scale up of HIV-related services, PEPFAR has supported the direct provision of services. This has included clinical, nonclinical, and laboratory services in public (government) and non–public health facilities, as well as in community facilities and home-based services. In addition to supporting providers and commodities required to deliver these services, PEPFAR has supported strengthening of infrastructure, such as equipment and facilities. Beyond supporting direct provision of services, PEPFAR has supported partners to provide training, mentoring, technical assistance, and other capacity building for not only service delivery but also program management, leadership and governance. PEPFAR has also supported policy development at the level of national and subnational management of the HIV response. In addition, PEPFAR also has supported routine data collection, surveillance, special studies, and evaluation and research activities.

The balance and combination among different activities and approaches to implementation vary according to the country's own resources, capacity and infrastructure. The implementation of these different models is discussed further in Chapters 4 and Chapter 10.

PERSPECTIVES ON INTERAGENCY IMPLEMENTATION

PEPFAR is the largest bilateral global health program in history, and in order to implement such large amounts of foreign assistance for such a range of activities in such a short time, the operational structure of PEPFAR was strategically designed to use a number of existing USG agencies in a whole-of-government approach (Simonds, 2012). In the course of collecting data about the implementation and effects of PEPFAR-supported programs in partner countries, the committee did learn about some of the advantages and challenges of the interagency implementation approach. These perspectives are reflected in a brief summary here, although this does not represent a comprehensive assessment of this topic because the committee was not charged nor was this study designed to carry out an assessment of the organizational infrastructure and operational management of PEPFAR, areas which fall under the scope and mandate of other organizations external to PEPFAR who have issued reports of their

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assessments, such as the U.S. Government Accountability Office and the Office of the Inspector General (GAO, 2009; OIG, 2008, 2009, 2010).

To be able to administer the large amounts of funding and diversity of programs that characterize PEPFAR, USG agencies did have to go through a "maturation process" (NCV 4-USACA). CDC, for example, had an administrative framework for grants primarily with a U.S. domestic focus, and experienced initial challenges in devising ways to manage large international grants (NCV 4-USACA; 272-34-USG). In addition, different agencies already had different approaches, systems, and mechanisms for contracting or granting funds to partners. These varied in the degree to which agency headquarters involvement was required and in what kinds of partners agencies typically fund, including whether agencies provide funds directly to partner country governments and public sector facilities or use funds to pay salaries directly for staff working in partner country facilities and ministries.

Interviewees across countries and stakeholder types associated several challenges with their efforts to implement PEPFAR programs through a whole-of-government, interagency model; this process was a notable source of tension in several countries. These challenges included the large amount of time spent on coordination; inefficiencies or non-optimal use of resources, particularly due to duplication of programs/services; tensions among staff around budget decisions and competition for funds, activities, and partners; a lack of clarity about the role and affiliation of the Country Coordinator position; communication and information-sharing challenges within USG and between USG and implementing partners and partner country stakeholders; and the extra administrative burden for implementing partners of multiple agencies. Across countries, PEPFAR mission teams described their efforts to identify the comparative advantages of each USG agency and assign responsibility for projects accordingly; this process was a considerable challenge in some countries where mission teams have struggled to reduce duplication and overlap of activities by USG agencies (272-ES; 331-2-USG; 587-2-USG; 240-8-USG). Even with the intent to focus on comparative advantages, in some countries there was not clarity or agreement among the agencies, neither in country nor from headquarters, on which agencies were better at which types of activities or working with which types of partners. One interviewee asserted "*OGAC does not promote interagency cooperation, no leadership in this area*" (331-2-USG). Another described the "one USG" philosophy as '*theoretical*' (587-2-USG).

In contrast, some interviewees emphasized the value of having multiple agencies with diverse capacities and expertise contribute to the country program, seeing this as an advantage compared to other single-agency development assistance programs. Interviewees identified the critical role the interagency approach played in achieving initial rapid scale up and emphasized the value of having multiple agencies with diverse capacities and expertise contribute to the country program, seeing this as an advantage compared to other single-agency development assistance programs. Interviewees identified factors and efforts that have contributed to reducing interagency tensions and creating more functional interagency operations. These included revisiting and refining strategies and processes for decision making and program management, including streamlining responsibility for potentially difficult decisions like budget allocations and strategic planning; empowering foreign service nationals to take leadership roles in the interagency team and technical working groups; and having strong leadership from the Chief of Mission that values and facilitates a more positive interagency process (461-ES, 935-ES, 331-ES; 587-ES). Some PEPFAR mission teams successfully conducted, either internally or with external involvement, a review of the PEPFAR portfolio to identify areas of overlap and opportunities to reduce duplication as well as, in several countries, a rationalization process of services and

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programs by agency, by region, and by partner (461-ES, 935-ES, 240-ES; 587-2-USG). One mission team mentioned that the Partnership Framework process helped their program identify what each agency was doing (116-7-USG).

Chapter 4 also discusses the topic of making more strategic and efficient use of resources by reducing duplication and overlap.

PEPFAR IMPLEMENTATION IN THE CONTEXT OF THE HIV EPIDEMIC IN PARTNER COUNTRIES

The diverse nature of the HIV epidemic in the range of partner countries where PEPFAR supports programs brings with it key contextual aspects that are not specific to PEPFAR but affect its implementation, and among the most influential of these are factors that relate to risk and vulnerability—both risk of HIV infection and transmission and vulnerability to poor health and other adverse outcomes. Understanding the many complex factors that contribute to risk and vulnerability is critical to understanding the nature of the epidemic and to the planning and implementing of an effective response to HIV; this principle is often articulated as "know your epidemic, know your response" (UNAIDS, 2007). While there may be general agreement on this principle, applying it is often difficult in practice. Some of the key factors that contribute to the epidemic and to some of the difficulty in implementing a response are discussed here from a broad perspective as context for this report because they apply to the whole of the response to HIV and not just to specific technical areas; these issues are also discussed in more depth throughout the report where they intersect with specific areas of PEPFAR-supported programs and other PEPFAR activities, especially in the chapters on prevention (Chapter 5), children and adolescents (Chapter 7), and gender (Chapter 8).

Although HIV continues to affect all regions of the world, the burden of HIV is not equally distributed among or within countries and populations. Certain populations are disproportionately vulnerable as a result of biological, behavioral social, cultural, economic, and political factors that can contribute to high rates of HIV infection. Some of these factors include poverty, lack of access to education, low access to and utilization of health care, gender-based violence, the effects of humanitarian crises, stigma, social and cultural marginalization, discrimination, and the criminalization of behaviors and activities that affect some populations at elevated risk. For many populations and individuals, many of these factors intersect. Taken together, in different parts of the world, they have facilitated particularly high rates of HIV infection among men who have sex with men, sex workers, people who inject drugs, and, particularly in southern Africa, young women (Gouws et al., 2008; UNAIDS, 2008, 2010). In addition to risk of HIV infection and transmission, many of these same factors contribute to vulnerability to poor health and other adverse outcomes both directly and through, for example, barriers to accessing health care and other support services. The relative influence of these factors that contribute to vulnerability and that drive the HIV epidemic varies by country, and by region within countries. In some cases, the epidemic is at a relatively low prevalence in the total population and is concentrated among specific populations, while in others with a high prevalence overall the risk of transmission is high for broad segments of the general population, while typically still having disproportionately high rates of infection in some specific populations.

It became clear during the committee's assessment of PEPFAR that there are widely varying perspectives in countries across all types of stakeholders on the populations that, based

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on both the available data and their experiences implementing HIV programs, are most vulnerable and most in need of support and services as part of the response to HIV (240-ES; 331-ES; 587-ES; 196-ES; 636-ES; 116-ES; 166-ES; 272-ES; 935-ES; 461-ES; 542-ES; 396-ES; 934-ES). These perspectives reflected many of the intersecting factors described previously. Although not a comprehensive listing, the wide range of populations identified as "vulnerable" or "most in need" by interviewees in PEPFAR partner countries is illustrated in Box 3-1. The populations that are identified as key populations at high risk in HIV programming were consistently among those identified as vulnerable, including people who inject drugs, men who have sex with men, and people who engage in sex work. Women and children were also commonly identified as vulnerable, as well as serodiscordant couples and people with multiple concurrent sexual partners. In addition, many interviewees mentioned populations as vulnerable because of factors such as life-stage, geographical region, socioeconomic status, occupation, and ability to access services. In many cases, interviewees also described those most vulnerable and most in need of services simply as those who are already HIV-positive.

BOX 3-1
Examples of Vulnerable Populations Identified From Country Visit Interview Data

- Women
- Children (in general as well as specifically infants exposed to HIV through maternal transmission, orphans, HIV positive children, children with disabilities, immigrant children, street children, youth/adolescents especially out-of-school youth, young women engaged in intergenerational sex, including marital relationships)
- Serodiscordant couples
- People with multiple concurrent partners, including people engaged in polygamy
- Sex workers and their clients
- Men who have sex with men
- People who inject drugs and their sexual partners
- Prisoners
- Trafficked persons
- Internally displaced persons
- Uniformed personnel (police and military)
- Taxi drivers
- Truckers and people near trucking routes
- Transient workers
- Isolated workforce, such as miners, loggers, fishermen
- People living in remote or otherwise hard-to-reach areas
- Minority ethnic groups, especially with language barriers
- People living in poverty or who are socioeconomically disadvantaged
- Elderly
- Health care workers
- People living in particular high prevalence areas within a country (rural, urban, high prevalence subnational regions)
- People living with HIV

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This wide range of identified needs and perspectives on vulnerability can pose a challenge in trying to plan strategically for a response to HIV that is prioritized according to the drivers of the epidemic and the populations most in need of services. Indeed, in some cases there was a lack of alignment and at times contention among stakeholders about how to target and prioritize the response (240-ES; 587-ES; 461-ES; 331-ES; 166-ES; 196-ES; 935-ES). An overarching challenge described by interviewees was the difficulty of allocating limited resources among a range of types of identified needs and available services. Another commonly expressed challenge was a lack of baseline prevalence and other data for specific populations that are vulnerable or at risk, which made it difficult to fully understand the epidemic and the performance of the ongoing response, and therefore to have a well-informed process for setting priorities. In some cases, it was noted by U.S. mission team members, civil society groups, and stakeholders within partner country governments that to achieve a shift in priorities can require a great deal of evidence and effort, especially if there are social, political, policy, or cultural barriers to implementing certain intervention approaches or focusing on certain marginalized populations. Examples of such barriers perceived by interviewees included a lack of government commitment to specific populations or programs, restrictive or punitive national policies, governmental resistance to acknowledging some populations at elevated risk as part of their epidemic, and the criminalization of some behaviors or practices associated with these populations (240-ES, 396-ES; 461-ES; 166-ES, 270-ES; 240-ES; 542-ES; 331-ES; 935-ES).

In many countries, PEPFAR was acknowledged for playing a facilitative role in acknowledging, addressing, and including in a country's HIV response the needs of populations that are vulnerable or at risk. One major contribution identified in interviews from several countries was that PEPFAR has supported the generation and use of epidemiological data, surveys, and special studies to better understand and respond to the specific drivers of epidemics (396-6-PCGOV; 934-24-PCGOV; 196-1-USG; 196-8-ML; 196-10-PCGOV; 196-11-USNGO; 196-13-OGOV; 116-1-USG; 116-4-USG; 166-4-USG, 240-9-USG; 240-12-USG; 272-13-USG; 331-3-USG; 331-10-PCGOV; 331-14-USG; 331-15-USG; 331-24-PCGOV; 587-9-USG; 636-1-USG; 934-21-USG; 461-1-USG; 396-1920-USG; 396-53-USNGO; 272-22-USG, 272-25-USG; 166-23-USG). This support for generating data to inform planning for the response is discussed further in Chapter 9 in the section on information systems in partner countries and in Chapter 11 on PEPFAR's knowledge management efforts.

In addition to supporting the generation of data, PEPFAR has both field- and headquarters-level efforts to review country operational plans to assure that PEPFAR's planned prevention and other programmatic activities align with the available epidemiological data in that country and to promulgate a response that addresses the specific drivers of the epidemics (Ryan, 2010). At the same time, PEPFAR also has the articulated goal of working to better harmonize its efforts with national priorities and the national response; these two goals are sometimes in conflict. For example, even where epidemiological data exist or had been produced through PEPFAR support, PEPFAR and partner countries sometimes experienced conflict about the translation of epidemiological data and other information about the response into aligned program priorities. In undertaking targeted prevention efforts, for example, PEPFAR and partner country stakeholders, particularly partner country governments, in some cases disagreed about the populations to be targeted. While PEPFAR might have put forth the need to address specific populations at elevated risk, some partner country stakeholders preferred instead to focus on, for example, the general population or on children and youth (542-9-PCGOV; 587-ES; 166-5-USG ; 240-08-USG; 331-18-USNGO; 587-07-PCGOV; 587-12-USG).

PEPFAR's role in the process of aligning its contribution to the HIV response with partner country government priorities and with the available evidence on the HIV epidemic in

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partner countries is a critical topic that is also discussed in the following section and in more depth throughout this report where it intersects with specific aspects of PEPFAR-supported efforts.

PEPFAR IMPLEMENTATION AND THE POLICY ENVIRONMENT

Since its creation, PEPFAR has operated in the context of domestic, global, and partner country policy environments, each of which introduce factors that can either facilitate or constrain PEPFAR's priorities and actions as well as the effectiveness of its efforts. Thus, in addition to attempting to implement well-established practices and interventions and to incorporate scientific advances, PEPFAR has also had to navigate diverse political pressures while developing its priorities, guidance, and programming. From within the United States, PEPFAR's efforts must contend with pressures coming from the U.S. Congress, advocacy groups, the media and the general public. The United States' domestic policy environment influences what PEPFAR is authorized to undertake or address for the U.S. response to global HIV, as well as how PEPFAR-supported programs activities are implemented. In addition, PEPFAR is influenced by its inherent role as a part of the diplomatic and foreign relations mission of the United States. Finally, PEPFAR must also navigate its relationship to global bodies, other donors, and, as discussed in the preceding section, the governments and other stakeholders in the countries where it works. Situated within this larger political environment, PEPFAR has played a key role at the global level and within countries in influencing HIV policy. This section is a brief overview that synthesizes some key general aspects of PEPFAR's relationship to and role in the policy environment; this overview is linked to the committee's assessment of specific policy issues that intersect with specific programmatic areas, which are discussed in more depth in the pertinent chapters of the report.

There are several related but distinct ways PEPFAR interacts to policy formulation and implementation. One is the development of PEPFAR's own guidance to set general policy and programmatic direction for PEPFAR's activities within partner countries, alluded to earlier in this chapter. This affects how PEPFAR money will be spent and what aspects of the HIV response will be prioritized, and often the effects are not limited to PEPFAR-supported activities but also influence activities that are supported through other resources. The other two primary pathways are through PEPFAR's relationship to the policy context in partner countries and PEPFAR's relationship to the broader global policy environment.

PEPFAR Implementation and the Policy Environment in Partner Countries

In the partner countries where PEPFAR is implemented, the country's policies affect every aspect of program implementation, from how prevention, treatment, and care services can be provided, to the infrastructure and functioning of health and other systems that contribute to the HIV response, to the broader policy and legal environment. As such, partner country policies are inextricably linked with PEPFAR's efforts to address the HIV epidemic and with the program implementation decisions that PEPFAR makes in different contexts. When well aligned, the local policy environment can facilitate PEPFAR's ability to achieve its goals and contribute to an effective HIV response in the partner country, but in some cases it can also be constraining; this was exemplified by one interviewee who stated that '*political issues with the government have slowed down the progress of PEPFAR*' (636-16-USG).

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Beyond adapting to operate and implement programs within the realities of the local policy environment, PEPFAR also works to inform or influence policy change in partner countries. Such efforts have included providing technical support to work towards the development and implementation of HIV-related laws and policies within countries, as well as other laws that affect the response to HIV. Examples include contributing to national guidelines and policies related to HIV-related services and commodities, the adoption of specific HIV-related laws, training of government officials on specific components of HIV-related policies, changing the legal environment for those made vulnerable by HIV, and addressing issues such as workplace discrimination, inheritance rights, property rights, and criminalization of behaviors and activities that affect some populations at elevated risk. These efforts have been occurring and evolving since the inception of PEPFAR, and the second Five-Year Strategy emphasized policy goals to address structural factors related to the HIV epidemic with implementation in part through the Partnership Framework process (OGAC, 2009). Policy-related activities have not always been consistently codified as part of the portfolio of PEPFAR-supported activities and country program planning processes. However, by 2012 policy development and alignment was offered as one of the selection of potential implementation activities in PEPFAR's guidance in nearly every program area (OGAC, 2011). In addition to specific activities aimed at policy development or policy changes, PEPFAR's direct engagement with partner country stakeholders, including both civil society and government, has also been a venue for PEPFAR to both respond to and influence partner country policies that affect the HIV epidemic and the response. As described previously, another major contribution has been PEPFAR's support for data collection efforts to better understand the epidemic and to inform partner country planning and policies.

PEPFAR Implementation and the Global Policy Environment

PEPFAR contributes to the global policy arena in a range of aspects of the global HIV response, such as developing normative technical guidelines and conferring with other donors and institutions with respect to global priorities and harmonizing elements of the global response, including participating in the global dialog around politically sensitive issues such as the intersections of HIV with drug use, sex work, and human rights. Although the committee was not mandated with examining the role of PEPFAR in global HIV policy and this study was not designed to carry out a comprehensive assessment in this area, this topic emerged from the evaluation planning and the data collection during the evaluation as an important aspect of PEPFAR operations and implementation that intersects with the effects of PEPFAR's programmatic contribution to the HIV response. Therefore, a broad synthesis of perspectives on PEPFAR's influence in the arena of global HIV is presented here, drawn from interviews conducted with individuals across a diverse range of stakeholders in the global HIV response, including advocates, representatives of bilateral and multilateral organizations involved in the AIDS response, and PEPFAR staff.

At the level of the global arena, as one of the largest donors in the international response to HIV, PEPFAR has the potential to have an outsized influence on the global HIV policy agenda given its immense resources in terms of not only funding but also personnel. PEPFAR was identified as a central force in the global AIDS response. Despite some challenges described further below, interviewees expressed the importance of PEPFAR's presence in the global policy community and saw this as fundamentally changing global HIV programming in predominantly positive ways (NCV-13-ML; NCV-14-ML; NCV-16-USG; NCV-22-USNGO; NCV-23-USNGO; NCV-24-USNGO; NCV-25-USNGO; NCV-29-ML).

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Several interviewees acknowledged that there was the potential for PEPFAR to be a dominating force as a result of the resources that it contributes to global HIV programming, (NCV-16-USG; NCV27-ML); however, it was generally not the experience of these and other global stakeholders that this happened in their engagement and interactions with PEPFAR leadership and staff, and several interviewees recognized the challenges faced by those responsible for implementing PEPFAR at all levels given the complex political and policy environment and range of influences under which PEPFAR operates. The overarching theme that emerged across stakeholders was that of PEPFAR's leadership, and several examples of ways in which PEPFAR positively influenced the global HIV agenda were offered by interviewees. One was PEPFAR's push from the beginning for prioritization of high burden countries; another was PEPFAR's demonstration that scale-up of HIV treatment and other services was feasible in these countries (NCV-13-ML; NCV-16-USG). Another example was PEPFAR's role as a driver for the implementation and scale-up of interventions based on existing and emerging evidence in some program areas, such as prevention of mother to child transmission, programs for orphans and vulnerable children, male circumcision, and the recent momentum for the call for an AIDS-free generation (NCV-13-ML; NCV-16-USG; NCV-27-ML; NCV-28-ML; NCV-29-ML). In addition to the use of evidence to inform programming, several interviewees also identified PEPFAR's focus on monitoring and evaluation of its programs as an important contribution to the global HIV response (NCV-13-ML; NCV-14-ML; NCV-25-USNGO; NCV-32-OBL), something that was also echoed at the country level (NCV-5-USACA; 461-14-USG; 272-15-PCNGO; 240-8-USG; 636-18-ONGO, 396-55-USG; 331-14-USG, 116-23-USPS, 166-23-USG, 272-22-USG, 461-18-USG). As noted by one interviewee:

> *I think that the constant insistence on accountability and evaluation programs, I think that's something, particularly since the advent of PEPFAR, and also before, actually, that the US was always pushing for, which I think that was a very good thing. (NCV-14-ML)*

The principle of support for using program monitoring and other evidence was nonetheless accompanied by considerable challenges in practice; this topic is discussed in depth by program area throughout this report and more comprehensively in Chapter 11 on PEPFAR's Knowledge Management.

Although overall PEPFAR's engagement in the global policy arena was seen as positive, specific PEPFAR policies and funding limitations were also identified as challenges in achieving a coordinated and well-aligned global response to HIV. These included some challenges that were highlighted but were noted as having improved over time including, for example, shifting to a less restrictive resource allocation for prevention to allow country programs to more appropriately match evidence-based programming to the epidemic and working towards improved harmonization of indicators (NCV-11-USG; NCV-3-USG, NCV-7-USG; NCV-21-ML; NCV-10-USG; NCV-17-USG). They also included some ongoing challenges, especially related to supporting evidence-based prevention programming for prevention of sexual transmission and for targeted interventions for people who inject drugs and people who engage in sex work (NCV-22-USNGO; NCV-24-USNGO; NCV-32-OBL). All of these challenges will be discussed in more depth in the relevant subsequent chapters of the report.

On the process of coordination with other stakeholders in the global response, multiple interviewees highlighted examples of PEPFAR's constructive participation with multinational organizations, including UNAIDS, the Global Fund, and UNICEF (NCV-13-ML; NCV-14-ML; NCV-21-ML;

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NCV-22-USNGO), and several interviewees noted that these relationships had expanded over the course of PEPFAR's implementation (NCV-13-ML; NCV-14-ML; NCV-21-ML). For example, one interviewee stated that trying to coordinate with multiple U.S. government organizations simultaneously had been a challenge, but that the introduction of PEPFAR effectively addressed this (NCV-14-ML). Interviewees also noted the participation of PEPFAR officials in the UNAIDS Programme Coordinating Board as an example of commitment to international collaboration, particularly when the highest levels of PEPFAR leadership were increasingly engaged (NCV-13-ML; NCV-14-ML; NCV-16-USG). There were challenges described in PEPFAR's coordination and work with the Global Fund, including a lack of discussion around strategic planning (NCV-21-ML; NCV-25-USNGO) and failure to identify synergies between the two programs (NCV-22-USNGO), and several interviewees expressed that PEPFAR's support for bolstering the Global Fund could be stronger (NCV-14-ML; NCV-16-USG). However, the recent introduction of a PEPFAR liaison to the Global Fund who is based in Geneva was identified as having a positive effect on dialogue between the two programs (NCV-21-ML; NCV20-USG).

PEPFAR and other global stakeholders intersect not only at the level of global policy dialog but also at the country level, where they are all contributing as a community of external donors to the national response to HIV. For this level of interaction, several interviewees noted mixed success in collaboration within partner countries between PEPFAR programs and other stakeholders, including UNAIDS, the Global Fund, the World Health Organization, and other bilateral donors (NCV-13-ML; NCV-14-ML; NCV-21-ML; NCV-23-USNGO; NCV-32-OBL). Some interviewees attributed this to the perception that the PEPFAR country activities and strategic planning remained siloed (NCV-13-ML; NCV-23-USNGO), whereas others noted that the large number of PEPFAR staff and implementing partners inherently introduce difficulties in the logistics of coordination, regardless of the program's intent (NCV-14-ML; NCV-32-OBL). The coordination between PEPFAR and other global stakeholders at the country level is discussed in more depth in the chapters on funding (4), health systems (9), sustainability of the response (10), and data collection, data use, and data sharing (11).

SUMMATION

As this chapter has described, PEPFAR is large, multifaceted, and complex, supporting a wide range of activities that are carried out by many different partners in a diverse group of countries. PEPFAR-supported programs also operate alongside programs supported through other external and partner country funding sources, other funders that share the same ultimate aim as PEPFAR. In addition, health outcomes are also influenced by cultural, societal, geographical, and political factors and influences that vary by country and are not within the control of PEPFAR-supported programs. As PEPFAR increasingly emphasizes country ownership and alignment with national plans, the extent to which the USG directly influences all levels of priority-setting, decision making, and implementation can be quite limited.

As discussed in depth in the description of the evaluation approach in Chapter 2, the IOM endeavored to conduct a rigorous evaluation of PEPFAR that took into account the complexities of implementation for a credible assessment of the contribution of PEPFAR to changes in health outcomes and health impact within the landscape of other funding sources, other HIV programs, and other factors that affect health.

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4

U.S. Funding for the PEPFAR Initiative

Main Messages

- The USG is the largest donor to the global HIV epidemic, and PEPFAR's investment represents an historic contribution in countries with few resources and a great need for support in their response to HIV.

- The greater part of PEPFAR's funding has always gone to support programs and activities implemented in partner countries. Consistent with one aspect of PEPFAR's articulated strategy to move towards sustainability, more PEPFAR funding over time has been directed to local prime partners. Based on an analysis of a subset of data and countries, the increase in local prime partner funding has been driven primarily by increased funding to nongovernmental entities based in partner countries; the proportion of funding to partner country governments as prime partners has remained relatively stable over time.

- PEPFAR is increasingly emphasizing a range of efforts to more strategically and efficiently use its resources through the generation and use of economic and financial data; the allocation of resources based on anticipated impact; improved collaboration with partner country governments, other donors, and the Global Fund to align priorities and programs; and streamlining of business processes. PEPFAR has started to see some gains from these efforts. Continuing to identify and implement opportunities for more strategic and efficient use of resources will be critical for making progress toward optimal return on investment in the response to HIV in partner countries.

- Due to limitations in the available financial data, it was difficult to fully assess the amount and distribution by program area and partner type of the annual direct investment of PEPFAR in partner countries. PEPFAR would benefit from the collection and reporting of financial data that serves not just for accounting purposes, but is also more closely aligned with programmatic data and program implementation. These data are critical for PEPFAR and external stakeholders to more easily and effectively understand how well PEPFAR is being implemented and how PEPFAR's investment relates to both the targets and goals of PEPFAR-supported programs and the broader goal of transitioning to more sustainable management of the response to HIV in partner countries.

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4

U.S. Funding for the PEPFAR Initiative

INTRODUCTION

PEPFAR is the largest global health initiative focused on a single disease ever undertaken, and the United States is the single largest donor to global HIV/AIDS efforts in the world (Donnelly, 2012c; OGAC, 2009d).The committee reviewed PEPFAR funding because it represents one of the most direct measures of the United States government's (USG's) investment to address the global AIDS pandemic and, as such, is an important metric by which to understand and assess the program's impact. It also represents a critical input for answering the questions pertaining to PEPFAR's effects that were considered in the evaluation of programmatic areas using the program impact pathway framework described in Chapter 2. The distribution of PEPFAR funding over time can provide insight into HIV prevention, treatment, and care programs as well as into additional broader goals, such as country ownership, sustainability, and the strengthening of health systems.

To describe the investments that the USG has made through PEPFAR and to assess the relationship between these investments and program's effects, the committee examined, to the extent possible, the level of funding over time and how the funds were budgeted and distributed. Unfortunately, due to limitations in the available financial data that are described more fully in this chapter, it was not feasible to make all of the assessments that the committee set out to make. In particular, it was difficult to describe the distribution of the annual direct expenditure of PEPFAR in partner countries, to comprehensively match accounting budget codes to programmatic activities, and to fully follow the types of partners that ultimately receive funding and implement PEPFAR-supported activities. Nonetheless, the funding data that were available did allow for the insights and observations that were important information for the evaluation, and these finding are presented in this chapter.

As described in Chapter 2, the committee focused most of its data collection and its assessment on the 31 countries that were writing country operational plans (COPs) when the IOM evaluation study process began in 2009.[1] As such, in some cases the committee's

[1] The 31 PEPFAR countries submitting Country Operational Plans at the time were the original 15 focus countries (Botswana, Republic of Côte d'Ivoire, Federal Democratic Republic of Ethiopia, Cooperative Republic of Guyana, Republic of Haiti, Republic of Kenya, Republic of Mozambique, Republic of Namibia, Federal Republic of Nigeria, Republic of Rwanda, Republic of South Africa, United Republic of Tanzania, Republic of Uganda, Socialist Republic of Vietnam, and Republic of Zambia) plus the following additional countries: Republic of Angola, Kingdom of Cambodia, People's Republic of China, Democratic Republic of the Congo, Dominican Republic,

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examination of PEPFAR funding in this chapter is limited to this subset of 31 countries. These countries represented 96 percent of PEPFAR planned funding in FY 2011 (OGAC, 2011d).[2] In addition, although the committee reviewed data on PEPFAR funding over time to contribute to this evaluation, the committee was not charged to conduct a financial audit of PEPFAR; that function is performed by the Offices of the Inspectors General at the USG agencies responsible for the implementation of PEPFAR programs and activities, including the Department of State (DoS), the Department of Health and Human Services (HHS), and the U.S. Agency for International Development (USAID).

This chapter begins with a brief discussion of the broader global funding environment for HIV/AIDS within which PEPFAR operates as a reflection of the context in which PEPFAR contributes to the HIV response in partner countries. This is followed by an overview of the USG budget and PEPFAR funding processes and a presentation of PEPFAR financial data describing the amount and distribution of funding over time as well as the characteristics of the partner countries that have been recipients of PEPFAR funding. The chapter then presents a brief discussion of the strategic use of PEPFAR resources. The chapter also discusses some questions of interest to the committee that could not be addressed due to limited availability of quality data.

The primary focus of this chapter is on funding processes within PEPFAR. The committee recognizes that in the response to HIV in PEPFAR partner countries there is an inherent interconnectedness among PEPFAR, partner countries, and other donors. This is touched upon briefly in this chapter, but the primary discussion can be found in the section on financing in Chapter 9, which discusses health systems strengthening, and in Chapter 10, which discusses progress toward a sustainable response in partner countries.

PEPFAR'S CONTRIBUTION RELATIVE TO OTHER DONORS

In most countries PEPFAR is situated within a broader landscape of global funding for HIV/AIDS which includes partner country governments; other donor governments; the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund); the World Bank; and other multilateral institutions.[3] The committee sought data on other sources of funding for HIV/AIDS in order to understand the context in which PEPFAR is implemented and to contribute to an assessment of the USG's relative HIV/AIDS investment. Unfortunately, few data were available to examine the financial contribution of partner countries to national HIV/AIDS responses. The committee reviewed data from National Health Accounts and National AIDS Spending Assessments for the 31 countries that are the focus of this evaluation, but was unable to address partner country contribution because data are unavailable for many countries and years. Thus, the data presented here focus on the contribution of PEPFAR only in the context of external donor assistance for HIV/AIDS. Chapter 9 provides a more thorough discussion of domestic financing for national HIV/AIDS responses and the implications of these data limitations.

Republic of Ghana, Republic of India, Republic of Indonesia, Kingdom of Lesotho, Republic of Malawi, Russian Federation, Republic of the Sudan, Kingdom of Swaziland, Kingdom of Thailand, the Ukraine, and the Republic of Zimbabwe.

[2] Planned/approved funding as reported in the FY 2011 PEPFAR Operational Plan. The committee's sources for this and other types of funding information will be explained throughout the chapter.

[3] Multilateral institutions are "international institutions with governmental membership." In the context of development assistance, multilateral institutions pool donor contributions and disburse funding at their own discretion (OECD, 2012a).

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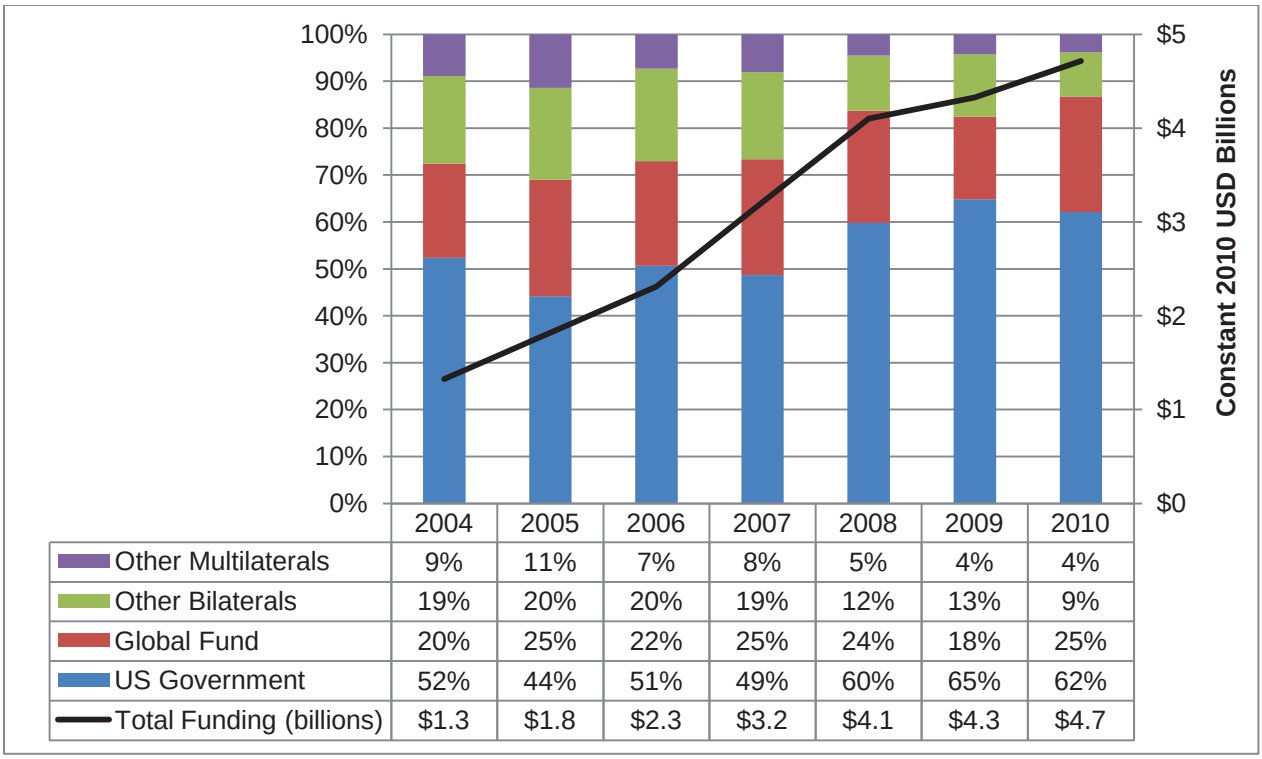

	2004	2005	2006	2007	2008	2009	2010
Other Multilaterals	9%	11%	7%	8%	5%	4%	4%
Other Bilaterals	19%	20%	20%	19%	12%	13%	9%
Global Fund	20%	25%	22%	25%	24%	18%	25%
US Government	52%	44%	51%	49%	60%	65%	62%
Total Funding (billions)	$1.3	$1.8	$2.3	$3.2	$4.1	$4.3	$4.7

FIGURE 4-1 Total donor disbursements for HIV/AIDS in PEPFAR partner countries (constant 2010 USD billions).
NOTE: Figure presents disbursements for the 31 PEPFAR countries that were writing COPs when the IOM evaluation study process began in 2009. Disbursements represent the sum of two OECD sector codes: STD control, including HIV/AIDS, and social mitigation of HIV/AIDS. Funding from the U.S. government and other bilaterals represents only bilateral funding (funding from a donor government to a partner country) and not contributions to the Global Fund.
SOURCE: OECD, 2012b.

To contextualize PEPFAR's financial contribution within the broader external donor funding landscape, the committee examined disbursement data on official development assistance for HIV/AIDS, as reported to the Organization for Economic Cooperation and Development Creditor Reporting System. For the 31 countries in the committee's analysis, total donor disbursements for HIV/AIDS were $21.8 billion from 2004 to 2010 (OECD, 2012b).[4] As shown in Figure 4-1, total disbursements for HIV/AIDS increased each year, from $1.3 billion in 2004 to $4.7 billion in 2010. Disbursements increased over time from all types of donors, including USG bilateral funding for PEPFAR, the Global Fund, other bilateral government donors, and other multilateral organizations.[5] The largest proportion of donor funding over this period was provided by the USG through bilateral funding for PEPFAR, followed by the Global Fund, for which the USG is the largest contributor (Goosby et al., 2012). During this time period, the proportion of donor funding from other bilateral donors and multilateral organizations decreased, while the proportions from the USG and the Global Fund increased.

As these data indicate, the USG's bilateral investments implemented through PEPFAR constitute the largest external source of funding in the response to the HIV epidemic across these 31 countries, providing almost two-thirds of the external funding for HIV in 2010. Although

[4] This 7-year period of time captures donor funding from the beginning of PEPFAR implementation to the most recent year available.
[5] Bilateral funding is provided to an aid-recipient country directly from a donor country (OECD, 2012a).

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these descriptive data do not demonstrate a causal relationship between funding and impacts on the epidemic, it is reasonable to conclude from the magnitude of PEPFAR's investment and the proportion of HIV funding that it represents that PEPFAR funding did contribute to changes in the trajectory of the HIV epidemic and in HIV-related outcomes. Using the approach of the program impact pathway described in Chapter 2, this evaluation report presents the committee's assessment of the effects of the activities and programs supported with these funds.

PEPFAR funding has represented a historic contribution in countries with few resources and a great need for support in their response to HIV. The dominance of one external donor, however, also brings with it the possibility that this one donor will drive the agenda and that the response in countries will be vulnerable to changes in that one donor's investment or policies. These issues are discussed throughout this report, and, in particular, the role of donor funding in supporting the response to HIV in partner countries, along with the additional factors of national investments, health systems financing, and implications for future sustainable management of the HIV pandemic, are discussed in Chapters 9 and 10.

OVERVIEW OF THE PEPFAR FUNDING PROCESS

Through review of publicly available documents and interviews with the Office of the U.S. Global AIDS Coordinator (OGAC) and other USG stakeholders, the committee developed a framework to represent the flow of PEPFAR funding and how it is ultimately used for the implementation of programs in partner countries. Figure 4-2 represents a simplified overview of this flow (NCV-1-USG; NCV-11-USG) (IOM and NRC, 2010).[6] In most respects, it mirrors the administrative and programmatic structure of PEPFAR as described in Chapter 3. The rest of this section expands on the subcomponents represented in Figure 4-2, describing the processes for the major steps within the framework. Box 4-1 provides definitions for key terms used in this chapter as part of the description of the U.S. federal budget process and PEPFAR's budgeting, planning, and programming.

[6] Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Noncountry Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO.

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BOX 4-1
Definitions for Selected Financial Terms

Authorization: "An authorizing measure can establish, continue, or modify an agency or program for a fixed or indefinite period of time" and "authorizes the enactment of appropriations for an agency or program" (Heniff, 2008, p. 2).
Appropriations: "An appropriations measure provides budget authority to an agency for specified purposes. Budget authority allows federal agencies to incur obligations and authorizes payments to be made out of the Treasury" (Heniff, 2008, p. 2).
Obligations: Commitments of funding, such as placing an order or awarding a contract, made by USG agencies in order to implement and carry out programs, projects, and activities.
Outlays: Payments from the U.S. Treasury, usually in the form of cash or check, for goods or services.
Planned/Approved Funding: How OGAC and PEPFAR mission teams plan to obligate and outlay funds, documented in annual operational plans.

SOURCES: OGAC (2011d); OMB (2011).

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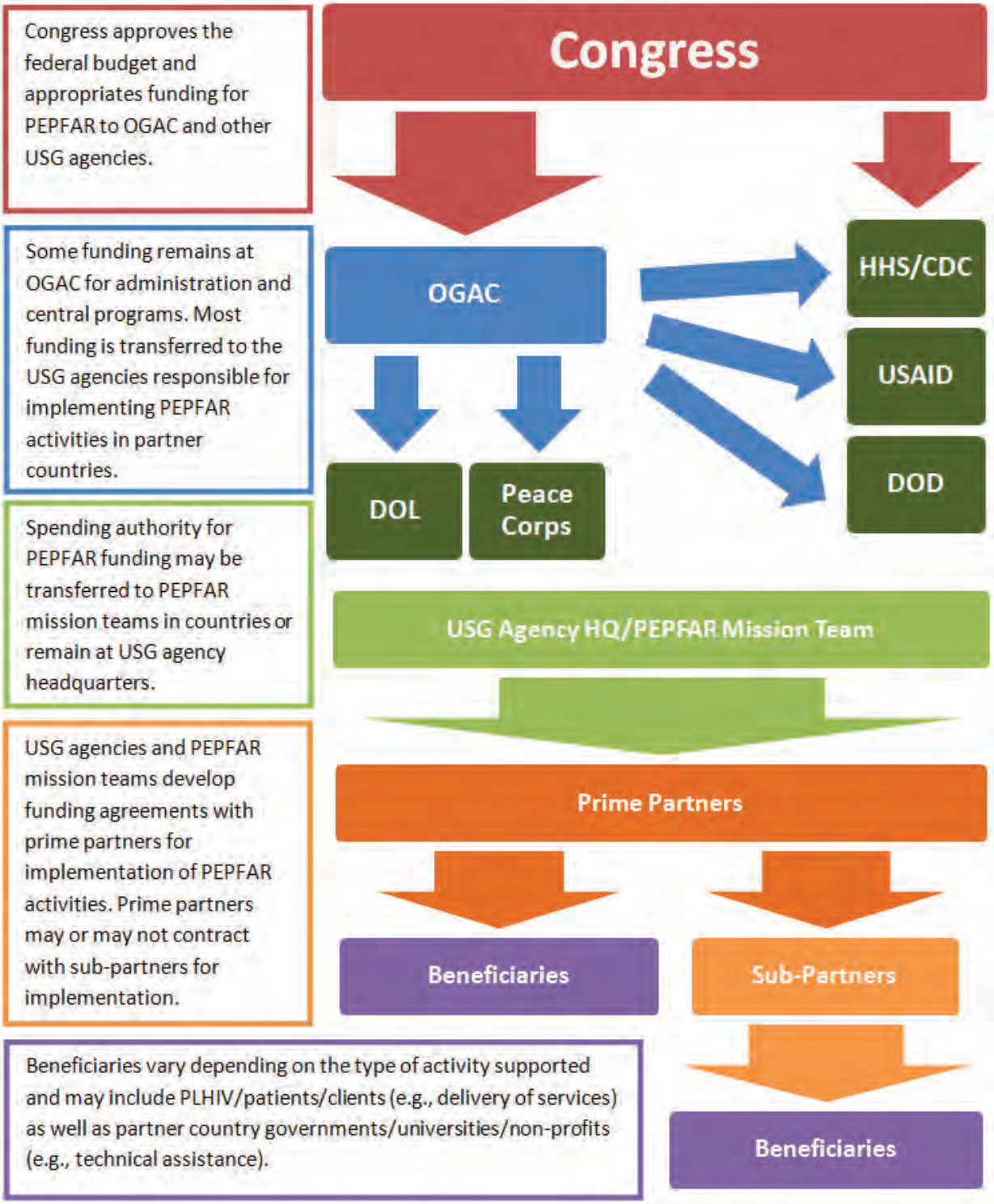

FIGURE 4-2 PEPFAR overall funding flows framework.
NOTE: CDC = U.S. Centers for Disease Control and Prevention, DOD = U.S. Department of Defense, DOL = U.S. Department of Labor, DOS = U.S. Department of State, HHS = U.S. Department of Health and Human Services, HQ = headquarters, OGAC= Office of the U.S. Global AIDS Coordinator, PLHIV = people living with HIV/AIDS, USAID = United States Agency for International Development, USG = United States Government
SOURCE: Developed by the committee after document review and consultations with OGAC.

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Congressional Authorization and Appropriations

The U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (the Leadership Act)[7] authorized up to $15 billion in funding, including funds for bilateral PEPFAR efforts and annual yearly contributions to the Global Fund, for fiscal years (FYs) 2004 through 2008.[8] In 2008 the U.S. Congress reauthorized PEPFAR for an additional 5 years (FY 2009–FY 2013) for up to $48 billion: $39 billion for bilateral HIV/AIDS programs and contributions to the Global Fund and $9 billion for bilateral tuberculosis and malaria programs.[9] These two pieces of legislation authorized Congress to appropriate up to a maximum level of funding in a 5-year period, but PEPFAR's annual budget is still dependent on the annual federal budget process. Congress may appropriate less or more than what is authorized. Early each year, the President prepares a budget for the following year and submits it to the Congress. The Global AIDS Coordinator requests a certain level of funding for each recipient country, and these requests are included in the President's budget proposal. Congress reviews the President's budget proposals, determines the final revenue and spending plan for the country, and eventually passes appropriations measures that provide budget authority to USG agencies (Heniff, 2008; OMB, 2011). The annual amount of PEPFAR funding is decided during this budget process.

The red arrows in Figure 4-2 represent the appropriations process whereby Congress appropriates a specific level of funding for USG agencies to implement PEPFAR programs and activities. The greater part of PEPFAR funding is initially appropriated by Congress directly to OGAC at the Department of State, and then most is eventually transferred to the other USG agencies responsible for implementing programs in partner countries (represented by the blue arrows in Figure 4-2). USAID, HHS and the Centers for Disease Control and Prevention (CDC), and the Department of Defense (DoD) may also receive direct appropriations of PEPFAR funding through separate appropriations acts.

All PEPFAR funding, regardless of the agency to which it is appropriated or transferred, is planned and coordinated through an interagency process overseen and led by OGAC (NCV-1-USG; NCV-4-USACA). Each year the USG agencies responsible for implementing PEPFAR work together to develop the PEPFAR Operational Plan as well as country and regional operational plans which include descriptions of previous achievements, proposals for new and continued activities, and funding requests for implementation of these activities. These plans are based on the amount of money requested by OGAC in the President's budget proposal, and operational plans must be approved by the Global AIDS Coordinator (NCV-1-USG; NCV-4-USACA). As described above, the ultimate amount of PEPFAR funding for each year is determined through the congressional budget and appropriations processes. The PEPFAR Operational Plan provides information about the planned distribution of congressionally appropriated funding to USG agencies for PEPFAR activities as well as details about how the funding that remains at OGAC is used for central programs, oversight, and administration. Country operational plans provide further information about which USG agencies will receive funding for implementation of specific activities and the mechanisms for disbursing that funding to implementing partners. Together, these operational plans document summary budget information regarding the planned and approved use of

[7] United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L.108-25, 108th Cong., 1st Sess. (May 27, 2003).
[8] *Ibid*., §401(a).
[9] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

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PEPFAR funding, including which activities will be implemented by which agencies, as determined during the interagency planning process (OGAC, 2011d).

Stakeholders interviewed for this evaluation identified challenges to program planning and implementation as a result of this annual USG funding process. In particular, interviewees indicated that long-term planning is often difficult for U.S. mission teams, partner countries, and implementing partners because of uncertainty from year to year about whether they will receive funding and how much they will receive (NCV-4-USACA; NCV-9-USG; NCV-11-USG; 166-10-USNGO; 166-13-PCGOV; 935-2-USG; 935-8-PCGOV; 396-16-PCGOV; 240-33-USG). These challenges are considered further in Chapters 9 and 10, where health systems financing and achieving sustainable management of the response are discussed.

Obligations and Outlays

Once Congress has appropriated funding for a given year and the headquarters and country-level planning processes are complete, PEPFAR funding is available to be obligated and outlaid for program implementation. *Obligations* are commitments of funding, such as awarding a contract, made by USG agencies in order to implement and carry out programs, projects, and activities (OMB, 2011). *Outlays* are the actual payments made from the U.S. Treasury (OMB, 2011). USG agencies obligate and outlay PEPFAR funding to prime partners. Prime partners may be nonprofit organizations, academic institutions, for-profit firms, multilateral organizations, partner country governments, or USG agencies. PEPFAR funding is obligated when a USG agency enters into a legally binding agreement (also known as an implementing mechanism) such as a contract, grant, or cooperative agreement with a prime partner. PEPFAR funding is outlaid when the U.S. Treasury actually makes a payment to a prime partner. Prime partners implement PEPFAR activities either directly or through sub-partners.

Historically, most PEPFAR funding appropriated to OGAC has been “no-year” money will never “expire”; that is, funding appropriated in any given fiscal year could be obligated or outlaid in that year or any year that follows (OGAC, 2008d). This type of funding remains available until expended and provides OGAC with some flexibility (Sessions, 2006). In FY 2012, a 5-year limit was put in place for the obligation of this funding (Donnelly, 2012b).[10,11] Funding that is directly appropriated to other USG agencies, including USAID, HHS, and DoD, may be subject to different periods of availability as determined by the relevant appropriations acts (OGAC, 2010e).

PEPFAR FUNDING LEVELS AND DISTRIBUTION BY PROGRAMS AND PARTNERS

To understand the level of investment and the allocation and distribution of PEPFAR resources, the committee collected data from multiple available sources on appropriations, which reflect congressional intent; obligations, which represent programmatic intent; and outlays, which represent the disbursement of funding for implementation. The following sections present the committee’s findings, to the extent that data were available, at each level within the overall framework for the flow of PEPFAR funding (Figure 4-2). Although the committee was interested

[10] Personal communication from OGAC, February 11, 2013.

[11] *Department of State, Foreign Operations, and Related Programs Appropriations Act, 2012*, P.L. 112-74, 112th Cong., 1st sess., (December 23, 2011), 392.

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in understanding the flow of funding through all levels, data were only available to the level of distribution of funds to prime partners, as discussed in more detail below.

Because the committee was charged with evaluating PEPFAR since its inception, the U.S. fiscal year (FY) 2004 was used as the baseline for assessing the financial data, and the following section presents financial data through the last complete year of data available during the timeframe of the evaluation, typically FY 2011. It is important to note that although FY 2004 was the first year of funding for PEPFAR, it was not the first year of USG funding for global HIV/AIDS efforts. Rather, USG assistance for global HIV/AIDS efforts began in 1986, with an initial investment of $1 million. By 2000, annual funding had grown to just over $360 million, and it reached about $1.5 billion in 2003 (Kates and Summers, 2004). Compared to this prior funding, PEPFAR represented a major scale-up and expansion of U.S. support, authorizing up to $15 billion for bilateral programs over its first 5-year period and creating a new office and coordinating mechanism for the USG global HIV/AIDS response.[12] What follows is a presentation of financial data for FYs 2004 through 2011 (where available).

Congressional Appropriations

Appropriations reflect the level of congressional commitment for PEPFAR programs. From 2004 to 2011, more than $38 billion (current USD) was appropriated to USG agencies for PEPFAR programs and the Global Fund (OGAC, 2011a). During PEPFAR I (FY 2004-FY 2008), actual congressional appropriations surpassed the $15 billion authorized in the Leadership Act. Total congressional appropriations over the 5-year period were $18.3 billion for bilateral HIV/AIDS programs and contributions to the Global Fund (excluding funding for tuberculosis and malaria) (OGAC, 2009a). In the first 3 years of PEPFAR II, actual appropriations totaled $19.8 billion, just over half of the $39 billion authorized through FY 2013 (OGAC, 2011a). From FY 2004 to FY 2011, $28.6 billion, or the greater part of PEPFAR funding, was appropriated for support of PEPFAR country programs. Approximately $3.3 billion was appropriated for research at the U.S. National Institutes of Health (NIH), and $6.1 billion was appropriated for the Global Fund. Figure 4-3 shows the annual appropriations for each of those categories from FY 2004 to FY 2011.

Cumulative Obligations and Outlays

To understand the level of PEPFAR investment intended by Congress that has been spent to support PEPFAR activities over time, the committee first assessed how appropriated funds have been obligated and outlaid over time. Figure 4-4 summarizes the cumulative funds made available, obligated, and outlaid for PEPFAR programs in all partner countries.

For the funds shown in Figure 4-4, Figure 4-5 provides more detail on the proportions that have been obligated and outlaid at the end of each fiscal year. As of the end of FY 2011, 72 percent of the total funding made available for PEPFAR through congressional appropriations had been outlaid, 17 percent had been obligated but not yet outlaid, and 11 percent had yet to be obligated or outlaid. The cumulative amount of available PEPFAR funding not outlaid at the end of each fiscal year has increased from $1.7 billion at the end of FY 2004 to $10.7 billion at the end of FY 2011; during this time, the total amount of cumulative available funding increased from $2.2 billion to $38 billion (Figure 4-4).

[12] The legislation also authorized "such sums as may be necessary" for contributions to the Global Fund.

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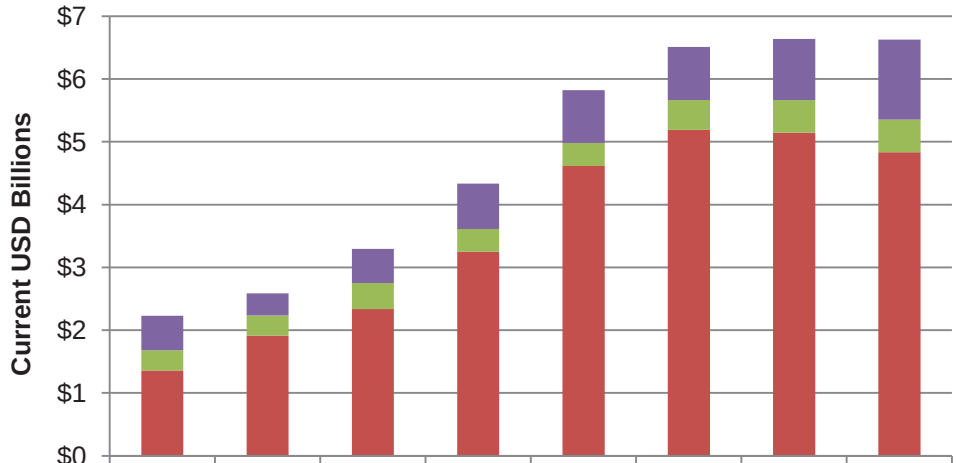
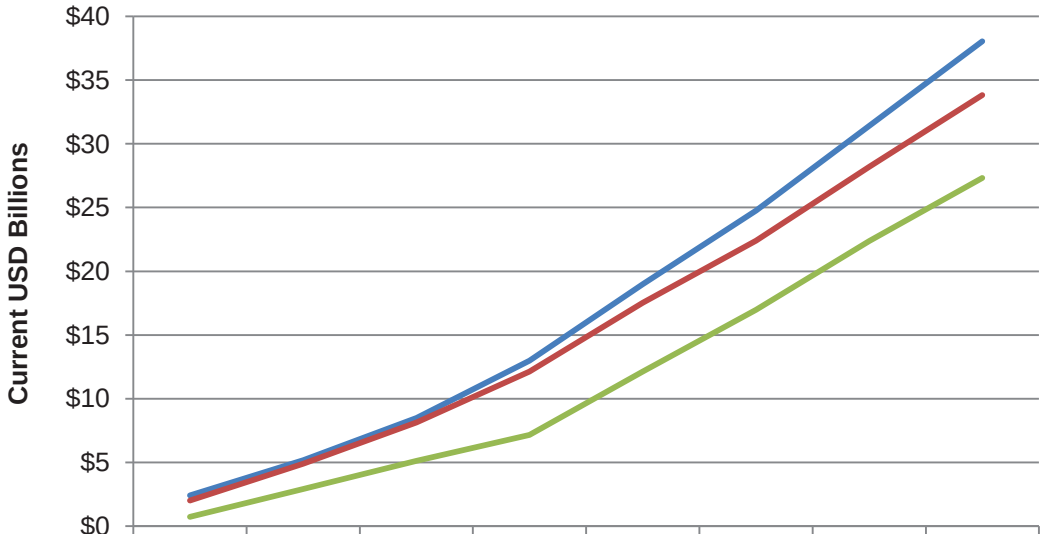


	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
Global Fund	$0.5	$0.3	$0.5	$0.7	$0.8	$0.8	$1.0	$1.3
HHS/NIH Research	$0.3	$0.3	$0.4	$0.4	$0.4	$0.5	$0.5	$0.5
Focus and Other Country HIV/AIDS Activities	$1.4	$1.9	$2.3	$3.2	$4.6	$5.2	$5.1	$4.8
Total Appropriations	$2.2	$2.6	$3.3	$4.3	$5.8	$6.5	$6.6	$6.6

FIGURE 4-3 Congressional appropriations for PEPFAR, FY 2004–2011 (current USD billions).
NOTE: Data represent total funding appropriated (made available) for all PEPFAR countries within each U.S. fiscal year (October 1–September 30) in current USD billions. NIH = the National Institutes of Health.
SOURCES: OGAC, 2004; 2006a; 2007a; 2008a; 2009a; 2010a,b; 2011a.



	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
Total Available	$2.4	$5.2	$8.5	$13.0	$19.0	$24.8	$31.4	$38.0
Obligations	$2.0	$4.9	$8.1	$12.1	$17.5	$22.4	$28.2	$33.8
Outlays	$0.7	$2.9	$5.1	$7.2	$12.1	$17.0	$22.4	$27.3

FIGURE 4-4 Cumulative obligations and outlays, FY 2004–FY 2011 (current USD billions).
NOTE: Outlays are a subset of obligations, which are a subset of total funding available.
SOURCES: OGAC, 2004; 2006a; 2007a; 2008a; 2009a; 2010a,b; 2011a.

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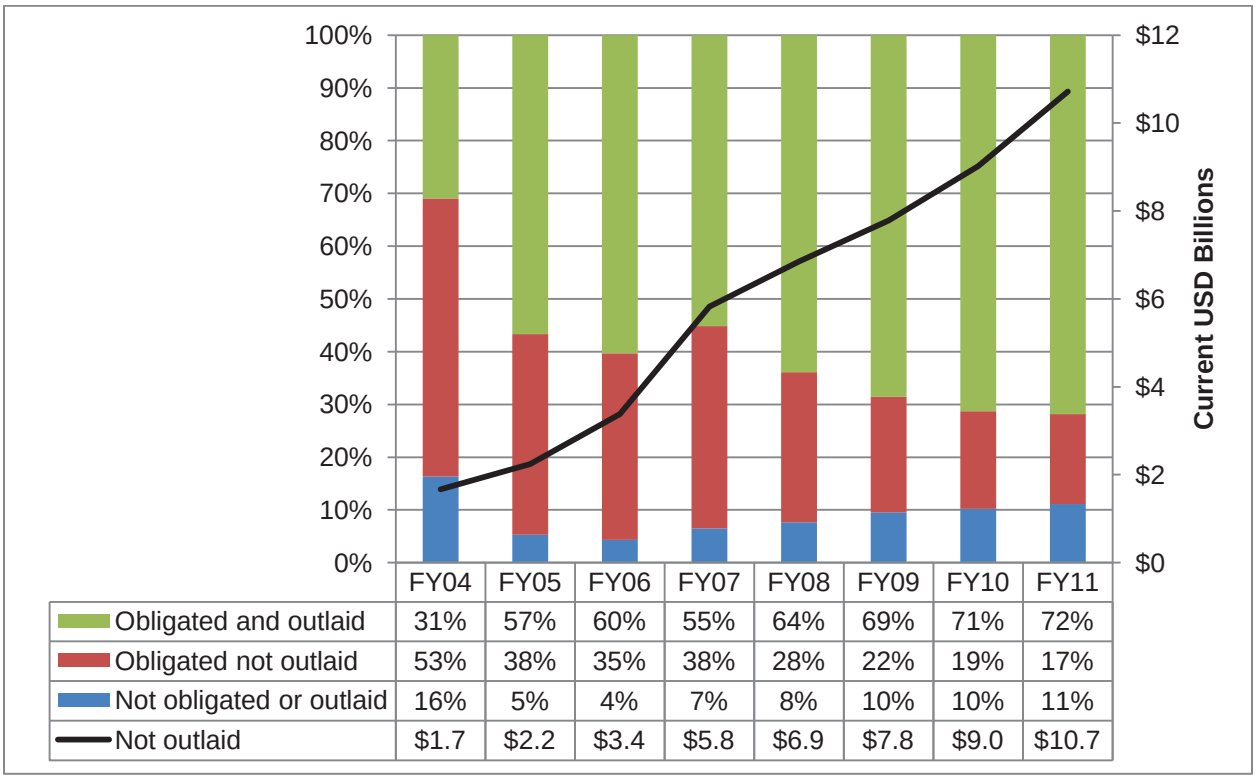

	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
Obligated and outlaid	31%	57%	60%	55%	64%	69%	71%	72%
Obligated not outlaid	53%	38%	35%	38%	28%	22%	19%	17%
Not obligated or outlaid	16%	5%	4%	7%	8%	10%	10%	11%
Not outlaid	$1.7	$2.2	$3.4	$5.8	$6.9	$7.8	$9.0	$10.7

FIGURE 4-5 Proportion of cumulative available PEPFAR funding by obligation and outlay status at the end of each fiscal year (bars) and the cumulative total of funding that has not been outlaid (line) (current USD billions).
NOTE: The black line represents the cumulative amount of PEPFAR funding that has been appropriated but not outlaid; it is the sum of funding that has been obligated but not outlaid and funding that has not been obligated.
SOURCES: OGAC, 2004; 2006a; 2007a; 2008a; 2009a; 2010a,b; 2011a.

The cumulative increase in funds not outlaid is the result of funds made available in the current year and prior years that have yet to be expended; some cumulative increase in funds not outlaid is to be expected for large-scale development assistance programs. As a proportion of cumulative PEPFAR funding available at the end of each fiscal year, the amount of funding that has not been outlaid has decreased from 69 percent at the end of FY 2004 to 28 percent at the end of FY 2011 (OGAC, 2004; 2011a).

These funds that have been appropriated and not yet spent are described as being in the "pipeline" (Donnelly, 2012b,c). In March 2012, OGAC reported $9 billion in the pipeline, $7.6 billion of which was "earmarked for programs or is within the acceptable range of 12 to 18 months worth of money in reserve for overseas development programs" (Donnelly, 2012c, p. 2). Global AIDS Coordinator Eric Goosby has explained that a 12- to 18-month funding reserve is reasonable because it allows services to continue in the case of a delay in congressional appropriations (Donnelly, 2012b). The remaining $1.46 billion has been described as a "bad pipeline" by USG officials, which means it has remained unexpended for too long (Donnelly, 2012c). More than two-thirds of this $1.46 billion pipeline is the result of delayed spending in 5 countries: Kenya, Tanzania, Ethiopia, Mozambique, and Zambia (Donnelly, 2012c).

Since 2011, OGAC has reviewed country and central budgets to identify unspent funds and has taken "corrective action to make sure the pipeline is considered" before allocating future funding to country programs (Donnelly, 2012b, p. 2). The USG currently plans to remove

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funding in the "bad pipeline" from country ledgers (Donnelly, 2012c) and reinvest these funds in other areas such as commodities, systems and institutions, and program strengthening for greater impact—"three major areas in which PEPFAR already has large investments and a track record of success" (Donnelly, 2012a, p. 1).

There are several factors related to partner countries, USG contracting processes, and implementing partners that may contribute to the increasing size of the pipeline. Ambassador Goosby attributed the unspent $1.46 billion to "inefficient bureaucracies; major reductions in the cost of AIDS treatment; delays due to long negotiations on realigning programs with recipient country priorities; and a slowdown in a few countries because the AIDS problem was much smaller than originally estimated" (Donnelly, 2012c, p. 2). At the partner country level in Kenya, for example, the large backlog of unspent funds is partially the result of inefficiencies due to "its two ministries of health, which were set up as part of a negotiated settlement following post-election violence in 2008" (Donnelly, 2012c, p. 2).

During interviews conducted by the IOM committee, interviewees from PEPFAR mission teams and implementing partners identified challenges or barriers to obligating and outlaying money in a manner that would facilitate a steady and timely funding flow. Bottlenecks may result from delays in disbursements and contracting at many steps in the PEPFAR funding flow process (including the release of funding from Congress to OGAC, the transfer of funding from OGAC to implementing agencies, and USG contracting), which may lead to gaps between partner contracts in countries (196-23-PCGOV; 196-24-PCNGO; 196-ES; 331-17-USG; 331-18-USNGO; 331-ES; 934-29-USNGO; 934-35-PCNGO; 116-24-USG; 935-20-PCNGO; 587-14-PCGOV; 587-23-USG; 166-17-USG; 396-9-PCGOV; 240-12-USG; 240-29-USNGO; 461-13-USACA). According to one interviewee:

> *"One of our biggest challenges is receiving our money in time. I think that one becomes a major challenge on our side. You know you make a plan and you are actually like four or five months behind. I'll give you a typical example now. […] We are in July; we are coming to the end of July. Fiscal year for PEPFAR for this grant started first April. I have no funds."* (461-13-USACA)[13]

There can also be longer-than-projected timelines for project initiation, for example, the time for prime partners or umbrella grant managers to identify and contract with grantees and sub-partners (196-9-USNGO; 240-ES; 331-17-USNGO; 166-17-USG; 636-16-USG; 396-41-PCGOV). As one interviewee said:

> *"The sub-grantees process, for a prime partner like [them], is a challenge, even though it's a headache they have always had. From a management perspective, the process is very good, but it is also cumbersome and has too many delays. They often need to build capacity of organizations before the organizations are able to respond to […] service or activity subcontracts. Prime partners need easier and more flexible mechanisms for easier roll-out of funds to organizations or sub-grantees."* (331-18-USNGO)

[13] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

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In addition, challenges with capacity can limit the rate at which local implementing partners can spend funding (240-21-PCGOV; 240-ES; 240-3-USG; 934-29-USNGO; 116-12-PCNGO; 116-24-USNGO; 196-9-USNGO). These issues are discussed in more detail in Chapter 9. Short-term contracts or other funding agreements for only 1- or 2-year terms with implementing partners can compound the difficulties associated with delays in disbursement and capacity challenges and lead to other challenges with planning for long-term implementation (116-24-USG; 166-10-USNGO; 166-ES; 240-26-PCNGO; 240-29-USNGO; 240-ES; 396-6-PCGOV; 396-16-PCGOV; 396-41-PCGOV; 396-8-PCNGO; 935-20-PCNGO).

More broadly, at the country program level an independent and external audit of PEPFAR funding for FY 2007 and FY 2008 revealed that, due to the timeline for development and review of country operational plans, OGAC generally distributed PEPFAR funds to implementing agencies in April—7 months after the start of the fiscal year (DoS OIG, 2010). Additionally, PEPFAR's reauthorizing legislation instituted new congressional requirements that must be met prior to disbursement of funding and, for FY 2010 funding, the need to meet these requirements has delayed outlays across the program (Kates et al., 2011).

Annual Expenditures

In addition to the cumulative outlay of funding over time, the committee was also interested in understanding how much money was actually spent by PEPFAR within each year, regardless of the year in which the money was appropriated or obligated. To achieve this, the ideal approach would have been to access the best possible estimate of the actual financial input towards activities in each year, with a breakdown by country, by partner, and by programmatic area; this corresponds to the first step in the program impact pathway framework described in Chapter 2. However, it is difficult to follow the funding actually spent in a given year because PEPFAR mission teams can simultaneously spend funding that was originally made available in multiple prior fiscal years (NCV-1-USG) and the financial data are reported as cumulative expenditures that do not readily reflect annual expenditures.

In an attempt to overcome this challenge, the committee requested the available reported financial data and worked with OGAC to determine an appropriate methodology for converting these reported data into annual expenditures. This is described in brief here; the request for these data and the methods used are described in more detail in Appendix C.

OGAC provided data that had been reported as cumulative expenditures for each fiscal year, from 2004 to 2011. These data were captured in a total of 78 Excel spreadsheets containing financial data for six agencies: DoD, the Department of Labor, HHS, the Peace Corps, USAID, and the Department of State, which included five bureaus that reported their data directly (the Bureau of African Affairs; the Bureau of East Asian and Pacific Affairs; OGAC; the Bureau of Population, Refugees, and Migration; and the Bureau of Western Hemisphere Affairs). These spreadsheets included data by country for every reporting year that each agency or bureau had participated in the PEPFAR program; for most agencies this represented 8 years of data (FY 2004–FY 2011). The totals recorded available, obligated, and outlaid funds by budget year (when the funds were made available) and reporting year (cumulative funding by that year). The data sent from each agency and bureau was organized so that each year's report contained data from its first year in the program until the year of the report. For example, the report for 2006 would contain the budget totals for each country for FY 2004, FY 2005, and FY 2006 on that sheet.

To convert these data into annual expenditures required two major steps. First, the data were harmonized across all 78 spreadsheets into a single dataset to ensure that the data could be

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used together to comprehensively represent PEPFAR spending across agencies, in total and by country. Second, cumulative expenditures were converted into annual expenditures. To get the annual expenditure for within a given fiscal year, all prior year outlays were subtracted from the cumulative total outlays reported for that year.

One challenge that emerged with these data was that there were many discrepancies identified when the countries' available totals were compiled and compared from their inception year to the following year across annual reports up until 2011. In particular, the major discrepancies came when the dollar amounts reported as available for a given budget year changed in subsequent reporting years (both increases and decreases were observed), although one would expect the amount made available in a budget year to be a fixed constant after that year. These discrepancies ranged in magnitude up to a maximum case of a $214 million difference between two reports for one budget year for one agency. As a result, it was difficult to determine the correct figures for the total amounts made available. Overall, the number of discrepancies and the magnitude of the changes from year to year decreased in later reporting years, and the reporting of the outlays did not exhibit the same degree of discrepancy. To have one consistent source for the calculations of annual expenditures and to base the calculations on the most recent data available, the FY 2011 reports were used as the source of data for all of the fiscal years.

Table 4-1 presents the total annual expenditure across PEPFAR agencies, disaggregated by the budget year in which those funds were originally made available. For example, in FY 2011 a total of $3.3 billion was expended; of this, $8 million had been made available originally in FY 2004, $18 million had been made available in FY 2005, and so forth. PEPFAR's total actual expenditures through FY 2011 on programs in partner countries managed by and reported through these agencies were $15 billion.

It is worth noting that these numbers do not match other publicly reported data sources on PEPFAR outlays; the total expended through FY 2011 as calculated from these data received from OGAC, $15 billion, is less than the total cumulative outlays shown in Figures 4-4 and 4-5, $27.3 billion, which is what is reported in OGAC's publicly available FY 2011 summary financial status report (OGAC, 2011a). This difference is because the data provided for this analysis includes only expenditures through activities allocated to country programs using funding made available to the individual agencies and reported to OGAC. It does not include funds being expended through central activities or through central management, such as funds for central Track 1.0 contracts, the Headquarters Operational Plan, international partnerships (Global Fund and UNAIDS contributions), and NIH Research.[14]

Table 4-2 shows the annual expenditure disaggregated by subsets of countries, representing successively larger portions of the total geographic scope of PEPFAR funding. The original focus countries and the additional COP countries that are the focus of this evaluation represent most of the PEPFAR expenditures over time.

Although the committee recognizes the complexity and the burden of tracking expenditures across multiple USG agencies and hundreds of diverse implementing partners, the lack of accessible data on actual annual expenditures, regardless of the year in which the money was appropriated or obligated, represents a significant data gap for PEPFAR. Annual expenditures would be a direct measure of the actual, real-time investment of the USG in the programs and activities supported by PEPFAR. These data are not available in a readily accessible repository to external stakeholders or to PEPFAR itself. This is a major limitation for

[14] Personal communication from OGAC, February 11, 2013.

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conducting a thorough assessment of the impact of the PEPFAR investment, through either descriptive or statistical analyses, that could incorporate a direct measure of the annual investment by country, by partner, and by programmatic area with annual data on variables such as overall mortality, HIV mortality, HIV prevalence, or antiretroviral therapy (ART) coverage, health outcomes, and other outcome and explanatory variables. Appendix C includes a more in-depth description of opportunities and limitations for analyses that the committee explored that could be feasible, valid, and informative; these could be considered in the future if reliable sources of data were available.

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TABLE 4-1 Total PEPFAR Outlaid Funding by Reporting Year (the Year the Funding Was Expended), with Disaggregation by Budget Year (the Year the Funding Was Made Available) (in Current USD Millions)

	Reporting year							
Budget year	*FY2004*	*FY2005*	*FY2006*	*FY2007*	*FY2008*	*FY2009*	*FY2010*	*FY2011*
FY2004	< $0.1[a]	$231.0	$10.9	$536.8	-$2.3[b]	$5.9	$16.5	$8.3
FY2005		$151.2	$234.1	$805.9	$53.3	$28.2	$19.7	$18.3
FY2006			$124.8	$907.7	$409.4	$86.4	$109.9	$26.2
FY2007				$224.9	$1,242.9	$688.6	$447.7	$36.9
FY2008					$246.4	$1,649.9	$1,436.1	$451.2
FY2009						$181.6	$1,700.4	$1,484.3
FY2010							$275.5	$1,100.5
FY2011								$176.4
Total outlays for reporting year	< $0.1	$382.2	$369.9	$2,475.4	$1,949.6	$2,640.5	$4,005.7	$3,302.2

Total outlays for FY2004–FY2011: $15,126

NOTE: Funding presented in current USD millions.

[a.] The actual number corresponding to budget year and reporting year FY 2004 is $7,198 in dollars (not millions).

[b.] The combination of budget year FY 2004 and reporting year FY 2008 ends up negative as a result of changes to amounts in later year reports.

SOURCE: Financial data provided by OGAC.

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TABLE 4-2 PEPFAR Outlays by Reporting Year (the Year the Funding Was Expended), for Subsets of Countries (Current USD Millions)

	Reporting year								
	FY2004	*FY2005*	*FY2006*	*FY2007*	*FY2008*	*FY2009*	*FY2010*	*FY2011*	*TOTAL*
Focus countries (15 total)	< $0.1[c]	$324.4	$326.9	$1,907.2	$1,691.8	$2,350.3	$3,620.9	$2,840.7	$13,062
COP countries as of 2009 (31 total)[a]	< $0.1[c]	$369.5	$358.7	$2,206.2	$1,849.9	$2,538.1	$3,893.6	$3,174.5	$14,391
All countries	< $0.1[c]	$375.3	$363.1	$2,336.8	$1,906.8	$2,605.5	$3,969.4	$3,244.2	$14,801
All countries and regions[b]	< $0.1[c]	$382.2	$369.9	$2,475.4	$1,949.6	$2,640.5	$4,005.7	$3,302.2	$15,126

Total outlays for all countries and regions, FY2004–FY2011: $15,126

NOTE: Funding presented in current USD millions. Each row is inclusive of the preceding rows.
[a.] These 31 countries represent those defined as the primary focus of this evaluation (as described in Chapter 2). These figures include funding to non-focus countries in years prior to becoming COP countries.
[b.] Regions refer to programs that support activities in countries but are managed/reported as multi-country regions.
[c.] The actual number corresponding to FY 2004 is $7,198 in dollars (not millions).
SOURCE: Financial data provided by OGAC.

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Planned/Approved Funding

Ideally, the committee would have liked to assess the distribution of PEPFAR outlays and annual expenditures among different types of programs and partners directly in terms of the inputs to the activities supported and who has implemented them. However, because these financial data are not available according to these parameters, the committee used the closest available approximation, which is the planned and approved PEPFAR funding documented through the operational plan budgeting process that was described previously. Each year, OGAC releases the PEPFAR Operational Plan, which provides more detail on how congressional appropriations will be used for program implementation. The PEPFAR Operational Plan includes summary budget information regarding the planned and approved use of PEPFAR funding, including which activities will be implemented by which agencies, as determined during the interagency planning process (OGAC, 2011d). Planned/approved funding reflects how OGAC and PEPFAR mission teams plan to obligate and outlay funds. The committee examined data on the distribution of planned/approved PEPFAR funding in order to understand how the program was intended to be implemented.

Planned/Approved Funding to USG Implementing Agencies

As described earlier, although the Congress appropriates the greater part of PEPFAR funding to the DoS, OGAC transfers most of this funding to other USG agencies for the implementation of programs, services, and activities. This interagency implementation approach was described in Chapter 3. USAID and CDC are the primary implementers of country programs, and the bulk of planned/approved funding is directed to these agencies through direct congressional appropriations or interagency transfers. For example, between FY 2005 and FY 2011, a total of 54 percent of PEPFAR funding was implemented through USAID, and 41 percent was implemented through CDC. Figure 4-6 shows the breakdown of planned/approved funding among the USG implementing agencies each year.

Planned/Approved Funding by PEPFAR Operational Plan Types of Programs

The PEPFAR Operational Plan also provides information on the planned/approved funding for different types of programs and activities that are classified by OGAC in the following categories: country activities, headquarters (HQ) programs (at OGAC and other USG agencies), and multilateral partners. Figure 4-7 displays the proportion of planned/approved funding for each type of program over time, and Figure 4-8 provides a 1-year snapshot from FY 2011 of the distribution of total planned/approved funding among the three broad types of programs, including subcategories. The next three sections will describe, in turn, the activities that fall within each of these three types of programs and provide a further breakdown of the funding distribution over time by additional subcategories. Each of these types of programs can include activities across PEPFAR's different programmatic and technical areas, which are discussed in more detail later in this chapter.

OGAC made some changes to how these categories are used to report planned/approved funding after the first phase of the program. To examine funding trends with as much consistency as possible, the committee used the FY 2011 categories to analyze all data; if necessary, programs and funding prior to FY 2011 were re-categorized to the FY 2011 categories.

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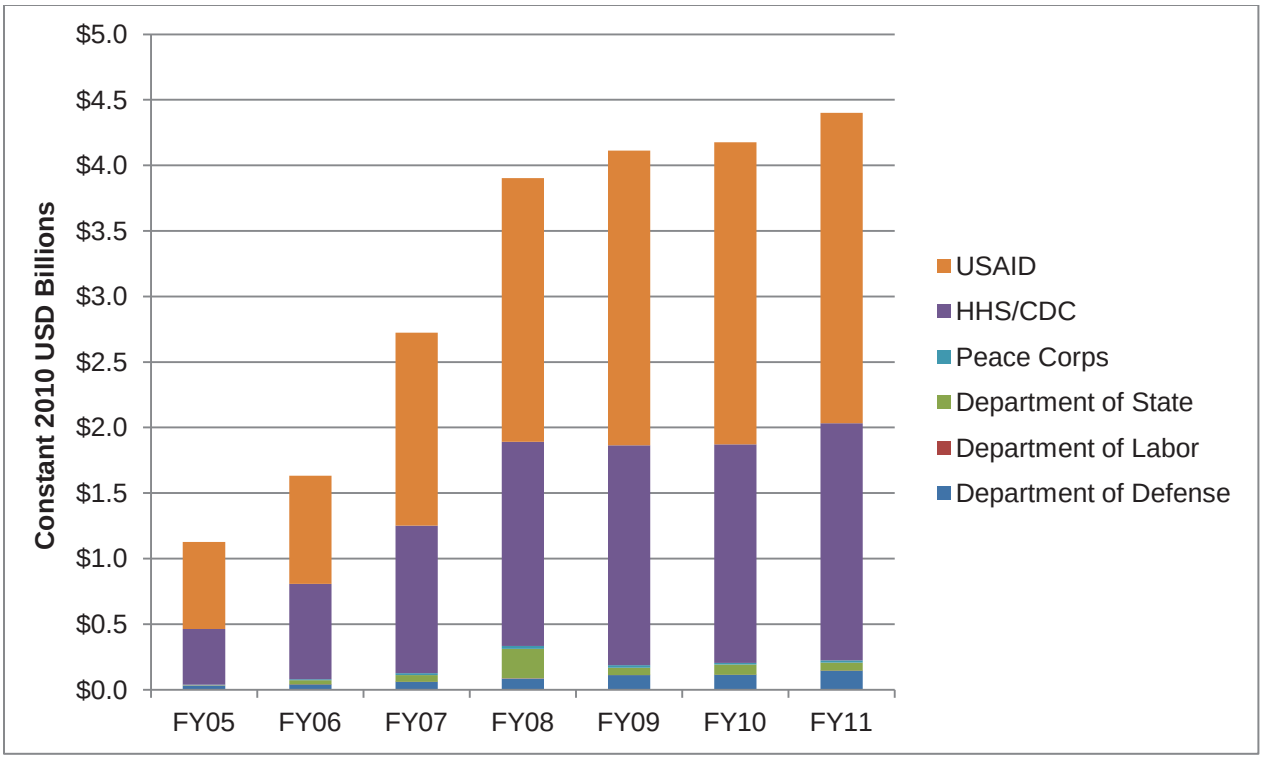

FIGURE 4-6 Planned/approved funding for USG implementing agencies, FY 2005–FY 2011 (constant 2010 USD billions).
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

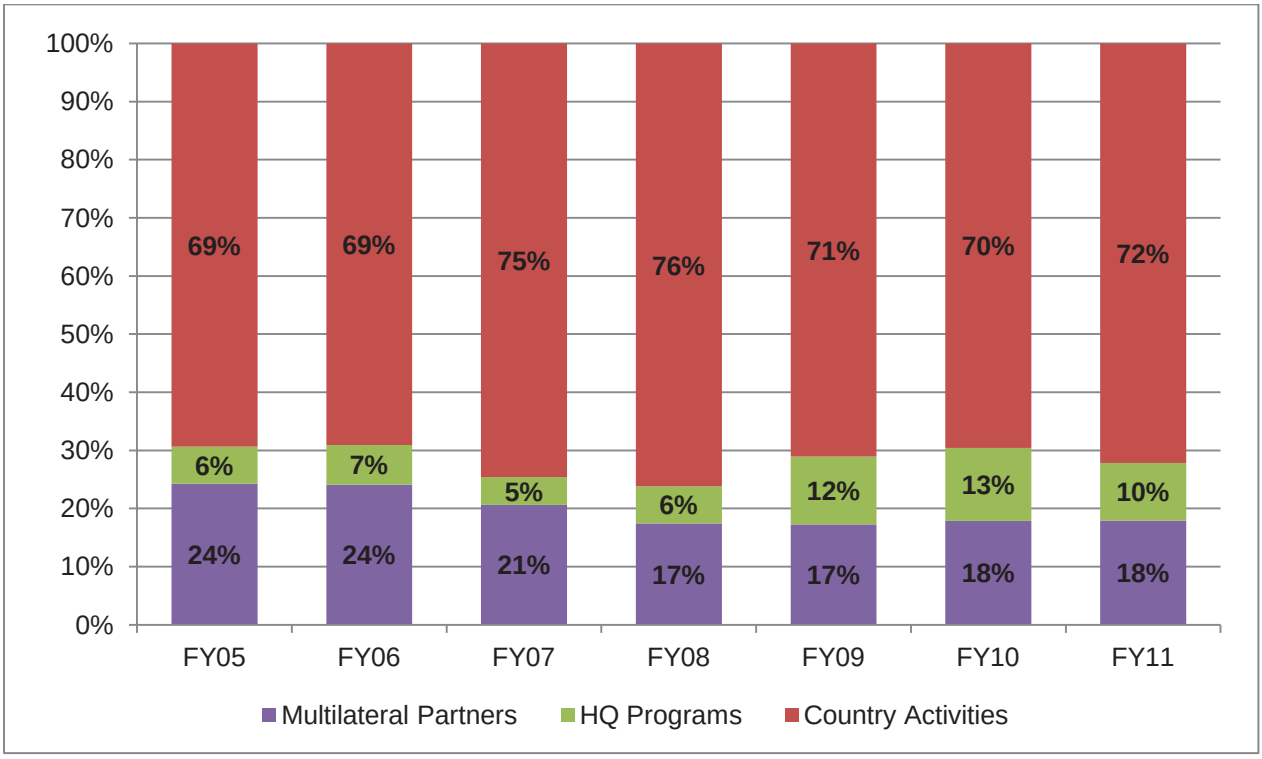

FIGURE 4-7 Proportion of planned/approved funding for PEPFAR operational plan programs, FY 2005–FY 2011.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

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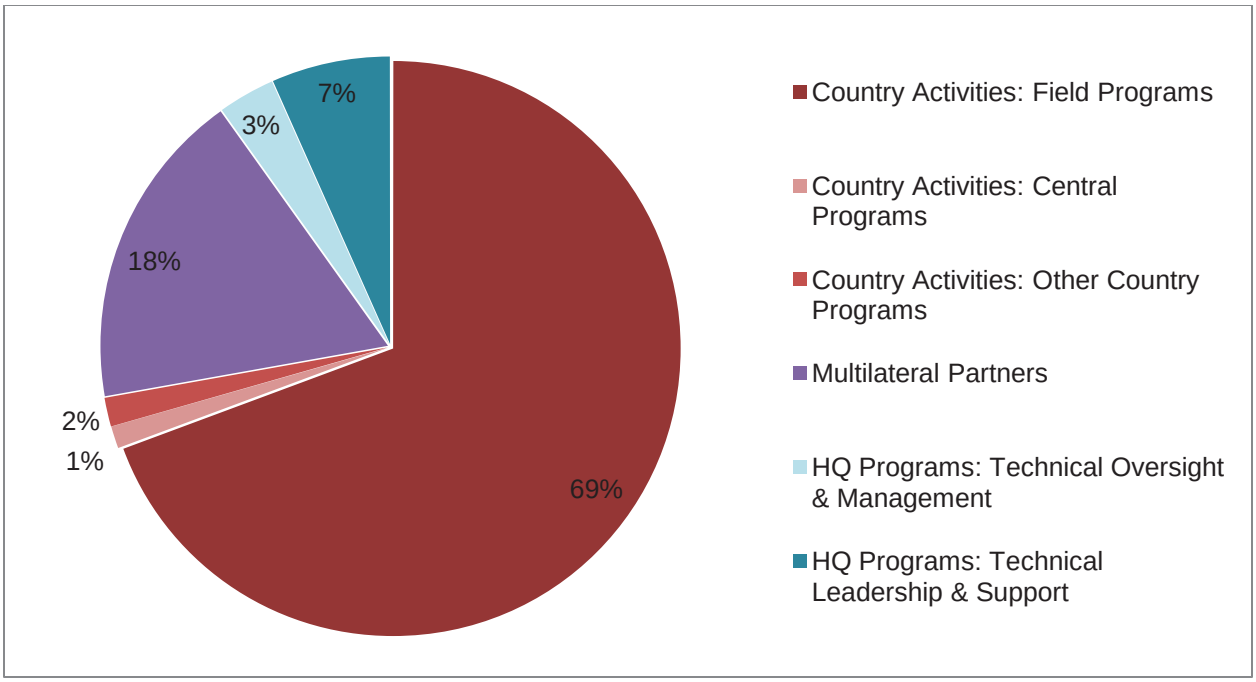

FIGURE 4-8 FY 2011 PEPFAR operational plan program funding summary.
NOTE: Data represent the planned/approved use of funding appropriated for PEPFAR in FY 2011.
SOURCE: OGAC, 2011d.

Country Activities Country activities include field programs, central programs, and other country programs. Funding for *field programs* represents the planned/approved funding for activities planned by mission teams in COPs or regional operational plans; *other country programs* is funding for programs in those countries that do not prepare COPs or regional operational plans. *Central programs* are funded and managed centrally by agency HQs yet implemented in partner countries (usually by large nongovernmental organizations, faith-based organizations, and academic institutions). Figure 4-9 shows the planned/approved funding over time for each of these subcategories of PEPFAR country activities as well as the proportion of total planned/approved funding that each subcategory represents.[15]

As a proportion of total funding, funding for all country activities has remained fairly steady throughout the period of PEPFAR at approximately 70 percent, peaking at 76 percent in FY 2008; most of this funding for country activities is accounted for by field programs (OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d). Most PEPFAR funding for country activities is approved for field and central programs within countries that prepare COPs. During much of the first phase of PEPFAR, this funding was limited to the 15 focus countries. By FY 2009, when the scope of this evaluation was established, 31 countries were preparing COPs, and by FY 2011, this had increased to 33 (GAO, 2011).

[15] From FY 2005 to FY 2008, OGAC classified the following as central programs within country activities: New Partner Initiative, Supply Chain Management, Technical Leadership Support, and Twinning. In FY2009, OGAC reclassified these as HQ programs. To maintain consistency and comparability over time, for all data presentations the committee included all funding for these four programs for all years as HQ programs (which are discussed in the next section).

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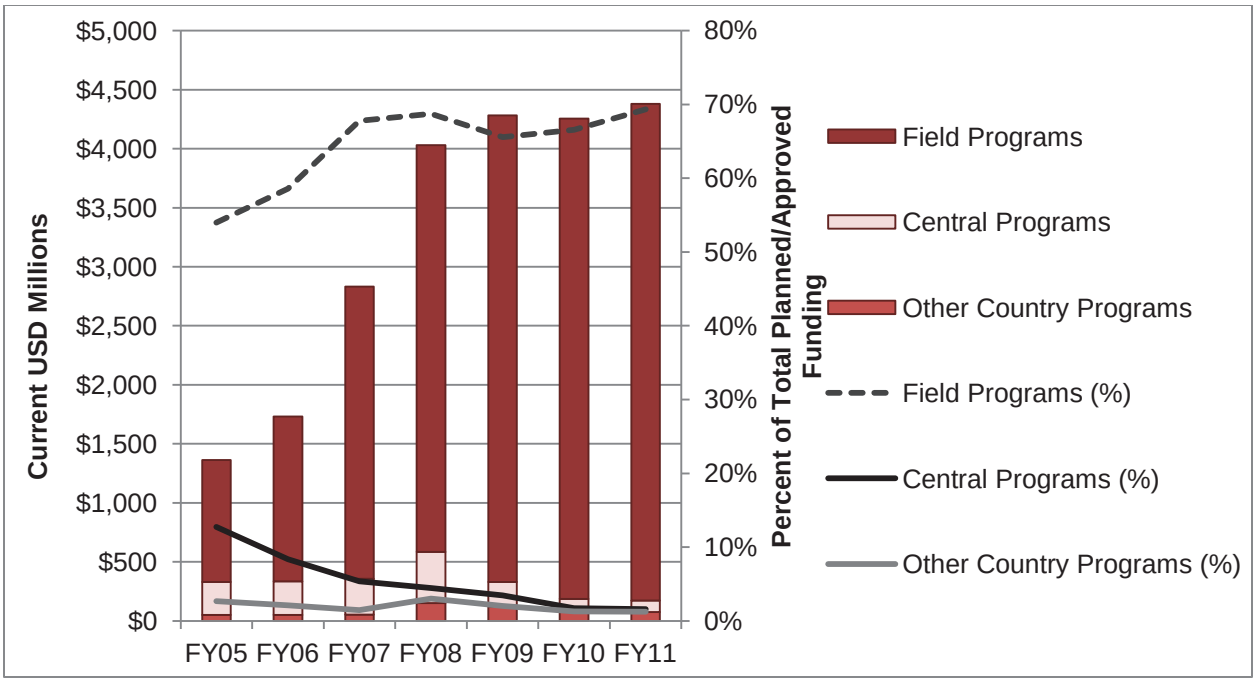

FIGURE 4-9 Planned/approved funding for PEPFAR country activities in current USD millions (left axis and bars) and as a percentage of total planned/approved funding (right axis and lines).
NOTE: Funding for *field programs* represents the planned/approved funding for activities planned in COPs or regional operational plans; *other country programs* include funding for those countries that do not prepare COPs or regional operational plans. Funding for *central programs* includes programs that are funded and managed by OGAC HQ yet implemented in partner countries (usually by large nongovernmental organizations, faith-based organizations, and academic institutions).
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

While programs implemented in partner countries have consistently represented the largest share of PEPFAR's funding, the way in which programs in countries were funded has shifted. In the early years of PEPFAR, more funding was directed to central country programs. In 2005, for example, funding for central programs was 13 percent of planned/approved funding; by 2011 it had dropped to 2 percent (OGAC, 2005). The decrease in funding for central programs may reflect increased national and local capacity and changing funding requirements for PEPFAR partners. When country programs were started, there was often no infrastructure, no mechanisms, and no processes that could be used to obligate large sums of money to entities within partner countries, including governments, for program and service implementation. In order to provide service delivery at the needed scale during PEPFAR I, a number of grants went to technical partners that were capable of supporting rapid scale-up of services in the focus countries; these were known as Track 1.0 partners. The Track 1.0 partners were centrally funded to implement antiretroviral therapy, orphans and vulnerable children programs, and prevention activities in multiple partner countries.

As PEPFAR programs in partner countries matured, systems were built and entities were strengthened to facilitate the obligation and outlay of PEPFAR funding to prime partners responsible for programs, projects, and activities within partner countries. As of FY 2009, Track 1.0 partners were required to transition their programs to national or local management (OGAC, 2009c). By FY 2011 only one central program remained (antiretroviral therapy), and funding for this program accounted for just 4 percent of all planned/approved funding (OGAC, 2011d).

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HQ Programs In FY 2011 funding for HQ programs included 2 components: technical oversight and management, and technical leadership and support. The category of technical oversight and management captures administrative costs for each of the USG agencies responsible for implementing PEPFAR, such as salary, benefits, travel, supplies, professional services, and equipment. The technical leadership and support category includes funding for technical assistance at all levels (e.g., USG agencies, implementing partners, and partner country governments), supply chain management, and HQ-level strategic information activities (e.g., public health evaluations, and inspectors general activities) (OGAC, 2011d). Funding is also captured here for some large-scale capacity building initiatives that are implemented in multiple countries and are classified as HQ programs. From FY 2005 to FY 2008, several technical leadership and support activities were considered central programs within country activities (described in the preceding section); where possible, the committee has retroactively classified these as HQ programs in order to examine funding trends consistently.

During PEPFAR I, funding for HQ programs accounted for 6 percent of total planned/approved funding; from FY 2009 to FY 2011, funding for HQ programs increased to 11 percent of total planned/approved funding (see Figure 4-10). This increase is largely a reflection of greater funding for technical leadership and support, which has increased since FY 2007, peaking at 9.6 percent of total planned/approved funding in FY 2010. However, as a proportion of total planned/approved funding, technical oversight and management has remained fairly steady around 3 percent. The increase in funding for technical leadership and support reflects PEPFAR II's greater emphasis on capacity building and the initiation of programs such as the New Partners Initiative/Local Capacity Initiative, the Medical Education Partnership Initiative, and the Nursing Education Partnership Initiative (described further in Chapter 9). Funding for these capacity building initiatives reflects OGAC's objective to transition "PEPFAR support from direct service provision to increased provision of technical assistance to governments" (OGAC, 2009b, p. 4).

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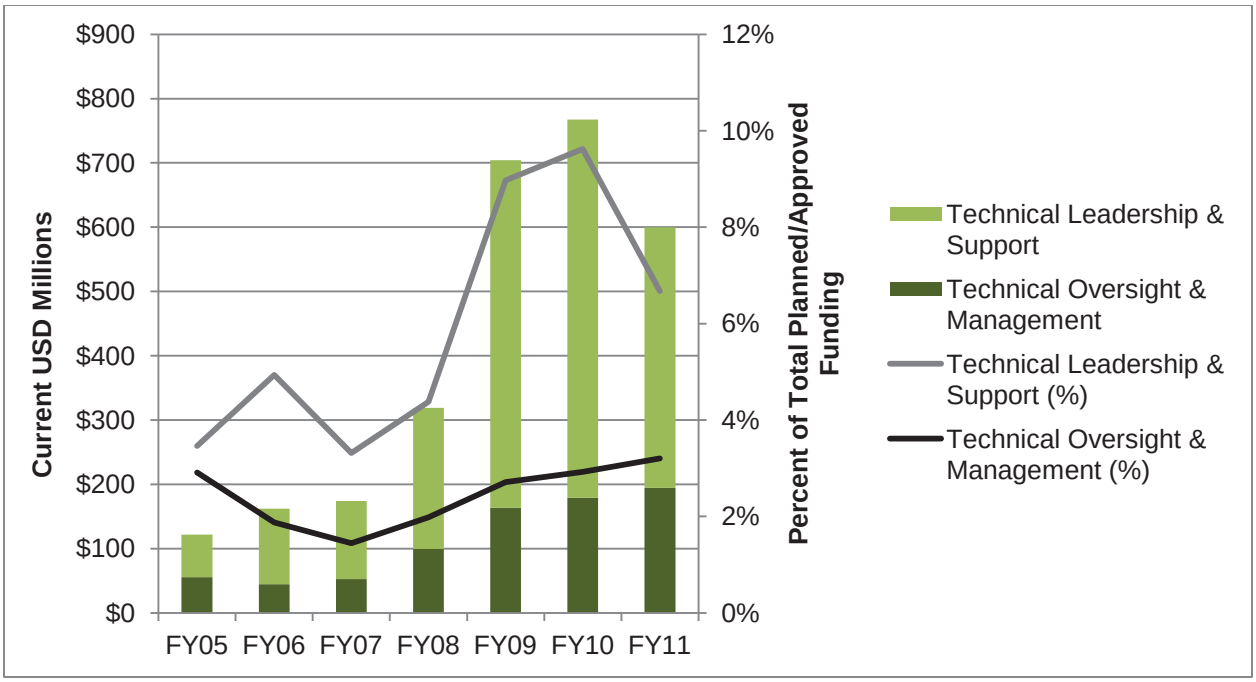

FIGURE 4-10 Planned/approved funding for PEPFAR HQ programs in current USD millions (left axis and bars) and as a percentage of total planned/approved funding (right axis and lines).
NOTE: Technical oversight and management captures administrative and management costs. Technical leadership and support includes funding for strategic information/evaluation activities, supply chain management, twinning, the New Partners Initiative/Local Capacity Initiative, the Medical Education Partnership Initiative, and the Nursing Education Partnership Initiative.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

Multilateral Partners Since FY 2005, almost $6 billion has been planned for multilateral partners. Most funding in the category of multilateral support has been directed to the Global Fund, which channels international financing for efforts against AIDS, tuberculosis, and malaria. The Leadership Act and the Lantos-Hyde Act authorized the use of PEPFAR funds for the USG contribution to the Global Fund, provided that USG contributions not exceed 33 percent of total contributions to the Global Fund. Also represented in this category is funding for the Joint United Nations Program on HIV/AIDS (UNAIDS). The USG is one of the largest contributors to UNAIDS, a partnership of ten United Nations agencies that leads the international response to HIV/AIDS through advocacy on behalf of those living with HIV/AIDS, technical support for country-led responses to HIV/AIDS, and monitoring global progress toward achieving universal access to HIV prevention, treatment, care and support (OGAC, n.d.; UNAIDS, 2010b). Funding for the Global Fund and UNAIDS increased each year between FY 2005 and FY 2010, when funding peaked at $1.05 billion and $43 million, respectively, and then dropped slightly in 2011 (see Figure 4-11). In FY 2005, OGAC also provided $2 million of multilateral support to the World Health Organization (WHO) to support efforts to coordinate and consolidate USG and WHO efforts to address tuberculosis in persons living with HIV/AIDS (OGAC, 2005).

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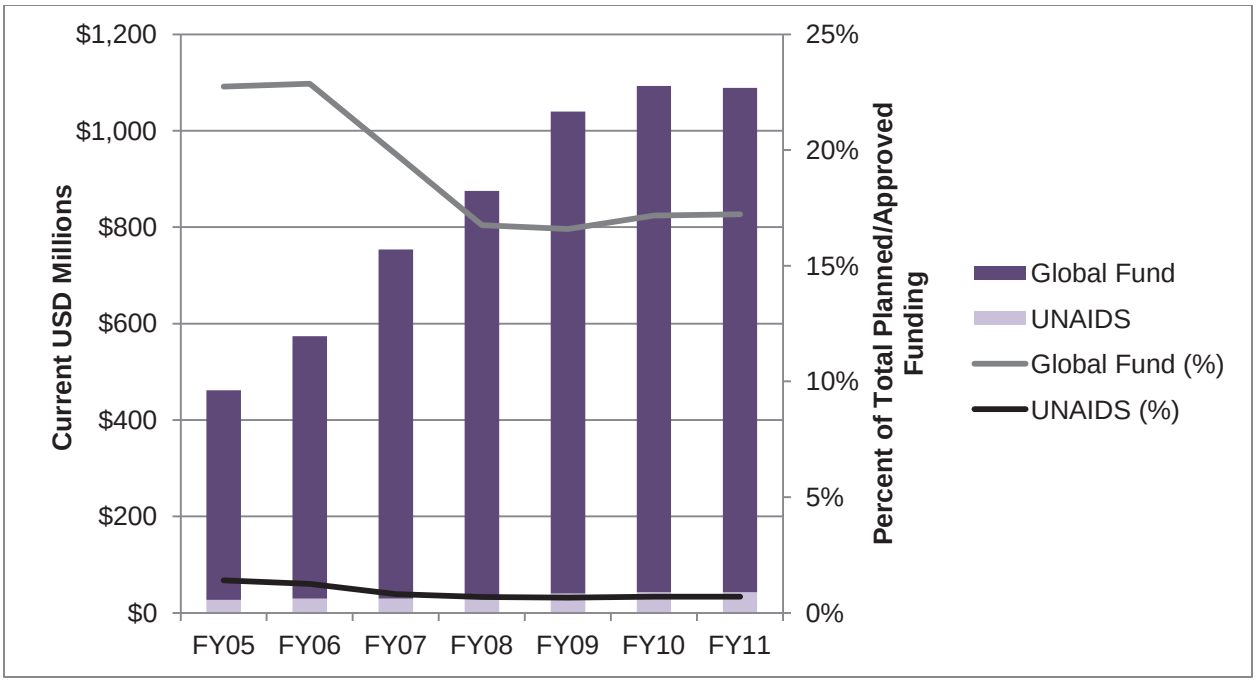

FIGURE 4-11 Planned/approved funding for multilateral partners in current USD millions (left axis and bars) and as a % of total planned/approved funding (right axis and lines).
NOTE: Global Fund = Global Fund to Fight AIDS, Tuberculosis, and Malaria; UNAIDS = Joint United Nations Program on HIV/AIDS. The World Health Organization also received $2 million in FY 2005, but this amount was too small to be displayed in this graph.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

Planned/Approved Funding by Technical and Program Areas

The committee was also interested in understanding how PEPFAR funding is distributed among the different services and activities that PEPFAR supports. The PEPFAR operational plans report planned/approved funding for four technical areas that correspond with the primary categories of HIV/AIDS services and systems strengthening efforts: prevention, care, treatment, and other. These data, disaggregated by technical area, represent funding for country activities in countries that prepare COPs or regional operational plans, including the field and central programs described in the previous section. Figure 4-12a shows PEPFAR funding for these technical areas over time. Treatment and prevention have received the most funding over time.

Through FY 2009, treatment received the largest amount of funding, but in the last 2 years, funding for prevention has surpassed funding for treatment. Figure 4-12b displays the proportions of funding for these technical areas over time. During PEPFAR I, the highest proportion of funding was approved for treatment and prevention activities. During PEPFAR II, beginning in FY 2009, the proportion of funding for treatment activities declined, while the proportion of funding for prevention activities increased slightly. Funding for care activities remained relatively steady. The proportion of funding for other activities, which include health systems strengthening, laboratory infrastructure, and strategic information activities, increased over time; this was largely driven by a continuous increase in funding for health systems strengthening.

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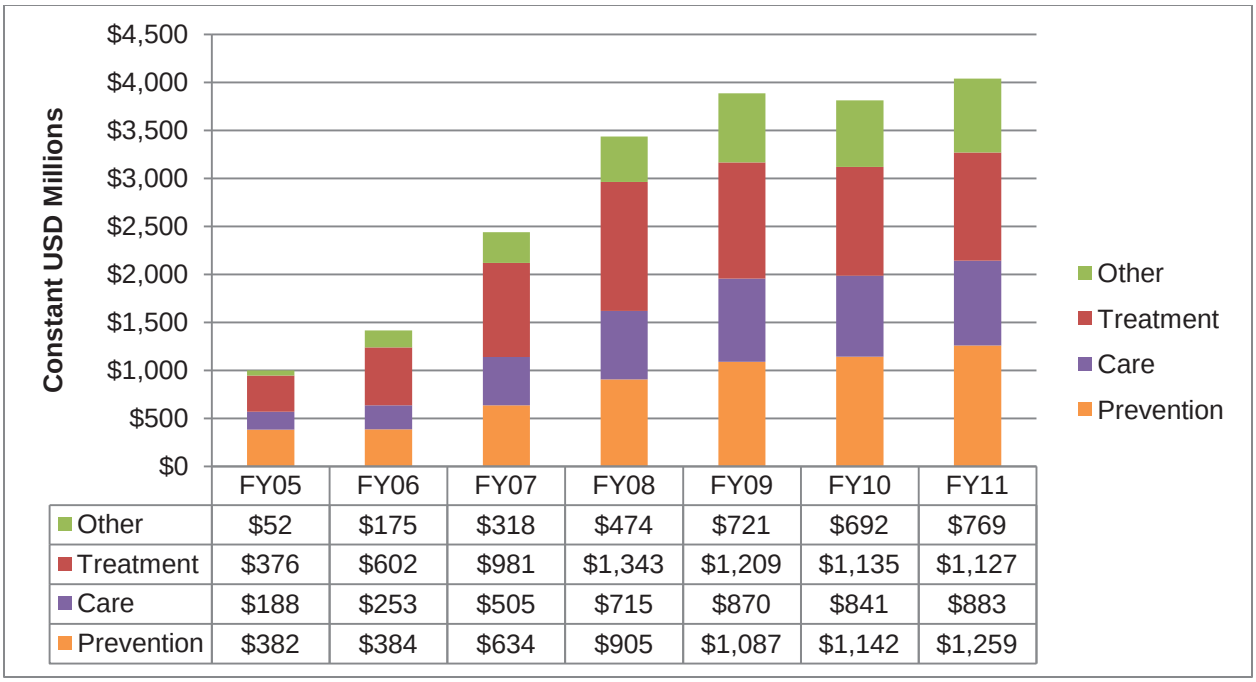

	FY05	FY06	FY07	FY08	FY09	FY10	FY11
Other	$52	$175	$318	$474	$721	$692	$769
Treatment	$376	$602	$981	$1,343	$1,209	$1,135	$1,127
Care	$188	$253	$505	$715	$870	$841	$883
Prevention	$382	$384	$634	$905	$1,087	$1,142	$1,259

FIGURE 4-12a Planned/approved funding by technical area (constant 2010 USD millions).
NOTE: The totals were calculated by retroactively categorizing budget codes as reported in FY 2011 to ensure consistency. The *Other* technical area includes health systems strengthening, laboratory infrastructure, and strategic information activities. Management and staffing costs were excluded from this analysis.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

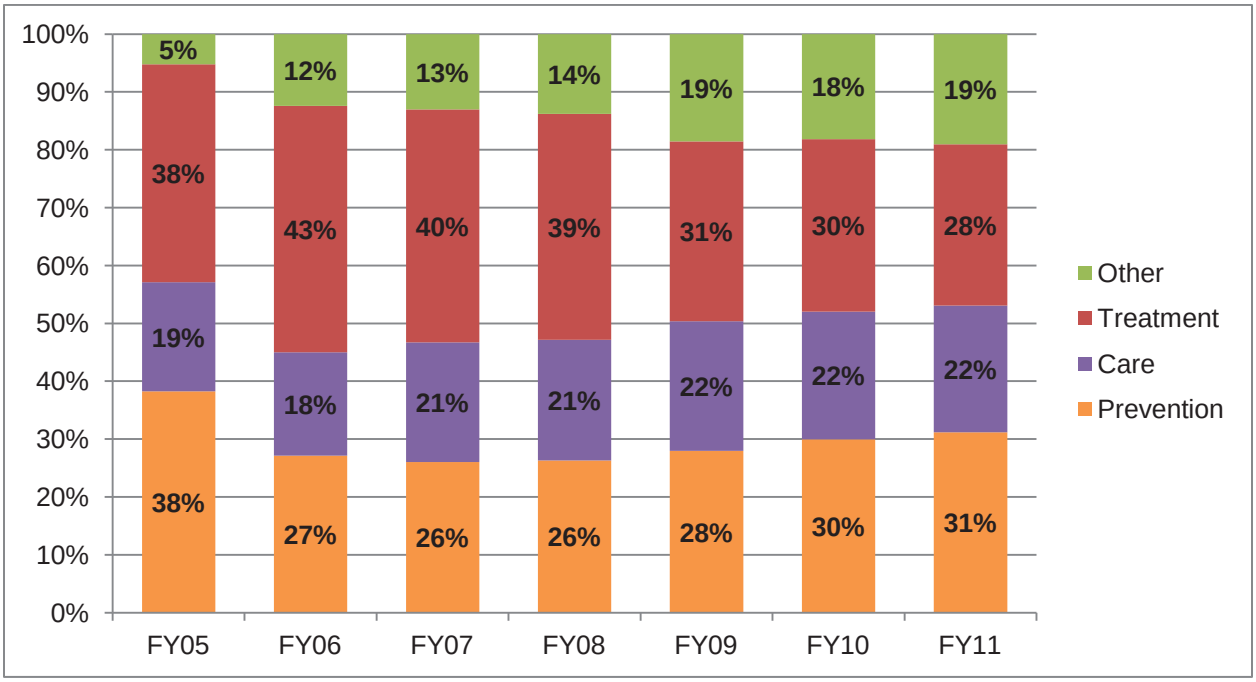

FIGURE 4-12b Proportion of planned/approved funding by technical area.
NOTE: The proportions above were calculated by retroactively categorizing budget codes as reported in FY 2011 to ensure consistency. The *Other* technical area includes health-systems strengthening, laboratory infrastructure, and strategic information activities. Management and staffing costs were excluded from this analysis.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

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PEPFAR funding is planned through budget codes which capture exclusive funding information about more specific activities within these categories. The technical areas shown here may contain funding from as many as eight budget codes, described in Box 4-2. The funding within these categories is presented and discussed in the subsequent chapters of this report, which assess PEPFAR's efforts in specific technical and program areas.

BOX 4-2
FY 2011 PEPFAR Budget Code Definitions by Technical Area

Prevention

Prevention of Mother-to-Child Transmission (PMTCT): activities (including training) aimed at preventing mother-to-child HIV transmission, including ARV [antiretroviral] prophylaxis for HIV-infected pregnant women and newborns and counseling and support for maternal nutrition. PMTCT-plus ART [antiretroviral therapy] activities should be described under ARV Drugs and Adult Treatment. Funding for HIV counseling and testing in the context of preventing mother-to-child transmission can be coded under PMTCT or Counseling and Testing; targets should be included in PMTCT. Early infant diagnosis should be included under Pediatric Care.

Abstinence & Be Faithful: activities (including training) to promote abstinence, including delay of sexual activity or secondary abstinence, fidelity, reducing multiple and concurrent partners, and related social and community norms that impact these behaviors. Activities should address programming for both adolescents and adults.

Other Sexual Prevention: other activities (including training) aimed at preventing HIV transmission including purchase and promotion of condoms, STI [sexually transmitted infection] management (if not in palliative care settings/context), messages/programs to reduce other risks of persons engaged in high-risk behaviors. Prevention services should be focused on target populations such as alcohol users; at risk youth; men who have sex with men (MSM); mobile populations, including migrant workers, truck drivers, and members of military and other uniformed services (e.g. police); and persons who exchange sex for money and/or other goods with multiple or concurrent sex partners, including persons engaged in prostitution and/or transactional sexual partnerships.

Blood Safety: activities supporting a nationally-coordinated blood program to ensure a safe and adequate blood supply including: infrastructure and policies; donor-recruitment activities; blood collection, testing for transfusion-transmissible infections, component preparation, storage and distribution; appropriate clinical use of blood, transfusion procedures and hemovigilance; training and human resource development; monitoring and evaluation; and development of sustainable systems.

Injection Safety: policies, training, waste-management systems, advocacy and other activities to promote medical injection safety, including distribution/supply chain, cost and appropriate disposal of injection equipment and other related equipment and supplies.

Prevention Among Injecting and Non-Injecting Drug Users: activities including policy reform, training, message development, community mobilization and comprehensive approaches including medication assistance therapy to reduce injecting drug use. Procurement of methadone and other medical-assisted therapy drugs should be included under this program area budget code. Programs for prevention of sexual transmission within IDUs [people who inject drugs] should be included in this category. Please refer to the July 2010 Revised Guidance on Comprehensive HIV Prevention for People Who Inject Drugs for more information. [This budget code was adopted in FY 2009.]

Voluntary Medical Male Circumcision: policy, training, outreach, message development,

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service delivery, quality assurance, and equipment and commodities related to male circumcision. All MC [male circumcision] services should include the minimum package; HIV testing and counseling provided on site; age-appropriate pre- and post-operative sexual risk reduction counseling; active exclusion of symptomatic STIs and syndromic treatment when indicated; provision and promotion of correct and consistent use of condoms; circumcision surgery in accordance with national standards and international guidance; counseling on the need for abstinence from sexual activity during wound healing; wound care instructions; and post-operative clinical assessments and care. HIV counseling and testing associated with male circumcision can be included in either counseling and testing or male circumcision. [This budget code was adopted in FY 2009.]

Counseling & Testing: includes activities in which both HIV counseling and testing are provided for those who seek to know their HIV status (as in traditional VCT [voluntary counseling and testing]) or provider-initiated testing and counseling. Funding for testing and counseling in the context of preventing mother-to-child transmission can be included under PMTCT or Counseling and Testing; targets should be included in PMTCT.

Care

Adult Care & Support: all facility-based and home/community-based activities for HIV-infected adults and their families aimed at extending and optimizing quality of life for HIV-infected clients and their families throughout the continuum of illness through provision of clinical, psychological, spiritual, social, and prevention services. Clinical care should include prevention and treatment of OIs [opportunistic infections] (excluding TB [tuberculosis]) and other HIV/AIDS-related complications including malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support including food. Psychological and spiritual support may include group and individual counseling and culturally-appropriate end-of-life care and bereavement services. Social support may include vocational training, income-generating activities, social and legal protection, and training and support of caregivers. Prevention services may include "prevention for positives" behavioral counseling and counseling and testing of family members. The purchase of OI drugs (excluding TB drugs) should be included under Adult Care and Treatment. ARV treatment should be coded under Adult Treatment and ARV Drugs.

Pediatric Care & Support: all health facility-based care for HIV-exposed children aimed at extending and optimizing quality of life for HIV-infected clients and their families throughout the continuum of illness through provision of clinical, psychological, spiritual, social, and prevention services. Clinical care should include early infant diagnosis, prevention and treatment of OIs (excluding TB) and other HIV/AIDS-related complications including malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support including targeted food interventions. Other services – psychological, social, spiritual, and prevention services – should be provided as appropriate. Pediatric care and support services should be counted if they are provided at a facility; community services should be included within programs for orphans and vulnerable children (OVC). [This budget code was adopted in FY 2009.]

TB/HIV: includes exams, clinical monitoring, related laboratory services, treatment and prevention of tuberculosis (including medications), HIV testing and clinical care of clients in TB service locations, TB screening, and diagnosis, treatment and prevention of TB in PLWHA. Funding for these activities, including commodities and laboratory, should be

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included in the TB/HIV budget code rather than other budget codes. The location of HIV/TB activities can include general medical settings, HIV/AIDS clinics, home-based care and traditional TB clinics and hospitals. Pediatric TB/HIV services should be included in this budget code.

Orphans & Vulnerable Children (OVC): activities are aimed at improving the lives of orphans and other vulnerable children (OVC) affected by HIV/AIDS, and doing so in a measurable way. Services to children (0-17 years) should be based on the actual needs of the child and could include ensuring access to basic education (from early childhood development through secondary level), basic health care services, targeted food and nutrition support, including support for safe infant feeding and weaning practices, protection, mitigation of factors that place children at risk, legal aid, economic strengthening, training of caregivers in HIV prevention and home-based care, etc. Household-centered approaches that link OVC services with HIV-affected families (linkages with PMTCT, palliative care, treatment, etc.) and strengthen the capacity of the family unit (caregiver) are included along with strengthening community structures which protect and promote healthy child development (schools, churches, clinics, child protection committees, etc.) and investments in local and national government capacity to identify, monitor and track children's well-being. Programs may be included which strengthen the transition from residential OVC care to more family-centered models.

Treatment

ARV Drugs: including procurement, delivery, and in-freight of ARV drugs. All antiretroviral Post-Exposure Prophylaxis procurement for rape victims should be included within this program area. Distribution/supply chain/logistics, pharmaceutical management and related systems strengthening inputs, including training, are to be included in the Health Systems Strengthening section.

Adult Treatment: including infrastructure, training clinicians and other providers, exams, clinical monitoring, related laboratory services, and community-adherence activities. Clinical monitoring and management of opportunistic infections is classified under Adult Care and Support.

Pediatric Treatment: including infrastructure, training clinicians and other providers, exams, clinical monitoring, related laboratory services, and community-adherence activities. Clinical monitoring and management of opportunistic infections is classified under Pediatric Care and Support. [This budget code was adopted in FY 2009.]

Other

Health Systems Strengthening: include activities that contribute to national, regional or district level health systems by supporting finance, leadership and governance (including broad policy reform efforts including stigma, gender etc.), human resources for health, institutional capacity building, supply chain or procurement systems, information systems, Global Fund programs and donor coordination. The HSS Steering Committee has identified the following areas for current emphasis: 1) focus on building government capacities to manage a health system that effectively serves its people; 2) invest more strategically to develop human resources for health; 3) continue transition to indigenous implementing partners; 4) invest in a formal health systems assessment process for each country; 5) put greater emphasis on innovative strategies for the private sector to become a more important part of a country's health system strengthening plan; 6) expand PEPFAR"s emphasis on

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monitoring of HIV services to including strategies to monitor broad health system changes over time; and 7) staff for success, in other words assess the skill mix in-country and fill staffing gaps aggressively and thoughtfully.

Laboratory Infrastructure: development and strengthening of laboratory systems and facilities to support HIV/AIDS-related activities including purchase of equipment and commodities and provision of quality assurance, staff training and other technical assistance. Specific laboratory services supporting TB testing goes under TB/HIV. Laboratory services supporting counseling should go under Counseling and Testing or PMTCT. Laboratory services supporting care should go under Adult or Pediatric Care and Support. Laboratory services supporting treatment should be included under Pediatric or Adult Treatment Services.

Strategic Information: HIV/AIDS behavioral and biological surveillance, facility surveys, monitoring partner results, reporting results, supporting health information systems, assisting countries to establish and/or strengthen such systems, and related analyses and data dissemination activities fall under strategic information. Program area-specific monitoring and routine evaluation should be incorporated under the specific program area.

SOURCE: OGAC, 2010d, pp. 20–24.

In general, budget codes have been fairly uniform and stable, but there have been some specific changes over time. Since 2005, new budget codes have been added, and the definitions for some budget codes have been changed. Each fiscal year's budget codes are unique to that year; OGAC and other USG programs do not go back and change how activities were coded when budget codes are changed or added. The budget codes provide one way of looking at PEPFAR-funded activities, but the interpretation of these trends is complex. For example, in FY 2010 a number of countries shifted funding from the treatment and laboratory infrastructure budget codes to health systems strengthening as a reflection of the increased emphasis on systems strengthening described in the reauthorization legislation and PEPFAR's second Five-Year Strategy. In some cases these funding shifts were interpreted as decreased support for service delivery, but it is more likely that the same activities intended to strengthen the quality and delivery of treatment or laboratory services were simply re-categorized (NCV-1-USG) (OGAC, 2010c).

As a standard approach to managing these inconsistencies described above, in Figure 4-12 and in the planned/approved funding data presented throughout this report the committee examined funding for budget codes as defined and categorized in FY 2011. As a result of the changing definitions, shifts in the way funding was programmed, and variability in how country programs interpreted the budget codes, PEPFAR's budget codes do not necessarily track funding consistently across countries and over time. This limited the committee's ability to draw major conclusions about the distribution of PEPFAR funding beyond descriptive findings; the limitations in tracking funding over time will also be discussed, where relevant, when funding for specific budget codes are presented and discussed in the subsequent chapters of this report.

PEPFAR Funding to Prime Partners

Within countries, PEPFAR activities and services are implemented by a variety of different partners, including local (partner country) and international nonprofit organizations (also known as nongovernmental organizations), for-profit firms or organizations, academic institutions, and partner country governments. Although in some cases USG agencies implement

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activities directly, for most PEPFAR-supported activities prime partners receive PEPFAR funding from USG agencies through grants, contracts, or cooperative agreements. A grant is used to transfer resources to a prime partner to carry out activities without substantial involvement from USG agencies. A cooperative agreement is used to transfer resources when substantial USG involvement is necessary to achieve a goal or objective. A contract is used to purchase goods or services (OGAC, 2011b). Prime partners may contract with and outlay funds to sub-partners to implement services or activities (GAO, 2012).

The committee wanted to explore funding to prime partners and sub-partners in order to understand the different kinds of actors that have been responsible for implementing PEPFAR services and activities over time. However, the committee's analysis in this area was limited by the unavailability of quality data. OGAC has not consistently tracked funding to prime partners across the whole of the program, and although some tracking of this information occurs at the HQ level, OGAC was unable to provide these data to the committee for the evaluation. In addition, USG agencies and PEPFAR mission teams are not required to report sub-partner funding to OGAC, so the committee was unable to examine funding flows through the sub-partner level (NCV-1-USG).

To examine this question, the committee was able to compile some limited data on PEPFAR funding to prime partners using a variety of publicly available sources, including a dataset previously released by the State Department (for FYs 2004, 2005, and 2006), PEPFAR partner lists (for FYs 2007 and 2008), and COPs (for FYs 2009 and 2010) (CGD, 2008; OGAC, 2012a). The process of extracting and compiling these data was time intensive, so to be feasible within the resources and time available for the study the committee's analysis was limited to a subset of partner countries. The committee chose to compile these data for the same 13 countries purposefully selected for country visits. Within this subset of 13 countries, to the extent that the data sources above were complete, the committee was able to compare partner data and planned/approved PEPFAR funding for those that were focus countries for FY 2004 through FY 2010 and for non-focus countries for FY 2008 through FY 2010. The number of prime partners for which data were available varied by country (from 4 to 176); during the time period for which data were available, focus countries had an average of 99 total partners and non-focus countries had an average of 19 total partners. For more information on the data sources and their limitations, the methods for this data extraction, and the committee's selection process for the 13 countries, see Appendix C.

To examine funding trends over time, the committee categorized each of the prime partners by origin and location of the organization's headquarters (U.S.-based, partner country, and other) and type (academia, nonprofit, for-profit, and government). A separate category was created for multilateral organizations such as WHO and the United Nations Children's Fund (UNICEF). Based on the subset of data available to the committee for review, there has been a shift in PEPFAR funding over time from U.S.-based to non-U.S.-based prime partners (See Figure 4-13). For this subset of countries and years, prime partners based in partner countries received an average of 33 percent of PEPFAR funding across all years, increasing from 22 percent in 2004 to 36 percent in 2010. U.S.-based prime partners received an average of 63 percent of PEPFAR funding, declining from 75 percent in 2004 to 61 percent in 2010. Prime partners based in other countries (i.e., not the United States or the partner country) received an average of 3 percent, and multilateral organizations received an average of 1 percent. It is important to note that these data do not represent the ultimate distribution of funds to partner country implementers, as many U.S.-based prime partners contract with sub-partners that are

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partner country-based organizations, including governments at the national and sub-national level; nongovernmental for-profit, nonprofit, and civil society organizations; and academia. As described previously, the committee was not able to assess the distribution of funds at the sub-partner level.

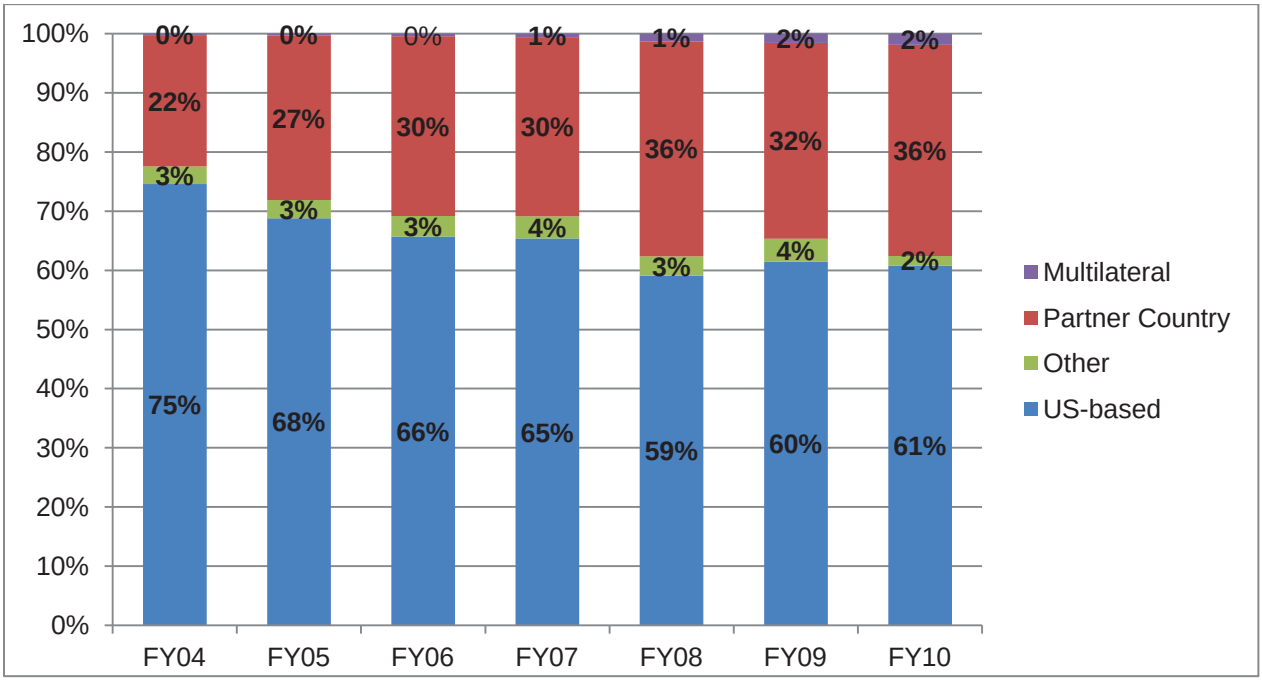

FIGURE 4-13 Proportion of PEPFAR funding by origin of prime partner in 13 PEPFAR partner countries.
NOTE: These data represent, based on the available sources, the proportion of PEPFAR funding directed to prime partners based in the United States, partner countries, other countries, or multilateral organizations.
SOURCE: Select country data extracted by IOM from PEPFAR Country Operational Plans, PEPFAR partner lists, and the Center for Global Development PEPFAR funding dataset (CGD, 2008; OGAC, 2012a).

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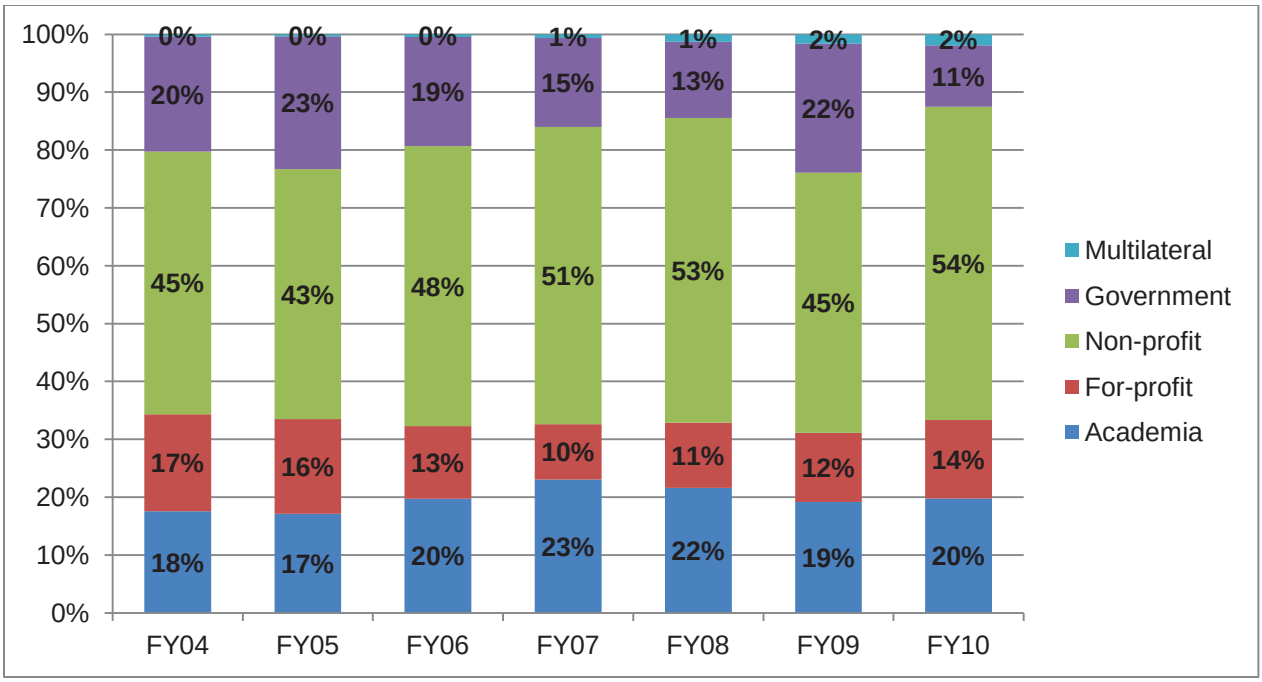

FIGURE 4-14 Percentage of PEPFAR funding by type of prime partner in 13 PEPFAR partner countries.
NOTE: These data represent, based on the available sources, the proportion of PEPFAR funding directed to governments, for-profit entities or firms, nongovernmental organizations (nonprofit organizations), academic institutions, and multilateral organizations, regardless of origin (see above).
SOURCE: Select country data extracted by IOM from PEPFAR Country Operational Plans, PEPFAR partner lists, and the Center for Global Development PEPFAR funding dataset (CGD, 2008; OGAC, 2012a).

The committee also examined the distribution of funding among types of prime partners, shown in figure 4-14. Throughout the duration of the program, the distribution among different types of partners has been variable from year to year, but nonprofit partners have consistently received a greater share of prime partner funding than any other category. On average, nonprofit organizations received the largest share of PEPFAR prime partners funding (49 percent), followed by academic prime partners (20 percent), governmental prime partners (17 percent), for-profit prime partners (13 percent), and multilateral organizations (1 percent). In Figure 4-14, types of partners are not disaggregated by origin; for example, the category of government prime partners includes partner country governments, USG agencies such as CDC and USAID (when these agencies are directly responsible for delivering technical assistance or implementing activities), and, very rarely, other country governments.

As described above, an increasing share of funding has been directed to local prime partners with headquarters based in partner countries. To better understand how this funding has been distributed among the types of partners within partner countries, the committee examined the breakdown of local prime partner funding between government and nongovernment entities. (see Figure 4-15). In this subset of countries and available data, the proportion of funding going to local governments as prime partners has remained relatively stable over time and generally under 10 percent of total funding. The increase in local prime partner funding is mostly accounted for by nongovernmental entities. OGAC has stated that it has the goal of transitioning funding to more local prime partners that are based in partner countries in order to increase the sustainability of PEPFAR programs. These efforts are described further in the discussions of the health systems financing in Chapter 9 and of sustainability in Chapter 10.

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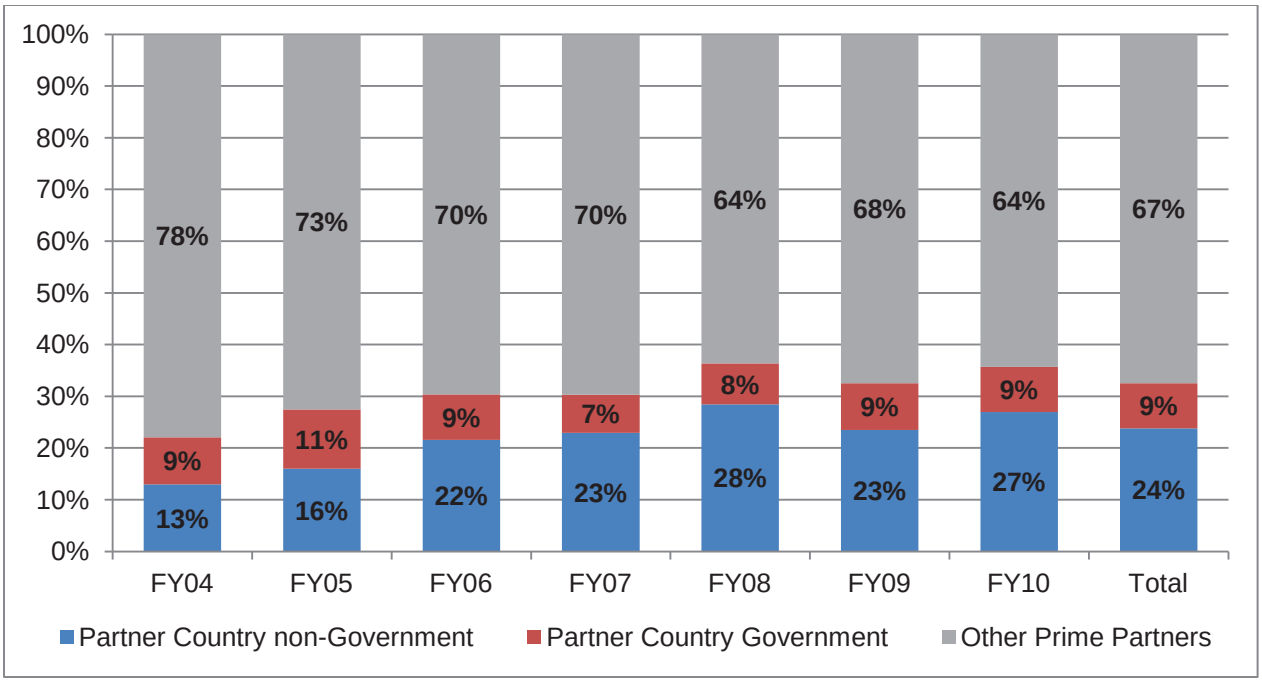

FIGURE 4-15 PEPFAR funding for local prime partners.
NOTE: Other prime partners include prime partners that are based in the United States or other countries as well as multilateral organizations.
SOURCE: Select country data extracted by IOM from PEPFAR Country Operational Plans, PEPFAR partner lists, and the Center for Global Development PEPFAR funding dataset (CGD, 2008; OGAC, 2012a).

Conclusion: The greater part of PEPFAR's funding has always gone to support programs and activities implemented in partner countries. Consistent with one aspect of PEPFAR's articulated strategy to move towards sustainability, more PEPFAR funding over time has been directed to local prime partners. Based on an analysis of a subset of data and countries, the increase in local prime partner funding has been driven primarily by increased funding to nongovernmental entities based in partner countries; the proportion of funding to partner country governments as prime partners has remained relatively stable over time.

As described in this part of the chapter, which focused on PEPFAR funding levels and distribution, the committee aimed to come to a full understanding of the amount and distribution of the annual direct investment of PEPFAR in partner countries, which is a critical input to assess in order to understand the performance of the program. However, limitations in the available financial data made this very difficult. In particular, there are limitations to understanding the amount and distribution of funds outlaid on an annual basis, with data only readily available for annual congressional appropriations and cumulative obligations and outlays. Furthermore, these data are not available disaggregated by type of activity or by type of partner. Thus, the committee used data on what was planned/approved in annual budgets to look at how PEPFAR funding is distributed at the country, program, and partner levels. Even within this planned/approved funding, there are limitations to matching the data in the reported budget codes to the program's activities, and data are limited on the types of partners that ultimately receive the funding.

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Until recently, OGAC has been unable to track and assess how PEPFAR funds have moved from congressional appropriations to OGAC to the implementing agencies to prime partners to subcontractors, since USG implementing agencies were not required to report on expenditures at all levels of the program (Donnelly, 2012b). In May 2012 OGAC requested approval from the U.S. Office of Management and Budget (OMB) to require all partners receiving PEPFAR funding to report annual program expenditures using an electronic template (60-Day Notice, 2012). It is important to note, however, that while this will improve the availability of useful financial data, requiring more financial reporting may also create additional reporting burden for partners and country teams (NCV-4-USACA). OGAC initially estimated that recipients of PEPFAR funding would need an average of 12 hours each year to comply with the new reporting requirements, but based on public comments received during the Paperwork Reduction Act approval process, the average burden estimate was increased to 24 hours (30-Day Notice, 2012; 60-Day Notice, 2012). The estimate was calculated by surveying diverse partners that participated in pilot expenditure analyses from 2009 to 2011 and taking an average of the responses; OGAC has noted that the time will vary considerably depending on the size of partners and the portfolio of programs they implement.[16] OGAC anticipates the burden to be reduced over time as partners familiarize themselves with the data collection process. The current estimate of 24 hours will be reassessed in 2014, 2 years after OMB's approval of the reporting form in November 2012. The reassessment will account for improvements in the data collection interface and greater experience with the data collection for partners.[17]

> **Conclusion:** Due to limitations in the available financial data, it is difficult to fully assess the amount and distribution by program area and partner type of the annual direct investment of PEPFAR in partner countries. PEPFAR would benefit from the collection and reporting of financial data that serves not just for accounting purposes but is also more closely aligned with programmatic data and program implementation. These data are critical for PEPFAR and external stakeholders to more easily and effectively understand how well PEPFAR is being implemented and how PEPFAR's investment relates to both the targets and goals of PEPFAR-supported programs and the broader goal of transitioning to more sustainable management of the response to HIV in partner countries. To this end, the committee, while acknowledging the realities of the additional reporting burden, supports OGAC's request to collect more information from implementing partners on PEPFAR program expenditures.

PEPFAR FUNDING BY COUNTRY CHARACTERISTICS

As described above, most PEPFAR funding is appropriated and budgeted for activities within partner countries. In addition to understanding how PEPFAR funding is distributed among the different program priorities and different mechanisms and partners for implementation, the committee was interested in assessing the characteristics of the countries that have received PEPFAR funding over time and the distribution of funding across these countries. PEPFAR's authorizing legislation recognized the need "to turn the tide against AIDS"

[16] Personal communication from OGAC, February 1, 2013.
[17] *Ibid.*

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in African and Caribbean countries most affected by HIV/AIDS.[18] The legislation stated that the required Five-Year Strategy should "establish priorities for the distribution of resources based on factors such as the size and demographics of the population with HIV/AIDS […] and the needs of that population and the existing infrastructure or funding levels that may exist."[19] As described in Chapter 1, at PEPFAR's inception bilateral USG HIV/AIDS programs encompassed activities in over 100 countries, and since FY 2004, at least 112 countries have received PEPFAR support. However, the authorizing legislation designated 14 specific countries in which all USG HIV-related activities should be under the direct authority of the newly established U.S. Global AIDS Coordinator, along with "other countries designated by the President."[20] The 14 countries had been previously chosen for the Mother-and-Child HIV Prevention Initiative, and these countries were among those with the highest HIV prevalence rates at the time and were home to nearly 70 percent of those living with HIV in Africa and the Caribbean (White House Office of the Press Secretary, 2003). The implementation of PEPFAR was focused on these countries as well as Vietnam, which was added subsequent to the legislation. Most of the investment was concentrated in these 15 "focus" countries, which together had HIV/AIDS burdens that accounted for over 50 percent of global HIV prevalence (Goosby et al., 2012).

The reauthorization legislation in 2008 specified that in designating additional countries for this direct authority, priority should be given to "those countries in which there is a high prevalence of HIV or risk of significantly increasing incidence of HIV within the general population and inadequate financial means within the country."[21] Those countries with the highest levels of investment that are under the direct authority of OGAC submit Country Operational Plans (COPs) to OGAC. Over time the COP countries—and, in a few cases, coordinated regions—have expanded from the original focus countries. At the time of the planning of this evaluation, there were 31 individual countries submitting COPs; these countries comprise the major focus of the committee's assessment.

To gain a more detailed understanding of the characteristics of these countries, the committee chose to examine how PEPFAR funding, as reflected in the total annual planned/approved funding reported by OGAC in the annual PEPFAR Operational Plans, is distributed using specific metrics for these 31 partner countries. As described in the sections that follow, in order to examine PEPFAR funding by the severity of the epidemic, the committee calculated summary statistics for three groups of countries based on HIV prevalence in 2009 as well as average PEPFAR funding per person living with HIV (PLHIV) from FY 2005 to FY 2011. Since low-income countries are most in need of external assistance with HIV/AIDS epidemics, the committee also looked at PEPFAR funding to countries by income level. As described previously, complete and consistent data sources across countries are not available to reflect internal resources for the HIV response in partner countries; as a result, this was not included in this analysis despite being one of the criteria for prioritization in the legislation. Chapter 9 provides a more thorough discussion of domestic financing for national HIV/AIDS responses and the implications of these data limitations.

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[18] *Supra.*, note 7 at §2(28)
[19] *Supra.*, note 7 at §101(a)(9)
[20] *Supra.*, note 7 at §102(a)(2), 22 USC 2651(f)(2)(B)(ii)(VII)
[21] *Supra.*, note 9 at §102(2)(E)(iii), 22 USC 2651a(f)(2)(B)(ii)(IX)

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PEPFAR Funding by HIV Prevalence

Although PEPFAR is focused on low- and middle-income countries with a high burden of HIV, PEPFAR funding provides support for the response to HIV to countries with a wide range of epidemiological profiles and HIV/AIDS prevalence levels. The committee used 2009 prevalence to group the 31 countries that were the focus of this evaluation into three categories; this year was chosen because it represented the most complete year for which prevalence data were available, and few countries would shift categories if another year were used. Information about PEPFAR's approved funding over time in these prevalence groupings is shown in Figure 4-16 and Table 4-3. Almost all PEPFAR approved funding (95 percent) over the FY 2005–2011 period went to countries with high HIV prevalence (>1 percent of the general population). From FY 2005 to FY 2011 the greatest share of PEPFAR funding (60 percent) was approved for 16 countries with adult HIV prevalence rates between 1 and 10 percent. During the same time period PEPFAR funded nine countries with prevalence rates greater than 10 percent; this subset of countries received approximately one-third of total funding (35 percent) and also had the highest median funding level and included the highest maximum in the range of funding per country. Six countries with national prevalence rates below 1 percent received 5 percent of total funding (OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d). Globally, there were nine countries with HIV prevalence rates greater than 10 percent in 2009, and PEPFAR funded all of them (UNAIDS, 2012a). There were 41 countries with HIV prevalence rates between 1 and 10 percent; in 2009 PEPFAR provided funding to 25 of these countries, including 16 that prepare COPs and are included in this analysis. This distribution of funding is consistent with the congressional and programmatic intent to focus primarily, although not exclusively, on countries with a high burden of HIV. Indeed, Ambassador Goosby has recently said that OGAC has "aggressively tried to re-equilibrate more appropriate allocations to prevalence rates" (Donnelly, 2012b).

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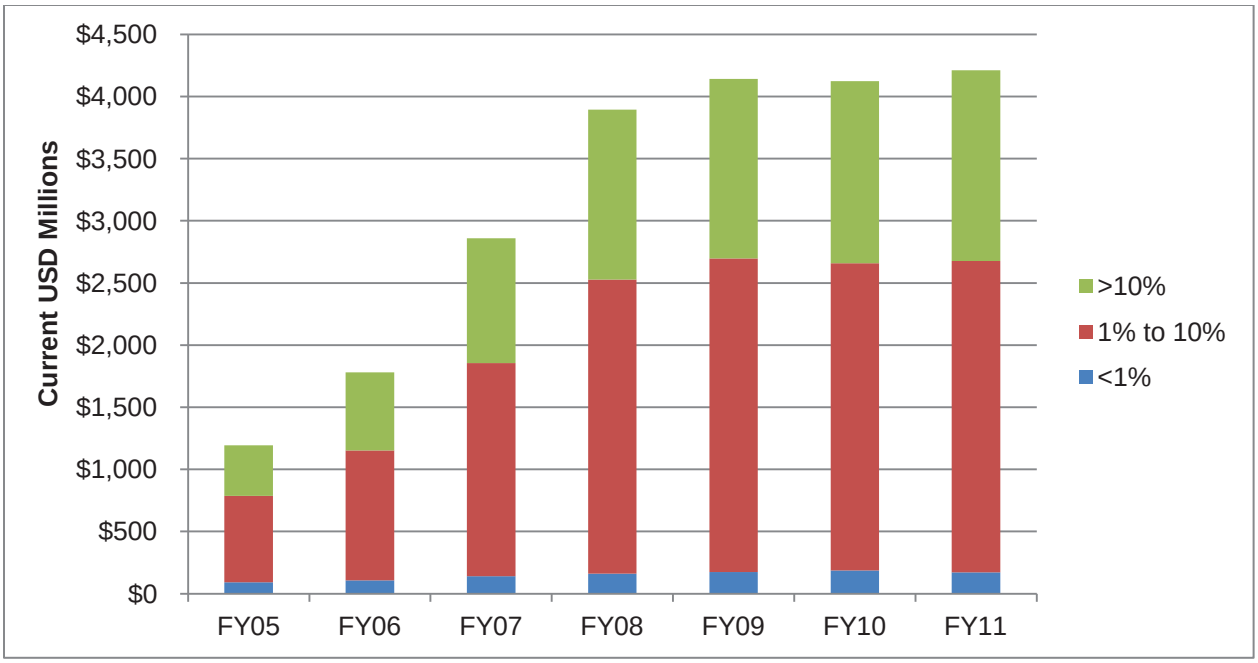

FIGURE 4-16 PEPFAR planned/approved funding by 2009 prevalence groupings in 31 PEPFAR partner countries (current USD millions).
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.

TABLE 4-3 PEPFAR Countries Grouped by 2009 Prevalence

Prevalence		Totals (FY 2005–2011)
<1%	Number of countries	6
	Median funding	$17.5
	Funding range (min, max)	($4.0, $97.8)
	Total funding	$1,034.6
1–10%	Number of countries	16
	Median funding	$39.1
	Funding range (min, max)	($4.0, $565.0)
	Total funding	$13,319.9
>10%	Number of countries	9
	Median funding	$62.5
	Funding range (min, max)	($6.5, $590.9)
	Total funding	$7,850.8
All 31 Countries	Number of countries	31
	Median funding	$33.0
	Funding range (min, max)	($4.0, $590.9)
	Total funding	$22,205.4

NOTE: Funding data are presented in current USD millions.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d.; UNAIDS, 2010.

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PEPFAR Funding per PLHIV

Another measure for examining PEPFAR funding by severity of the epidemic is average PEPFAR funding per PLHIV. Although the number of PLHIV is not a perfect proxy for the HIV prevention, care, and treatment needs in a country, this approach does provide a reasonable approximation of the funding relative to the burden which allows for a richer assessment of the distribution of funding than simply the HIV prevalence level. The committee used planned/approved PEPFAR funding and yearly estimates of PLHIV from UNAIDS to calculate the average PEPFAR funding per PLHIV (age 15+) from FY 2005 to FY 2010 (UNAIDS, 2010a). Figure 4-17 shows this calculation, which for context is presented alongside the population of each country and the HIV prevalence grouping as a reflection of the disease burden.

The funding per PLHIV varied significantly, from $11.84 in Thailand to $3,842.71 in Guyana (see Figure 4-17). Guyana received by far the most funding per PLHIV. Seven other countries received greater than $250 per PLHIV, including two countries from the East Asia and Pacific region with concentrated epidemics (Vietnam and Cambodia). Seven countries received between $100 and $250 per PLHIV, eleven countries received between $20 and $100 per PLHIV, and five countries received less than $20 per PLHIV. Based on the committee's assessment and the perspectives expressed by stakeholders interviewed for this evaluation, there are a number of factors worth discussing that may contribute to the distribution of funding per PLHIV, although it is not possible to draw causal conclusions about the relationship between the funding and these factors.

Although there are exceptions, many of the largest countries (by population) have received less funding per PLHIV, while many smaller African countries with high disease burden have received higher investments per PLHIV. Some small countries may require higher investments per PLHIV for a similar level of programming and services because, although initial startup costs to initiate a robust response to HIV may be either greater in larger countries or similar regardless of population size, larger countries subsequently have more opportunities to achieve economies of scale and to reduce per-person costs of the provision of services. Not all small countries are in the higher grouping, however, which may be because in some countries the available infrastructure had more initial readiness to support service delivery at lower per-person costs. In addition, regardless of size, the country's own resources, capacity, and infrastructure may affect the necessary balance between PEPFAR's support for higher-cost direct service delivery programs versus lower-cost technical assistance programs.

Countries with different prevalence groupings are distributed across different levels of funding per PLHIV. Some countries in lower prevalence groupings receive among the highest levels of funding. Lower-prevalence countries may receive high levels of funding per PLHIV for various reasons, including political or foreign policy considerations; availability of other external donor and country resources for the HIV/AIDS response, which in some cases may be influenced by how active a role the country government takes in the response; lack of economies of scale for service delivery; and initial or existing capacity levels and infrastructure development that affect the costs of service delivery.

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	Population Size	2009 HIV Prevalence Grouping	Average PEPFAR Funding per estimated PLHIV (FY 2005–2011)	
Guyana	753,013	1-10%	$3,842.7	Greater than $250 per PLHIV
Haiti	9,864,241	1-10%	$806.5	
Rwanda	10,311,275	1-10%	$632.8	
Namibia	2,242,078	>10%	$469.2	
Ethiopia	81,187,751	1-10%	$368.3	
Cambodia	13,977,903	<1%	$275.4	
Kenya	39,462,188	1-10%	$270.8	
Vietnam	86,901,173	<1%	$252.4	
Botswana	1,981,576	>10%	$242.7	Between $100-250 per PLHIV
Zambia	12,723,746	>10%	$224.7	
Uganda	32,367,909	1-10%	$206.2	
Cote d'Ivoire	19,350,026	1-10%	$186.2	
Dominican Republic	9,796,852	<1%	$173.7	
Tanzania	43,524,738	1-10%	$173.1	
Mozambique	22,858,607	>10%	$132.4	
Nigeria	154,488,072	1-10%	$99.4	Between $20-100 per PLHIV
Swaziland	1,168,345	>10%	$99.2	
South Africa	49,751,503	>10%	$73.8	
Lesotho	2,149,201	>10%	$55.3	
Angola	18,555,115	1-10%	$51.1	
Indonesia	237,414,495	<1%	$42.0	
Ghana	23,824,402	1-10%	$37.9	
Dem. Repub. Congo	64,204,304	1-10%	$36.1	
Sudan	42,478,309	1-10%	$35.7	
Malawi	14,442,290	>10%	$32.1	
Zimbabwe	12,473,992	>10%	$25.0	
Ukraine	45,715,010	1-10%	$19.9	Less than $20 per PLHIV
China	1,334,908,820	<1%	$13.8	
Russia	143,064,078	1-10%	$12.7	
India	1,207,740,408	<1%	$12.1	
Thailand	68,706,122	1-10%	$11.8	

FIGURE 4-17 Average PEPFAR funding per PLHIV (current USD).
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d; UNAIDS, 2012b.

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PEPFAR Funding by Income Level

Finally, to assess how PEPFAR funding is distributed by resource needs, the committee calculated summary statistics for planned/approved PEPFAR funding by partner country income level as a proxy for resources available. Of the 31 countries included in the committee's analysis, 19 were classified by the World Bank in 2004 as low-income, nine as lower-middle-income, and three as upper-middle-income.[22] From FY 2005 to FY 2011, most planned/approved PEPFAR funding (78 percent) was directed to 19 low-income countries. Nine lower-middle-income countries have received 6 percent of planned/approved funding, and three upper-middle-income countries have received 16 percent (see Figure 4-18 and Table 4-4).

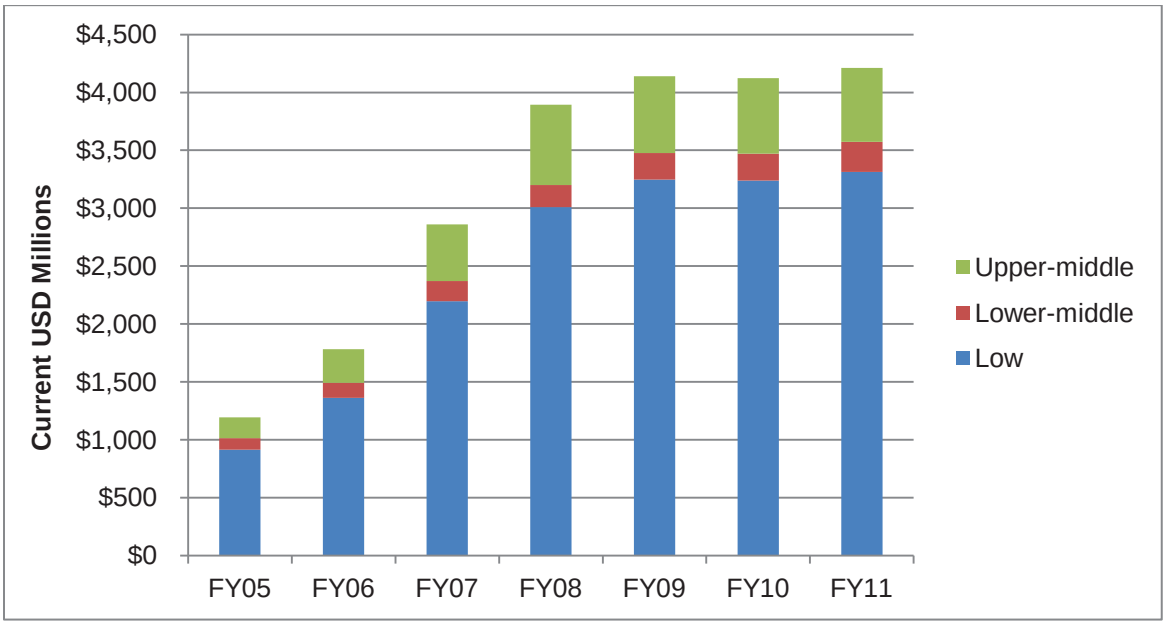

FIGURE 4-18 PEPFAR planned/approved funding by income level in 31 PEPFAR partner countries (current USD millions).
NOTE: Countries were categorized based on income level in 2004 (the year that PEPFAR began).
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d; World Bank, 2012.

[22] The World Bank categorizes economies based on gross national income (GNI) per capita and in 2004 used the following criteria: GNI per capita of $735 or less = low-income, $736–$2,935 = lower-middle-income, $2,936–$9,075 = upper-middle-income, greater than $9,075 = high-income (World Bank, 2012).

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TABLE 4-4 PEPFAR Countries Grouped by 2004 Income Level

Income Level		Totals (FY 2005–2011)
Low income	Number of countries	19
	Median funding	$75.7
	Funding range (min, max)	($4.0, $565.0)
	Total funding	$17,284.0
Lower-middle income	Number of countries	9
	Median funding	$9.8
	Funding range (min, max)	($4.0, $108.9)
	Total funding	$1,308.9
Upper-middle income	Number of countries	3
	Median funding	$84.4
	Funding range (min, max)	($5.0, $590.9)
	Total funding	$3,612.5
All 31 Countries	Number of countries	31
	Median funding	$33.0
	Funding range (min, max)	($4.0, $590.9)
	Total funding	$22,205.4

NOTE: Funding data are presented in current USD millions.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d; World Bank, 2012.

Summary of PEPFAR Funding By Country Characteristics

In order to understand the distribution of PEPFAR funding among countries, the committee considered funding levels by disease burden, income level, and funding per PLHIV, which have been described in the preceding sections and are put together in Figure 4-19. The patterns of distribution of PEPFAR funding by disease severity and income level in partner countries are variable. Overall, PEPFAR funding has predominantly gone to support low-income countries with a high burden of HIV. Five countries fall into both the lowest income grouping and the highest prevalence grouping, and about half of the total number of partner countries (16 of 31) are both low income and have a high prevalence, at greater than 1 percent. Four other countries that receive funding but are not in the lowest income grouping (Namibia, Swaziland, South Africa, and Botswana) are priority partner countries for investment because of their very high prevalence of HIV. As described previously in this chapter and in Chapter 1, this is consistent with the legislative intent to focus on high-burden countries with limited resources. Countries that are not in the income category of greatest need nor in the highest prevalence grouping, as well as those with concentrated epidemics that are in the lowest income category, may have been selected as recipients of PEPFAR funding for other reasons, including the need for external support for a robust HIV response due to limited resources or a limited engagement of country governments in the response.

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The level of PEPFAR funding per PLHIV varies across partner countries; the reasons for this may include level of governmental commitment and the levels of other available country resources and external donor resources, such as the Global Fund and other bilateral donors, as well as factors of size, capacity, and infrastructure that can affect what types of assistance is needed and how costly services are in the country (NCV-3-USG; NCV-9-USG; NCV-12-USG) (USG, 2012). In addition to differences in the costs and scale of programs and the types of programmatic support needed, foreign policy, geopolitical, or other factors can be strategic drivers for supporting bilateral engagement and investment in some countries, and past or current political instability or uncertainty may contribute to decisions about foreign assistance investment (NCV-3-USG; NVC-9-USG; NCV-12-USG) (USG, 2012). Different models of PEPFAR assistance and how they are determined are discussed in more depth in Chapter 10.

Conclusion: Although there is variability in how the distribution of PEPFAR funding relates to country characteristics of disease severity and income level, PEPFAR funding overall has predominantly, but not exclusively, gone to support low-income countries with a high burden of HIV.

		Income Level					
		Low Income		Lower-middle Income		Upper-middle Income	
HIV Prevalence	<1%	India	$12.1	China	$13.8		
		Vietnam*	$252.4	Indonesia	$42.0		
		Cambodia	$275.4	Dominican Republic	$173.7		
	1-10%	Nigeria*	$99.4	Thailand	$11.8	Russia	$12.74
		Ethiopia*	$368.3	Ukraine	$19.9		
		Dem. Repub. Congo	$36.1	Angola	$51.1		
		Tanzania*	$173.1	Guyana*	$3,842.7		
		Sudan	$35.7				
		Kenya*	$270.8				
		Uganda*	$206.2				
		Ghana	$37.9				
		Cote d'Ivoire*	$186.2				
		Rwanda*	$632.8				
		Haiti*	$806.5				
	>10%	Mozambique*	$132.4	Namibia*	$469.2	South Africa*	$73.76
		Malawi	$32.1	Swaziland	$99.2	Botswana*	$242.71
		Zambia*	$224.7				
		Zimbabwe	$25.0				
		Lesotho	$55.3				

FIGURE 4-19 Average PEPFAR funding per PLHIV (FY 2005–2010) (current USD) for partner countries grouped by income and HIV prevalence.
NOTE: Income levels are from 2004; HIV prevalences are from 2009. * = original focus country. Within each box (e.g., <1% and low-income), countries are sorted by population from largest to smallest.
SOURCES: OGAC, 2005; 2006b; 2007c; 2008d; 2010e; 2011c,d; UNAIDS, 2010a; 2012b; United Nations, 2011.

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STRATEGIC USE OF PEPFAR RESOURCES

In addition to describing the amount and distribution of PEPFAR funding over time, the committee assessed some available information about how decisions are made about the allocation of PEPFAR resources, including mechanisms and efforts to try to maximize the strategic and efficient use of PEPFAR resources as a contribution to the response to HIV in partner countries. This is becoming increasingly important as a part of the future plans for the evolving implementation of USG funding for global HIV, especially in the context of an increasingly resource-constrained environment (NCV-5-USACA; NCV-6-USNGO; NCV-9-USG; NCV-21-ML; NCV-27-ML). A few key topics in this area are described in brief here; the primary discussion of these topics can be found in the section on financing in Chapter 9, which discusses health systems strengthening, and in Chapter 10, which is a discussion of progress toward a sustainable response in partner countries.

In 2011 OGAC launched PEPFAR's Impact and Efficiency Acceleration Plan, which is "a framework for making smart investments" (Goosby, 2012b, p. S45). This plan calls for the generation and use of economic and financial data; the allocation of resources based on their anticipated impact; collaboration with governments, the Global Fund, and others to align programs; and streamlining of business processes to maximize the impact of PEPFAR resources. As discussed below, these strategies have been in place to some extent through the history of the program but have been receiving greater emphasis in more recent years.

Generation and Use of Economic and Financial Data

To support better decision making, OGAC has prioritized the generation and use of financial data, as discussed earlier in this chapter, as well as economic data such as costing studies, expenditure analysis, and support for partner country governments to understand national funding streams (Goosby, 2012b; Holmes et al., 2012).

In one recent initiative to support enhanced partner management and improve the efficiency of program implementation at the country level, during the last 3 years OGAC has piloted different types of expenditure analysis in nine partner countries (Goosby, 2012b; Holmes et al., 2012; PEPFAR, 2012). From 2009 to 2012, the PEPFAR Expenditure Analysis Initiative collected data on PEPFAR expenditures in eight partner countries. By linking expenditure data to HIV/AIDS program results, the results of these analyses are intended to inform internal PEPFAR partner management, PEPFAR portfolio allocations and budget projections, program planning, and country-level harmonization of expenditure tracking and coordination of resources with governments. For example, PEPFAR has supported the estimation of per-patient expenditure for treatment services in South Africa, Mozambique, and Zambia; for HIV testing and counseling in Mozambique; for different behavioral prevention services in Uganda; and for prevention of mother-to-child transmission (testing, treatment, and care services) in Nigeria (PEPFAR, 2012; Rosen, 2011). In South Africa, the PEPFAR mission team mapped PEPFAR expenditures to the objectives of the National Strategic Plan and is using these data to facilitate planning with the national and provincial government (PEPFAR, 2012). The results of these expenditure analyses are also intended to help inform global budgeting and resource allocation at the headquarters level by estimating the PEPFAR costs to support HIV/AIDS programs (PEPFAR, 2012).

PEPFAR's support for efforts to track and assess expenditures, costs, resource needs, and funding streams in partner countries is discussed in more detail in Chapter 9 in the section on PEPFAR's efforts in the area of health systems financing in partner countries.

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Allocation of Resources Based on Anticipated Impact

In addition to understanding program costs, OGAC calls on PEPFAR mission teams and partners to use scientific evidence as a guide for allocating resources to the interventions that will have the most impact within each country (Goosby, 2012b). Operational and programmatic guidance from headquarters helps mission teams with the allocation of resources based on evidence for likely impact (NCV-7-USG). In addition to guidance on what activities are priorities for implementation, PEPFAR's mechanisms for program monitoring and evaluation are also intended to provide an ongoing assessment of program performance and to therefore inform the future allocation of resources. The reporting and guidance specific to different programmatic areas supported by PEPFAR are discussed in the relevant subsequent chapters of this report.

In addition to using routine program monitoring data, the Expenditure Analysis Initiative described above has also contributed to the resource allocation based on impact. In Mozambique, for example, the expenditure data on HIV counseling and testing was used to shift investments to target populations and modalities that were most likely to identify HIV-positive people (PEPFAR, 2012). OGAC expects that better access to economic, financial, and indicator data will allow governments and partners to avoid inefficient allocation of resources (OGAC, 2011e).

Interviewees noted that an increasingly resource-constrained environment in the second phase of PEPFAR has required prioritizing activities that are aligned with guidance and that are reported on (NCV-2-USG; NCV-9-USG). Interviewees shared a common perspective that '*what gets measured gets done*' (NCV-2-USG; NCV-23-USNGO; 272-36-USG; 396-1920-USG). In some countries, interviewees felt that the emphasis on showing results forced them to focus on interventions for which impact could be measured quickly (272-12-USNGO). Across countries, interviewees also mentioned the need to target PEPFAR resources to populations that are most vulnerable, in need, or at risk as a current or needed strategy for making the best use of resources (587-1-USG; 166-17-USG; 331-ES; 396-7-PCGOV). The role of PEPFAR's monitoring and evaluation and other data collection efforts in guiding program priorities is discussed in much more detail in Chapter 11.

Collaboration with Governments, Other Donors, and the Global Fund to Align Programs

OGAC has also identified the importance of working with partner country governments, the Global Fund, other donors, and other stakeholders involved in the HIV/AIDS response to ensure that PEPFAR resources complement funding from domestic and external sources and that interventions are aligned with partner country HIV/AIDS strategies (Goosby, 2012b). Interviewees from several countries and across stakeholder types identified coordination and non-duplication as strategies to make the best use of resources (331-ES; 587-10-USG; 196-ES). Beyond coordination and non-duplication, PEPFAR has in some cases leveraged funding in order to mobilize more resources for the HIV/AIDS response. For example, PEPFAR may provide funding to roll out an intervention in one geographic region and use that to leverage other donor and partner country resources to fund other geographic regions, or PEPFAR may commit to making investments and use that to elicit matched funding for similar investments from other sources (NCV-9-USG; 240-ES; 542-ES; 396-ES; 935-ES; 166-4-USG).

Collaboration with Partner Country Governments

OGAC has instructed PEPFAR mission teams to align and harmonize PEPFAR planning processes with national planning for the HIV/AIDS response. Further, mission teams must consult with partner country governments to get their buy-in, and the partner country

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governments must approve the strategic direction of the PEPFAR program (OGAC, 2011b). In some cases the alignment process may happen primarily through a broader arena than direct dialog between PEPFAR and the partner country government, such as through donor forums of the kind described in the next section. In many countries representatives from the PEPFAR mission team meet regularly with representatives from the partner country government to share information and to discuss joint planning for the HIV response and issues that arise; from both perspectives, collaboration and alignment was seen as improving over time and helping the HIV response (240-5-PCGOV; 331-4-PCGOV; 196-6-USG; 587-12-USG; 166-8-USG; 166-13-PCGOV; 272-36-USG; 396-55-USG; NCV-6-USNGO; 116-2-USG, 116-4-USG; 240-7-PCGOV; 240-15-USG; 587-7-PCGOV; 396-57-USG). In some countries, in addition the mission team, PEPFAR implementing partners are also actively involved in regional or district-level planning and/or coordinating processes (240-15-USG; 461-14-USG; 331-30-USPS; 196-28-USG; 166-5-USG; 272-36-USG; 935-23-PCNGO; 542-8-USNGO), which was described as having improved alignment (240-15-USG; 396-39-USG; 272-7-USG). However, partner country governments have also experienced a lack of information about PEPFAR-supported activities in some countries, which poses a challenge to collaboration for planning (272-36-USG; 166-16-PCGOV; 166-19-PCGOV; 240-33-USG; 396-16-PCGOV; 461-8-PCGOV), and some government representatives described dissatisfaction with the approach to collaboration, specifically when presented with the COP only after it had been drafted (116-11-PCGOV; 166-13-PCGOV). The sharing of information between PEPFAR and partner country governments and other stakeholders is discussed in more depth in Chapter 11 on knowledge management.

PEPFAR mission teams described struggling to collaborate with partner country governments with competing priorities or those that did not view the HIV/AIDS response as a priority; interviewees noted in some cases that PEPFAR was providing lots of funding for the HIV response while the government really needed or wanted funding for a broader approach to health (240-1-USG; 934-5-USG; 542-2-USG). For example, in one country where PEPFAR and Global Fund funding comprise a very large proportion of the government's total budget for health, the partner country government felt that PEPFAR was driving the priorities of the HIV response (240-2-USG; 240-21-PCGOV). Other examples of challenges for alignment with partner country priorities described by interviewees included government priorities that do not match OGAC guidance or PEPFAR focus areas (935-17-USG), lack of engagement by the partner country government (461-4-USG), incomplete or underdeveloped national strategies (240-3-USG), a lack of joint planning processes with government and other donors (587-2-USG), a lack of national commitment from ministries of health for coordinating partners (636-9-USACA; 636-16-USG; 272-15-PCNGO; 396-18-USG), and no mapping of who does what in the HIV response (636-9-USACA; 331-6-CCM). Although there were examples of misalignment of priorities (240-1-USG; 240-7-PCGOV; 331-6-CCM), there were also instances in which PEPFAR was described as supporting the government's vision (240-2-USG; 636-3-USG; 331-15-USG).

Alignment and collaboration between PEPFAR and partner country governments is discussed further in the section on leadership and governance in Chapter 9 and in Chapter 10, which discusses the sustainability of the response.

Collaboration with Other Donors

Many countries have at least one mechanism for coordination and collaboration among donors and partners, such as donor forums, technical working groups, or other joint processes for the review and planning of allocation of resources and programming (240-5-PCGOV; 331-2-USG; 331-4-PCGOV; 331-ES; 196-6-USG; 196-ES; 636-9-USACA; 636-16-USG; 116-2-USG; 116-4-USG; 272-2-USG; 272-ES; 166-12-USG; 116-5-PCGOV). These coordination efforts can be led by external donors, by multilateral organizations such as UNAIDS, by Global Fund Country Coordinating Mechanisms, or by the partner country

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government. In most countries, representatives from PEPFAR mission teams or implementing partners are actively involved in these groups (240-5-PCGOV; 240-7-PCGOV; 240-15-USG; 331-4-PCGOV; 587-7-PCGOV; 196-6-USG; 196-20-PCNGO; 636-9-USACA; 116-2-USG; 116-4-USG; 166-12-USG; 272-6-ML; 934-2-USG). The process of developing Partnership Frameworks has also provided an opportunity to engage all stakeholders (331-5-ML; 116-2-USG; 396-57-USG). As one interviewee observed:

> *"I think that the partnership frameworks changed the way we interacted and the openness to listening to folks on the other side who could say, you know, we're really appreciative of the resources that you're bringing in through the HIV window, but let's think about how we can do this in a more comprehensive manner. And in that conversation, it's not all about just our resources. And it's about, okay, so, government, this is what you're bringing to the table. Other partners, this is what you're bringing to the table. So let's think collectively."* (116-2-USG)

In addition to more formal processes of engagement, interviewees also described informal methods (e.g., meeting over coffee) of coordinating with other donors (331-2-USG; 196-8-ML; 240-2-USG). Interviewees in several countries also mentioned "gap-filling"—targeting resources to populations or services not addressed by the national response or other partners—as a strategy to make the best use of resources (331-ES; 272-22-USG; 396-ES; 934-ES; 196-ES; 935-8-PCGOV; NCV-21-ML). The process of collaboration and coordination among donors is discussed further in both Chapters 9 and 10.

Collaboration with Global Fund

In some countries, PEPFAR and the Global Fund provide 90 percent of total funding for HIV/AIDS responses, yet the planning and implementation processes of the two donors are not always aligned. Recently, PEPFAR has started planning country programs in greater coordination with the Global Fund, and Ambassador Goosby has stated that he foresees significant cost savings as the two donors become more aligned (Donnelly, 2012b). Many interviewees described PEPFAR efforts to coordinate activities with the Global Fund (240-3-USG; 196-ES; 636-ES; 543-ES); in some countries, non-duplication is formalized through a memorandum of understanding between the two donors and partner country governments (KFF, 2009). In one example of coordination, Global Fund resources may be used to procure first-line antiretroviral drugs (ARVs) while PEPFAR supports procurement of second-line ARVs (NCV-21-ML; 587-22-USG). In Angola and South Sudan, Global Fund finances procurement of ARVs and PEPFAR supports the delivery of ARVs to patients and also supports health worker training (Goosby, 2012a). In Malawi, PEPFAR funding is targeted to urban areas and Global Fund financing supports rural communities, while PEPFAR and UNICEF (with Global Fund financing) jointly support different elements of the PMTCT program (Goosby, 2012a). A recent article described improved communication, sharing of information, and coordination of activities in Tanzania between PEPFAR and the Global Fund (Bilimoria, 2012). Interviewees believed that coordination between PEPFAR and the Global Fund could be improved in some countries (240-5-PCGOV; 587-1-USG; 272-ES). Some PEPFAR countries with fewer donors or smaller programs described fewer challenges with coordination and cooperation (196-1-USG; 196-8-ML; 636-2-USG). PEPFAR's collaboration with the Global Fund is discussed further in both Chapters 9 and 10.

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Streamlining of PEPFAR Business Processes

The final element of OGAC's plan to maximize PEPFAR resources calls for USG implementing agencies and PEPFAR partners to improve effectiveness and efficiency and adjust the size of and staffing of country programs to match the needs of the national response (Goosby, 2012b). Efforts to improve routine business practices for the whole of the program have resulted in considerable cost savings (Donnelly, 2012b). Several strategies for streamlining processes are described here.

Cost Reductions for Drugs Procured by PEPFAR

Systemic changes in the selection and procurement of antiretrovirals (ARVs) has contributed to dramatic reductions in the cost of treatment; per-patient treatment costs have fallen from over $1,100 per year to approximately $335 (OGAC, 2012c). To ensure quality, ARVs purchased with PEPFAR funding must be approved by the U.S. Food and Drug Administration (FDA) or another acceptable regulatory authority. When PEPFAR began, only proprietary/brand name ARVs had been approved by the FDA, which resulted in significantly higher costs for first-line regimens (up to $450 more per patient per year) compared to the lowest-priced generics available in focus countries and/or provided by other global HIV/AIDS initiatives (GAO, 2005). To increase the availability of generic ARVs for purchase with PEPFAR funding, the FDA modified an expedited review process — FDA tentative approval — to rapidly evaluate the quality of generic ARVs (Holmes et al., 2010). The percentage of generic ARVs purchased with PEPFAR funding increased from 16 percent in 2005 to 89 percent in 2008, reducing drug costs by more than $323 million; in 2010, 97 percent of ARVs procured by PEPFAR were generic (El-Sadr et al., 2012; Holmes et al., 2010). The Supply Chain Management System estimates that switching to generics has saved $1.1 billion through September 2011 (SCMS, 2012).

In addition to decreased costs due to use of generic ARVs, pooled procurement of commodities (including ARV drugs as well as other commodities such as laboratory reagents) within, across, and between countries has led to savings in the form of discounts from suppliers. Changing the methods by which these ARVs are procured and delivered has also achieved significant cost savings (Jamieson, 2011). Through FY 2011 PEPFAR saved more than $59 million by using sea and road freight instead of air freight (SCMS, 2012).

USG Interagency Implementation Process

A key feature of PEPFAR (and the Global Health Initiative) is that programs are to be implemented through a "whole of government" approach with the aim that agencies will focus on their core competencies and coordinate efforts to maximize the effectiveness of PEPFAR funding (OGAC, 2009d). Within PEPFAR mission teams, OGAC has mandated that all USG agencies be involved in the annual COP process (described briefly above) (OGAC, 2007b; 2008c). This interagency implementation approach was also described in Chapter 3.

Stakeholders in partner countries had mixed perspectives on the "whole of government" approach. In some countries, interviewees reported competition for funding among USG agencies (934-40-ML; 935-17-USG; 461-4-USG; 272-ES). One interviewee described situations where CDC and USAID put out competing funding announcements and another situation in which representatives from both agencies *'looked like fools in front of the government because they were fighting with each other'* *(NCV-6-USNGO).*

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Many interviewees from PEPFAR mission teams described challenges with interagency coordination (240-3-USG; 272-1-USG; 272-36-USG; 461-4-USG; *935-17-USG*) and struggles to reduce duplication and overlap of activities by USG agencies (240-8-USG; 587-2-USG; 272-1-USG; 272-33-USG; 272-ES). In some cases the time spent on interagency coordination was described as a burden that took away from other responsibilities (461-4-USG; 396-47-USNGO; *166-4-USG;* 331-3-USG) and an inefficient use of resources (587-25-ML; 396-47-USNGO; 331-3-USG). The following comments are representative:

> *"I think what that's also meant is we spent a lot of our time doing coordination and collaboration. And you could see that as a good thing, or you could see that as a potentially inefficient thing. A lot of time and energy and effort and probably money is spent making sure that everyone under the PEPFAR umbrella, all included, all said their say, all harmonized. And it takes up a lot of time. And it's definitely, I think we all would have examples of where it's obstructed the pace or the results of implementation, for sure."* (396-47-USNGO)

> *'The PEPFAR team feels under-resourced for coordination. The USG staff often feels burdened by huge workloads and limited time.'* (166-4-USG)

The COP preparation and submission process for interagency mission teams was also described in multiple countries as a significant burden of time and effort, especially as the size and scope of PEPFAR-supported programs has grown, resulting in lengthy COPs and time-consuming preparation (240-1-USG; 240-3-USG; 331-48-USG; 636-16-USG; 166-4-USG; 272-24-USG; 542-3-USG; 396-1-USG). To help address this, OGAC has recently streamlined the COP process by shifting to a 2-year framework with a reduced COP every other year (OGAC, 2010c). At least two mission teams remarked that the new streamlined COP process was an improvement (240-1-USG; 240-33-USG; 272-24-USG).

The relationship and decision-making status between country programs and USG headquarters (HQ) was also noted as part of the challenge. For example, interviewees asserted that *'OGAC does not promote interagency cooperation, no leadership in this area'* (331-3-USG), noted '*a lack of clear guidance from DC [HQ] regarding what USAID should be doing versus CDC*' (240-3-USG), and described the "one USG" philosophy as '*theoretical*' (587-2-USG). Interviewees provided contrasting solutions to these challenges:

> *'HQ should leave the division of labor to the country office to work out. HQ can influence discussions about activities with a mentality of, "Our agency portfolio should look like this."'* (240-8-USG)

> *'Why not have the fights over money and resources at the DC [HQ] level not transfer the coordination burden to every country. If the money was earmarked to the agencies in DC [HQ], then it would lead to less planning burden in the country and more time to do development thinking.'* (461-4-USG)

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> '*Would prefer funding decisions made at a higher level. Would rather trust DC to make the funding decisions than fight it out on the country team level.*' (331-3-USG)

Despite the challenges described with the interagency process, some interviewees described interagency cooperation and coordination as at least partially successful or as having improved over time (396-57-USG; 116-27-USG; 636-16-USG; 934-1-USG; 461-19-USG; 935-10-USG; 935-28-USG). Interviewees highlighted some examples of successful efforts to use and improve the interagency process to more strategically use PEPFAR funds. In some countries, having multiple technical working groups with representatives across agencies was described as helping coordinate the planning and implementation of activities (396-57-USG; 461-4-USG). Interviewees in some cases described efforts that had been put in place or were planned to identify the comparative advantages of each USG agency and assign responsibility for projects accordingly (240-8-USG; 331-2, 15-USG; 272-36-USG). Some countries conducted a review of the PEPFAR portfolio or processes to identify areas of overlap and opportunities to reduce duplication (587-2, 12-USG; 272-36-USG). One team mentioned that the Partnership Framework process helped its program identify what each agency was doing (116-7-USG). Other interviewees believed that successful interagency collaboration is dependent on the personalities and leadership of the staff involved (636-16-USG; 934-1-USG).

Coordination of Implementing Partners

Another ongoing approach or future opportunity for more strategic and effective use of resources which emerged from country visit interviews is improving coordination among PEPFAR implementing partners. Although the number of implementing partners varies by country, some partner country programs have more than 100 prime partners and at least that many sub-partners. The sheer number of implementing partners in some countries was described as a challenge (240-5-PCGOV; 240-21-PCGOV; 272-5-PCGOV). In some countries multiple implementing partners are funded to deliver the same services (e.g., antiretroviral treatment) or to conduct similar activities (e.g., capacity building), and this duplication or overlap was seen as a challenge (636-ES; 272-5-PCGOV; 272-36-USG; 196-11-USNGO; 196-12-PCGOV; 240-15-USG). An implementing partner that shares technical assistance responsibilities with another implementing partner noted that '*there are two projects, with two chiefs of party, two finance directors, two offices, two monitoring and evaluation processes, two head offices […it] is not effective and efficient—it is a duplication of positions*' (196-11-USNGO). In one country multiple partners are funded to provide different yet related services (e.g., prevention of mother-to-child transmission, HIV care, TB/HIV) within the same district, which has caused challenges for integration; the implementing partner interviewed expressed a desire to be responsible for all the services within a district (636-9-USACA).

To address these challenges, some PEPFAR mission teams have convened partners meetings, done portfolio reviews, or used other approaches to reduce overlap and duplication among implementing partners (636-6-USG; 935-ES; 461-18-USG; 587-23-USG; 272-36-USG;). In one country, for example, PEPFAR partners were described by a partner country government interviewee as '*well-coordinated*' (240-7-PCGOV). Several PEPFAR mission teams described various reasons for choosing to fund multiple implementing partners for related activities, such as having different partners provide comprehensive services within certain geographic regions (935-2-USG; 461-18-USG) or specific facilities (166-20-USG) and ensuring that a specific service or activity receives the necessary funding and attention:

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> *'It's difficult to have one implementing partner do everything, because some things get lost. In previous PEPFAR-funded programs, capacity building wasn't getting the attention it needed. Therefore, they decided to split into two PEPFAR implementing partners, one of which would focus explicitly on organizational capacity building, and the other would focus on technical assistance.'* (196-28-USG)

Another challenge was that partners may be funded by multiple USG agencies (396-47-USNGO; 636-11-PCNGO; 636-21-USNGO). In one case where there are few local organizations, these local partners may be funded by multiple USG agencies through multiple funding streams (as high as four); there was a concern that these organizations may not have the capacity to address the needs of multiple funders (636-11-PCNGO; 636-21-USNGO).

Public–Private Partnerships

PEPFAR's authorizing and reauthorizing legislation specified that public–private partnerships (PPPs) should be an element of the U.S. strategy against HIV/AIDS; in some cases these offer another way of making strategic use of partnerships and resources. PPPs are part of a "larger trend in global health and development practice that began in the 1980s" (Sturchio and Cohen, 2012, p. 1451). OGAC has created multiple partnerships across program areas and agencies that typically involve a 50–50 joint investment by the USG and a private-sector partner. The private-sector partner usually contributes expertise and in-kind resources such as training (Sturchio and Cohen, 2012). Some examples of PPPs that have introduced efficiencies or reductions in resource use are

- Supply Chain Management System (SCMS), managed by the Partnership for Supply Chain Management (a legal entity established by JSI Research & Training Institute, Inc. and Management Sciences for Health) is "a network of commercial private-sector organizations, nonprofits, academic institutions, and faith-based organizations with a wide range of capabilities [brought together] to expand and strengthen global supply chains for antiretrovirals, HIV test kits, laboratory supplies, and other products" (Sturchio and Cohen, 2012, p. 1452). In 2011, 71 percent of ARVs funded by PEPFAR were delivered by SCMS (SCMS, 2012).
- In 2012, PEPFAR, USAID, UNITAID and the Bill & Melinda Gates Foundation partnered to increase access to a new rapid test to diagnose tuberculosis. Funding provided through this PPP reduces the cost of the rapid test for high-burden and developing countries by 40 percent for 10 years (through 2022) (OGAC, 2012b).

Conclusion: PEPFAR is increasingly emphasizing a range of efforts to use its resources more strategically and efficiently through the generation and use of economic and financial data; the allocation of resources based on anticipated impact; improved collaboration with partner country governments, other donors, and the Global Fund to align priorities and programs; and the streamlining of business processes. PEPFAR has started to see some gains from these efforts. Continuing to identify and implement opportunities for more strategic and

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efficient use of resources will be critical for making progress toward optimal return on investment in the response to HIV in partner countries.

SUMMATION

The committee reviewed the overall PEPFAR funding process and data on PEPFAR funding over time as an important means by which to understand how the program is implemented and as a critical input for answering questions pertaining to the effects of PEPFAR-supported programs. The United States is the single largest donor to global HIV/AIDS efforts in the world, and between 2004 and 2011 the U.S. Congress appropriated more than $38 billion (current USD) for PEPFAR, of which $28.6 billion was designated for programs in partner countries. PEPFAR spending has been invested primarily, although not exclusively, in countries with low incomes and high disease burden.

Due to limitations in the available financial data, it is difficult to fully describe the distribution of the annual direct investment of PEPFAR in partner countries, to match the accounting budget codes to programmatic activities, and to follow the types of partners that ultimately receive the funding and implement PEPFAR-supported activities. This led the committee to conclude that PEPFAR would benefit from the collection and reporting of financial data that serve not just an accounting purpose but are also more closely aligned with programmatic data and program implementation. These data could thus be more easily and effectively used to understand and assess how PEPFAR is being implemented and the relationships between the amount and distribution of the investment and the targets and goals for PEPFAR-supported programs. PEPFAR has begun to take steps in this direction.

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PART III

PEPFAR Programmatic Activity

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5

Prevention

Main Messages

Overall

- PEPFAR's support for the scale-up of HIV prevention activities across prevention modalities has been an achievement and a contribution to the response to the epidemic in partner countries. Within PEPFAR there has been an evolution in prevention programming, from an initial focus on a limited number of behavioral and biomedical interventions, to an expansion of prevention portfolios to reflect both existing and emergent evidence-based approaches.
- Although PEPFAR has articulated a commitment to overarching goals for prevention, PEPFAR lacks clear target outcomes and objectives across all prevention modalities; this is especially the case for behavioral and structural interventions for prevention of sexual transmission, the primary global driver of HIV infection. To achieve its overall goal of reducing new infections and stopping the spread of the epidemic, PEPFAR will need a more comprehensive and balanced approach, with greater clarity in its operational guidance and mechanisms to support the development, implementation, monitoring, and evaluation of prevention portfolios in country programs that are aligned with the drivers of epidemics and the needs for prevention services. Greater attention to developing appropriate approaches to assess the effectiveness of prevention interventions across all modalities and modes of transmission would contribute to this more balanced and comprehensive operational approach.
- There are limitations to measuring the effects of prevention programs across modalities, and in particular for behavioral and structural interventions. These limitations are not unique to PEPFAR and a substantial increase in attention and effort will be required to address them, yet more comprehensively identifying and understanding the outputs, coverage, and outcomes of prevention interventions would be of immense value in accurately assessing and documenting the impact of prevention efforts. Across modalities, measuring and achieving key intermediate outcomes for prevention efforts is as important a goal for PEPFAR as achieving estimated impact on the number of infections averted.

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Prevention of Sexual Transmission

- Interventions targeted at prevention of sexual transmission, including biomedical, behavioral, and structural interventions, are all critical components of a balanced and comprehensive prevention portfolio. Yet within PEPFAR, there is disproportionately less program monitoring data and rigorous research evidence available on these interventions, especially behavioral and structural interventions, than on prevention of mother to child transmission (PMTCT) and other biomedical prevention programs. As a result, the committee was unable to assess the effectiveness or determine the outcomes or impact across partner countries of PEPFAR's efforts to reduce sexually transmitted HIV infections. There is a critical need for improved application of advances in social and behavioral science-based research and evaluation science for prevention to determine the most effective combination of prevention interventions in diverse country contexts Given the scale of its programs and its commitment to implementation research, PEPFAR can contribute to a more effective HIV response by serving as a platform for innovation to fill the gap in knowledge and availability of effective interventions.
- There is recognition in PEPFAR of the important role of efforts for sex workers as a part of the national response in both concentrated and generalized epidemics. There are some examples of success as a result of PEPFAR-supported activities for this population, and increased flexibility over time for prevention budgeting and programming has enabled country programs to more readily plan activities for sex workers.
- Over time PEPFAR has increasingly supported data collection efforts and prevention programming for men who have sex with men, which PEPFAR has recently codified in programmatic guidance. Men who have sex with men are recognized as an important population for prevention and other PEPFAR-supported programming.

Prevention of Mother-to-Child Transmission

- PEPFAR support for scale up of services for PMTCT has made a major contribution to meet the need in partner countries. Integration of PMTCT into maternal and child health is occurring and is a sign of evolution of the program. However, integration at the facility level with other services is variable, and the link between PMTCT and antiretroviral therapy for both women and children is still a challenge.

Prevention with People Who Inject Drugs

- PEPFAR has been increasingly instrumental in facilitating and supporting some harm reduction approaches in countries with epidemics for which injecting drug use is a major or emerging driver. Notwithstanding restrictive U.S. and partner country policy and legal environments, a positive effect of these activities and programs is being seen in countries in which PEPFAR works, but substantial unmet need remains for harm reduction and other services for this population.

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Recommendation Presented in This Chapter

Recommendation 5.1 To contribute to sustainable management of the HIV epidemic in partner countries, PEPFAR should support a stronger emphasis on prevention. The prevention response should prioritize reduction of sexual transmission, which is the primary driver of most HIV infections, while maintaining support for interventions targeted at other modes of transmission. The response should incorporate an approach balanced among biomedical, behavioral, and structural interventions that is informed by epidemiological data and intervention effectiveness evidence. PEPFAR should support advances in prevention science to expand the availability of effective interventions where knowledge is lacking.

Further considerations for implementation of this recommendation:

- PEPFAR has made a commitment to overarching goals for prevention and for achieving an AIDS-Free Generation, but this does not constitute a long-term prevention strategy that clearly states prevention objectives and the pathways to achieving them. The following elements will be critical for a more comprehensive strategy to achieve successful execution of prevention programs:
    - PEPFAR should continue to enhance its efforts to involve partner country stakeholders and incorporate country-specific epidemiology, context, and priorities in planning appropriately-matched prevention programs that achieve a balanced approach to HIV prevention across the available modalities. To provide greater technical and operational clarity, OGAC should provide mechanisms to support the development, implementation, and monitoring of comprehensive prevention portfolios; including how to determine what populations need which directed prevention activities in which settings. Areas of prevention where current interventions are successful and effective, such as PMTCT, should be continued and scaled up to ensure access, coverage, and quality. As new PEPFAR-supported prevention activities are adopted, OGAC should communicate their objectives and the methods for introducing or scaling up with specified populations.
    - OGAC should improve mechanisms to collect and incorporate evidence on the effectiveness of prevention activities implemented in partner countries. The key components for future assessment and evaluation of HIV prevention should include need, coverage of need, quality of services provided, and behavioral and epidemiological outcomes. OGAC should provide clearly defined process and outcome measures as well as impact assessment methods to evaluate progress.
    - PEPFAR's prevention strategy should include balanced support for innovation, research, and evaluation to contribute to the evolving evidence base and advance understanding of the effectiveness of interventions within all prevention modalities. To define and ensure this balance, OGAC should, through its existing mechanisms, convene and use expertise spanning behavioral, structural, and biomedical prevention intervention approaches. PEPFAR-supported research and evaluation activities should employ appropriate methodologies and study designs, without unduly emphasizing random assignment designs. PEPFAR should support innovations in prevention science methodologies where needed to achieve its programmatic research aims (see also Recommendation 11-1).

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5

Prevention

Making strong global, national, and programmatic commitments to HIV prevention is critical to any balanced attempt to change the course of the HIV epidemic, and PEPFAR has made major investments in activities aimed at reducing HIV transmission. The congressional charge for this evaluation, as laid out in the Lantos-Hyde Act of 2008, requested both "an assessment of progress toward prevention, treatment, and care targets" as well as "an evaluation of the impact of prevention programs on HIV incidence in relevant population groups."[1] This chapter presents the committee's assessment of PEPFAR's prevention activities.

In this chapter, a brief overview of the evolution of HIV prevention science is followed by an overview of PEPFAR's programmatic targets and funding for prevention and then discussions about prevention of sexual transmission, including prevention with people who engage in sex work and prevention for men who have sex with men; prevention of mother-to-child transmission (PMTCT); prevention with people who inject drugs; and a limited assessment of PEPFAR's efforts in the areas of blood and medical injection safety. The sections for each prevention area contain relevant historical and contextual framing and an assessment using the program impact pathway framework of inputs, activities, and, to the extent possible, outcomes and impact of PEPFAR's prevention efforts. This is followed by a discussion of the role of counseling and testing within a prevention context, with more in-depth discussion and analysis of this topic in Chapter 6, Care and Treatment. Lastly, there is a discussion of emerging prevention interventions and the committee's recommendation for strategically strengthening PEPFAR's prevention efforts. Further discussion of PEPFAR's activities related to reducing HIV risk for women and girls and for men who have sex with men can be found in Chapter 8, Gender.

The IOM committee is mindful that, over the course of its existence, PEPFAR has had dual roles as both a catalyst and respondent to various developments in global HIV prevention. The committee recognizes both the opportunities and the challenges inherent in these roles and results of this evaluation are described in this context.

[1] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008) at §101(c), 22 U.S.C. 7611(c)(2)(B)(i) and (v).

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EVOLUTION OF HIV PREVENTION SCIENCE

Throughout the history of the HIV epidemic, including the years of PEPFAR implementation, HIV prevention has been evolving, influenced by developments in science, policy, and advocacy in the context of an ever-changing epidemiological, political, and economic landscape. There are multiple, overlapping constructs through which HIV prevention efforts have been envisioned and organized. These include

- *modes of transmission* (sexual, parenteral, perinatal);
- *populations and HIV-risk exposure behaviors* (heterosexual men and women, men who have sex with men (MSM), transgender persons, people who inject drugs, HIV serodiscordant couples, pregnant women, young people, sex workers, etc.);
- *unit- or level-targeted* (individual, couple, network, community); and
- *disciplinary, science-based approaches* (biomedical, epidemiological, behavioral, social/structural).

Over time and in different geographic locations, some of these constructs have been emphasized over others, based on current science, epidemiological trends, or political shifts.

Evolution of Interventions to Prevent or Reduce HIV Infection

The search for an AIDS vaccine—considered an ultimate goal to prevent infection—began as soon as HIV was discovered to be the causative agent of AIDS. Finding an effective vaccine quickly proved to be elusive and remains a challenge given the rapidly adaptive nature of the virus. Meanwhile, in the early years of the HIV response, most prevention efforts were focused on behavioral change strategies that had the potential to be effective in slowing the epidemic. These efforts were supported by observational data from developing countries suggesting that behavioral change made a significant difference in reducing HIV transmission (Gregson et al., 2006; Stoneburner and Low-Beer, 2004).

In addition to behavior change efforts, biomedical approaches became a focus of HIV prevention. One of the most exciting developments in biomedical prevention approaches was the discovery that the administration of antiretroviral drugs (ARVs) (initially zidovudine and then nevirapine) to pregnant women and their newborns could significantly reduce HIV transmission from mother to child before, during, and after delivery (Connor et al., 1994; Guay et al., 1999; Shaffer et al., 1999; Sperling et al., 1996). Research on reducing the risk of transmission through breastfeeding followed this initial finding.

The focus on PMTCT added urgency to addressing HIV infection in women, and epidemiological data has shown high and often disparate rates of HIV infections among women as compared to men in many countries (WHO, 2011). In addition, the recognition that women do not control male condom use, the most widely available method to prevent sexual transmission of HIV (UNAIDS, 2009), highlighted the need for women-focused and women-initiated HIV prevention strategies. Female condoms have become more widely available since 2009, but have several disadvantages, including cost and difficulty of use based on current designs, which have limited their utilization. The global availability and distribution of female condoms remains less than for male condoms and the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) are encouraging more widespread access and use to

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prevent pregnancy and sexually transmitted infections (Avert.org, 2012). Research to develop effective vaginal microbicides began to gain support in the early 1990s, but clinical trials of various compounds proved unsuccessful until recently, when the Centre for the AIDS Program of Research in South Africa (CAPRISA) trial results were released in 2010 showing reduced risk of HIV infection with use of an antiretroviral-based gel (Abdool Karim et al., 2010).

In the 1990s, evidence emerged supporting the effectiveness of harm reduction strategies as a way to prevent HIV transmission among people who inject drugs. Harm reduction efforts seek to minimize negative health outcomes associated with drug use, including reducing the risk of HIV transmission, for people who are unwilling or unable to quit their addiction (International Harm Reduction Association (IHRA), 2009). These strategies may include sterile needle and syringe exchange programs, the relaxation of drug paraphernalia and possession laws, and the provision of medication for substitution therapy (Harm Reduction International, 2012). The adoption of harm reduction approaches varied considerably, but in places where expanded sterile syringe access was implemented, HIV epidemics where transmission was concentrated among people who inject drugs were significantly reduced (Hurley et al., 1997). Despite the mounting evidence of its effectiveness, harm reduction has continued to be very politically and culturally controversial, and was not widely implemented even in some countries with ongoing or emergent concentrated HIV epidemics (Auerbach, 2009).

Other HIV prevention strategies explored and implemented in the first two decades of the global epidemic included the treatment of other sexual transmitted infections (STIs) to reduce the increased risk of HIV infection that accompanies STIs; expanded blood donor HIV testing and other efforts to ensure the safety of blood and blood products; and infection control practices in hospitals and other health care settings to reduce iatrogenic transmission (Auerbach et al., 2006).

By the time PEPFAR was initiated in 2003-2004, global experts had identified several effective, evidence-based, prevention strategies and interventions that were recommended for implementation and scale-up to address HIV epidemics in developing and developed countries alike (Global HIV Prevention Working Group, 2003). These included

- behavioral change programs to reduce sexual risk behaviors and behavioral prevention programs specifically targeted to HIV-positive individuals;
- harm reduction services for people who inject drugs;
- antiretroviral prophylaxis for prevention of mother-to-child transmission;
- universal safety precautions, blood safety practices and infection control in health care settings;
- identification and treatment of STIs in addition to HIV
- HIV counseling and testing; and
- policy reforms (such as those to reduce the vulnerability of women and girls or to expand access to effective prevention strategies).

The HIV prevention field has continued to evolve, influenced by ongoing research on approaches to address social, economic, political, and environmental factors linked to HIV risk, also referred to as structural interventions for HIV prevention (Gupta et al., 2008). Such interventions aim to create an enabling environment to allow individuals to act in their own and their partners' best interests by supporting policy or legal and environmental changes, shifting harmful social norms, catalyzing social and political change, and empowering communities and groups (Auerbach, 2009; Gupta et al., 2008). Multiple structural interventions have been

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effective at achieving HIV prevention outcomes such as reductions in HIV transmission and social and structural risks that contribute to HIV vulnerability (Baird et al., 2012; Gupta et al., 2008; Pronyk et al., 2006). Studies in this area are important as they provide evidence that structural interventions can influence the social determinants of HIV risk, reduce sexual and other HIV risk behaviors, and lower the rate of HIV infection.

Clinical interventions have also been a part of the evolution of the field of HIV prevention. In 2005, evidence of the efficacy of medical male circumcision for preventing HIV acquisition among men emerged (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). More recently, findings have been reported from clinical trials investigating the effectiveness of interventions such as oral pre-exposure prophylaxis (PrEP), topical microbicides, and antiretroviral therapy (ART) for prevention of HIV transmission (Abdool Karim et al., 2010; Cohen et al., 2011; Microbicide Trials Network (MTN), 2012a, b). These advances tremendously altered the prevention landscape—shifting from the historic emphasis on behavioral change strategies to one focused on biomedical prevention technologies.

As HIV prevention has evolved over time to encompass a broad array of strategies and interventions that have been informed by an evolving evidence base, appreciation has grown for a "combination approach" that integrates effective biomedical, behavioral, and structural components of HIV prevention—appropriate to a given setting or population—for maximum effect (Auerbach and Coates, 2000; Global HIV Prevention Working Group, 2003; Hankins and de Zalduondo, 2010; Kurth et al., 2011; Padian et al., 2011; WHO, 2011).

In addition, the adoption and implementation of interventions to prevent HIV infection also occur in the context of historical and contemporary stigmatization. Both the ways in which HIV is transmitted—predominantly through sexual intercourse and illicit drug injection—and the social attitudes about people identified as most vulnerable—including men who have sex with men, sex workers, people who inject drugs, individuals with multiple or concurrent sex partners, young women, and HIV serodiscordant couples—have contributed to stigmatization. These political and cultural aspects of HIV prevention must be acknowledged when assessing how donors, governments, civil society, communities, and individuals have addressed the epidemic.

OVERVIEW OF PEPFAR-SUPPORTED PREVENTION PROGRAMS

Programmatic Targets and Goals for HIV Prevention Over Time

The key programmatic target for prevention activities during the first phase of PEPFAR was to prevent 7 million new infections worldwide (OGAC, 2004b). In the 2008 reauthorization legislation, this target was increased to preventing 12 million new infections by 2013, and the goal was added of providing "at least 80 percent of the target population with access to counseling, testing, and treatment" for PMTCT.[2]

History of PEPFAR Funding for Prevention

Figure 5-1 depicts the amount of planned or approved funding for PEPFAR's prevention activities, not including counseling and testing, from FY 2005-FY 2011, disaggregated by PMTCT and all other prevention activities combined. Publicly available funding data do not

[2] *Supra*. Note 1 at § 301(b), 22 U.S.C. 2151b-2(b)(1)(A)(i) and (iv).

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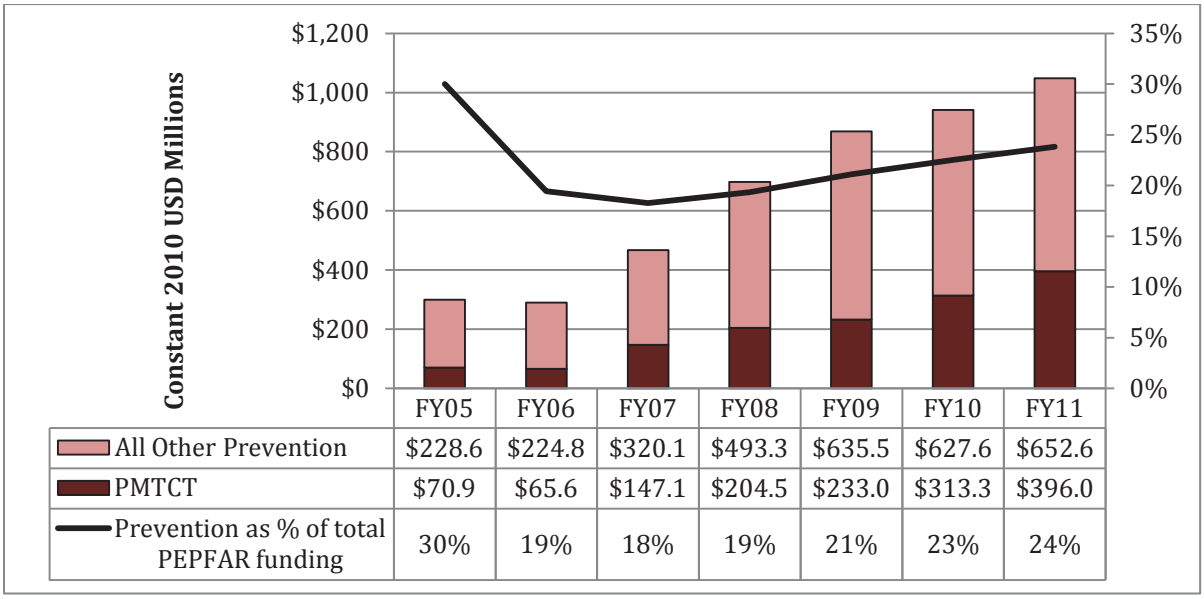
provide any disaggregation of spending within prevention modalities, for example, how much is spent on activities, procurement of supplies, workforce training, infrastructure, etc. The aggregate dollar amount of funding for these prevention activities has increased each year. The proportion of funds spent on prevention relative to total PEPFAR funding was highest in FY 2005 at 30 percent, and then declined for 2 years, followed by a steady increase from 18 percent in FY 2007 to 24 percent in FY 2011.



	FY05	FY06	FY07	FY08	FY09	FY10	FY11
All Other Prevention	$228.6	$224.8	$320.1	$493.3	$635.5	$627.6	$652.6
PMTCT	$70.9	$65.6	$147.1	$204.5	$233.0	$313.3	$396.0
Prevention as % of total PEPFAR funding	30%	19%	18%	19%	21%	23%	24%

FIGURE 5-1 PEPFAR's planned/approved funding over time for prevention (FY 2005-FY 2011).
NOTE: This figure represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by programmatic area (see Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding). Data are presented in constant 2010 USD for comparison over time. These data represent planned/approved funding for the Prevention budget codes for PMTCT and All Other Prevention. In this graph, "All Other Prevention" includes funding for Abstinence & Be Faithful, Other Sexual Prevention, Blood Safety, Injection Safety, Male Circumcision, and Injecting & non-Injecting Drug Use budget codes (Male Circumcision and Injecting & non-Injecting Drug Use were not reported as unique budget codes until FY 2009; prior to FY 2009 they were included in a budget code labeled "Other Prevention.") Funding for Counseling and Testing is not included in Prevention here (this differs from the presentations in Chapter 4). The funding data for the Counseling and Testing budget code, which was included first in the Care technical area and since 2009 in the Prevention technical area, is presented independently in Chapter 6.
SOURCE: (OGAC, 2005b, 2006c, 2007c, 2008c, 2010d, 2011f, g).

The 2003 authorizing legislation included a prevention funding allocation requirement which required that not less than 33 percent of PEPFAR prevention funds be spent on programs promoting abstinence until marriage,[3] which PEPFAR interpreted as including programs addressing both abstinence and being faithful within a monogamous relationship (later

[3] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong., 1st sess. (May 27, 2003), § 402 (b)(3).

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commonly referred to as "AB") (Ryan et al., 2012). Early in the implementation of PEPFAR, frustration was expressed by PEPFAR headquarters (HQ), mission teams, and other stakeholders about the rigidity of budget allocations that explicitly required a certain proportion of expenditures on abstinence and be faithful activities, which limited PEPFAR's ability to tailor activities to respond to country epidemiological information and to align with national AIDS plans (GAO, 2006; IOM, 2007a). The 2007 IOM committee recommended that these not be legislative requirements (IOM, 2007a) and the earmark was removed in the 2008 reauthorization legislation. The requirement was amended to state that prevention program portfolios should include a balanced funding approach within their prevention of sexual transmission activities.[4] Additionally, in countries with generalized epidemics, a justification was required if programs promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction constituted less than 50 percent of funds spent of prevention of sexual transmission.[5]

Evolution of PEPFAR Prevention Programming

As the evolution in HIV prevention science has occurred, PEPFAR's programming has shifted, from an initial focus on a limited number of behavioral and biomedical interventions, to an expansion of its prevention portfolio to include new, evidence-based biomedical, behavioral, and structural approaches. When PEPFAR began in 2004, its prevention programs built on existing U.S. government (USG) activities focused on the prevention of mother-to-child transmission (PMTCT) and expanded to include blood and medical injection safety, as well as behavior change strategies in line with the "Abstinence, Be faithful, and correct and consistent Condom use" approach (also known as "ABC") (OGAC, 2004b). While PMTCT remains a central pillar of prevention programming, the PEPFAR portfolio has since broadened to include a more diverse array of strategies for people vulnerable to sexual and drug-use-related HIV transmission. This includes the incorporation of strategies for which evidence emerged or for which evidence existed but had not yet been adopted or scaled up by PEPFAR, such as voluntary medical male circumcision, promoting use of female condoms, and harm reduction programs. In line with the global HIV prevention movement, PEPFAR now supports a combination prevention strategy, which it defines as

> HIV prevention using a suite of mutually reinforcing interventions to address the risks of transmission and acquisition as thoroughly and strategically as possible. It is predicated on the idea that no single intervention is efficacious enough to bring an HIV epidemic under control on its own, but that the optimal set of interventions implemented with quality and to scale can significantly reduce HIV incidence. (OGAC, 2011a, p. 7)

This process of evolution in PEPFAR's support for prevention programs, which has been occurring much more slowly than many in the public health community would like, reflects the difficulties of implementing these programs, which, more than care and treatment, intersect with a particularly sensitive context globally, domestically in the United States, and in partner countries. This affects both general programming for the prevention of sexual transmission and

[4] *Supra*. Note 1 at § 403, 22 U.S.C 7673(a)(1)(A).
[5] *Supra*. Note 1 at § 403, 22 U.S.C 7673(a)(2)(B).

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even more so, programming to meet the prevention needs of marginalized populations at elevated risk for HIV infection. As one stakeholder interviewed for this evaluation noted:

> *"I think one of the great challenges for PEPFAR has been on the one hand, professing to be evidence driven and interested in best practice and standards for HIV prevention treatment and care and at the same time, being constrained by the very real political realities of the US where both sex work and injection drug use have been identified as things that the US should not be funding."*[6]
> (NCV-24-USNGO)[7]

A more in-depth discussion of the evolution of PEPFAR's activities within specific areas of HIV prevention programming is provided in subsequent sections of this chapter. The IOM committee chose to focus on three components of PEPFAR's prevention programming for its primary analysis: prevention of sexual transmission, including prevention with people who engage in sex work and prevention with men who have sex with men; prevention of mother-to-child transmission; and prevention of HIV transmission among people who inject drugs. These were selected because they correspond to the greater share of HIV transmission; comprise the majority of PEPFAR's prevention efforts, accounting for 58 to 70 percent of the program's prevention spending from FY 2005-FY 2011 (OGAC, 2005b, 2006c, 2007c, 2008c, 2010d, 2011f, g); and were a reasonable and feasible focus given the time and resource limitations for this evaluation. Additionally, these three components allowed the committee to evaluate PEPFAR's prevention activities over time across the broadest possible range of countries, populations, and epidemic types. The remaining PEPFAR prevention program components are also addressed briefly, but, because the committee did not conduct an extensive analysis of these activities, no conclusions were drawn in these areas.

PREVENTION OF SEXUAL TRANSMISSION

Background

More than 85 percent of new HIV infections are estimated to be sexually acquired (Abdool Karim et al., 2007; Gouws et al., 2006). As such, the prevention of sexual transmission of HIV infection among both heterosexuals and men who have sex with men (MSM) (including

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[6] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

[7] Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Non-country Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO

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sexually active people who inject drugs) is critical to bringing the epidemic under control and has been a primary focus of global prevention efforts.

Early in the HIV/AIDS response in the United States, rigorously tested behavioral change intervention models in areas of health that pre-dated HIV/AIDS were adapted to develop HIV interventions (FHI 360, 2004; National Cancer Institute, 2005). These models focused on an individual's conceptualization of and action on health-related beliefs and behaviors that are relevant to transmissible diseases, such as HIV. Behavior change strategies have continued to be expanded and refined—particularly with respect to focusing on specific populations. Predominant strategies that have been used over time to increase male condom use, reduce number of sex partners, and, for young people, delay onset of sexual activity, include individual and group behavioral change interventions, social marketing techniques, and mass media-based communications campaigns.

Today, the modalities available for the prevention of sexual transmission are varied and expanding, and most contain a mixture of biomedical and behavioral elements. The quantity and type of evidence available for each prevention modality varies substantially, ranging from interventions having multiple scientific studies demonstrating efficacy and population level impact, to interventions based on established theory or observational data only. This was illustrated by a recent review of prevention interventions in generalized epidemics conducted as part of a consultation for the World Bank, the United Nations Population Fund (UNFPA), and UNAIDS by Hearst and colleagues (Hearst et al., 2012). Hearst et al. found that voluntary medical male circumcision and interventions designed for identifiable sex worker populations have the most robustly documented evidence base within generalized epidemics. For behavior change activities designed to reduce multiple concurrent partnerships, observed changes in sexual behavior have been followed by declines in HIV transmission in several countries (Hearst et al., 2012); however, several randomized clinical trials of behavior change interventions to reduce sexual risk behaviors have not yet been able to replicate this effect (Corbett et al., 2007; Cowan et al., 2010; Gregson et al., 2007; Jewkes et al., 2008; Kamali et al., 2003; Pronyk et al., 2006; Ross et al., 2007). The efficacy of correct and consistent male and female condom use is well-proven, but the effectiveness of condom promotion and distribution campaigns has yet to be established in a real world context (Hearst et al., 2012). Finally, for other interventions, especially structural efforts and new biomedical tools such as microbicides and prevention benefits of antiretroviral therapy, evidence for potential effectiveness is emerging and ongoing data collection is under way. The committee's analysis of the implication of these gaps in knowledge regarding the prevention of sexual transmission and the pressing need to address them is presented in the section on the Analysis of Prevention Impact later in this chapter.

In addition to the varying levels of evidence for intervention approaches, there has also been large variation across countries and populations in the extent to which prevention of sexual transmission strategies have been adopted. For example, UNAIDS estimated that in 2011 there were nine male condoms for each male aged 15-49 in sub-Saharan Africa purchased with donor support, and 2 billion condoms were procured by low- and middle- income countries in 2010; however, this is far short of the 13 billion condoms estimated to be needed by 2013 (UNAIDS, 2012b). There is very little known about the coverage of individual and mass media behavior change education programming, but in 26 countries with generalized epidemics reporting to UNAIDS, less than half of all women reported comprehensive knowledge of HIV transmission and prevention (UNAIDS, 2012b). Only 13 countries have established national targets for

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voluntary medical male circumcision, and, of these, ten had achieved 20 percent or less of their goal by 2011 (UNAIDS, 2012b).

PEPFAR's Prevention of Sexual Transmission Efforts

Initially, PEPFAR efforts and activities to prevent sexual transmission focused on the promotion of behavior change interventions. The 2003 PEPFAR authorizing legislation highlighted the "ABC model"—Abstinence, Be faithful, and correct and consistent Condom use—as a successful approach to prevention of sexual transmission of HIV.[8] It instructed PEPFAR to support "programs and efforts that are designed or intended to impart knowledge with the exclusive purpose of helping individuals avoid behaviors that place them at risk of HIV infection" which included delay of sexual debut, fidelity and monogamy, abstinence, reduction of casual sexual partnering, and condoms.[9] The 2008 reauthorization legislation expanded the scope of program activities, incorporating additional approaches, such as health education for serodiscordant couples, and structural interventions to address sexual transmission risk from vulnerabilities related to gender and age.[10]

In addition to the legislative directives, PEPFAR's portfolio of HIV prevention activities is also driven by guidance documents—directives specifying what can and should be supported with PEPFAR resources—that are fundamental to operationalizing programmatic targets and goals. A general discussion on the role of Office of the U.S. Global AIDS Coordinator (OGAC) in issuing PEPFAR guidance can be found in Chapter 3. For the purposes of this chapter, the following sections include a brief review of the guidance for the prevention of sexual transmission issued by OGAC over time and provide a reflection of how PEPFAR-supported activities have evolved.

PEPFAR Guidance for the Prevention of Sexual Transmission

In 2005, PEPFAR released *ABC Guidance #1*. With respect to the relative role and incorporation of the different elements of the ABC approach in its prevention program, the guidance stated that, "Emergency Plan funds may be used for abstinence and/or be faithful programs that are implemented on a stand-alone basis. For programs that include a 'C' component, information about the correct and consistent use of condoms must be coupled with information about abstinence as the only 100 percent effective method of eliminating risk of HIV infection; and the importance of HIV counseling and testing, partner reduction, and mutual faithfulness as methods of risk reduction" (OGAC, 2005a, p. 5). A distinction was made between youth (aged 10-14 years), for whom only AB programs were appropriate, and older youth (14+ years), for whom a combination of ABC could be permitted. PEPFAR funds were not allowed for the distribution or marketing of condoms in schools. The *ABC Guidance #1* called special attention to specific populations that include "sex workers and their clients, sexually active discordant couples or couples with unknown HIV status, substance abusers, mobile male populations, men who have sex with men, people living with HIV/AIDS, and those who have sex with an HIV-positive partner or one whose status is unknown," and encouraged a range of interventions related to counseling, testing, and behavior change approaches be used for these populations (OGAC, 2005a, p. 8).

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[8] *Supra*. Note 3 at §2(20)(c).
[9] *Supra*. Note 3 at §301(a)(2), 22 U.S.C. 2151b(d)(1)(A).
[10] *Supra*. Note 1 at §101(a) 22 U.S.C. 7611(a)(12)(A-J).

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Six years later, in 2011, OGAC released its *Guidance for the Prevention of Sexually Transmitted HIV Infections* (OGAC, 2011a). This was the first comprehensive prevention guidance related to sexual transmission released since *ABC Guidance #1*. In the document, PEPFAR endorsed combination prevention for all country programs, and reorganized the categorical divisions within prevention of sexual transmission from the original ABC organization to biomedical and behavioral interventions, structural supports, and prevention for specific populations. Biomedical interventions include the provision and promotion of male and female condoms; voluntary medical male circumcision (VMMC); HIV counseling and testing; diagnosis and treatment of sexually transmitted infections; antiretroviral drug-based prevention for post-exposure prophylaxis, and, in keeping with country guidelines, offering antiretroviral therapy to HIV-positive partners who are in known serodiscordant relationships and have CD4 counts of 350/mm^3 or lower. Behavioral interventions include stand alone behavioral interventions to minimize risk or increase protection; and supportive behavioral interventions to optimize biomedical prevention. Structural supports include legal and policy reform. Prevention packages for specific populations include comprehensive prevention for populations at elevated risk of HIV infection; positive health, dignity and prevention for PLHIV; and prevention interventions for young people (OGAC, 2011a).

One challenge in implementing prevention programs for specific populations is that occasionally there is a lack of agreement among the range of stakeholders involved in the response about which populations are at elevated risk in a country or how they should be prioritized for intervention (204-9-USG; 331-5-ML; 587-3-USG; 166-5-USG)—even with the newly released guidance and considerations for a given country or setting. Although PEPFAR indicators specifically mention people who inject drugs, MSM, and sex workers (OGAC, 2009c), in some countries these categories are not sufficient to capture all the populations understood or demonstrated to be at risk and in need of targeted prevention services; examples of other populations include HIV serodiscordant couples (including those desiring family planning), clients of sex workers, truckers, young women, transgender persons (especially those who engage in sex work), and non-injecting substance abusers (including those who abuse alcohol).

Overall, the difference between the updated guidance on prevention of sexual transmission and the *ABC Guidance #1* represents notable progress, providing a more transparent and detailed technical articulation of the strength of the scientific evidence supporting each HIV prevention method and the rationale for suggesting program implementation measures. In addition, it takes a more operational approach and is less proscriptive and more amenable to contextualization for different country programs.

PEPFAR-Supported Activities for the Prevention of Sexual Transmission

Since its inception in 2003, PEPFAR has supported the scale-up of a broad range of interventions designed to prevent sexual transmission of HIV. The types of activities that PEPFAR has supported over time for the prevention of sexual transmission are described here and summarized in Table 5-1. Across PEPFAR programs, supported interventions have always included behavior change communication activities, mass media campaigns, and condom distribution (OGAC, 2005a). As described above, an initial focus of behavior change activities on messaging that promotes abstinence and partner faithfulness has substantially broadened to include more tailored and comprehensive risk-reduction counseling and outreach approaches, as well as biomedical and structural interventions (OGAC, 2005a, 2009b, 2011a). The promotion and distribution of condoms and condom-compatible lubricants continues to be a core element of

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PEPFAR's prevention portfolio across countries and epidemic types, especially for populations at elevated risk of HIV acquisition (OGAC, 2005a, 2009b). More recently, greater emphasis has been placed on addressing structural barriers to prevention of sexual transmission and creating a supportive and enabling environment for individuals to access prevention services (OGAC, 2009b). PEPFAR also supports prevention activities for specific populations at elevated risk, including men who have sex with men, sex workers, and people who inject drugs and their sexual partners (more information on these activities can be found in the relevant sections that follow within this chapter and in Chapter 8, Gender (OGAC, 2009b).

TABLE 5-1 Interventions included in PEPFAR guidance over time for prevention of sexual transmission of HIV

Biomedical	**Behavioral**	**Structural**
Provision of male and female condoms Treatment of sexually transmitted infections Antiretroviral-based prevention: Post Exposure Prophylaxis for occupational exposure and survivors of sexual assault Voluntary medical male circumcision (since 2009) Antiretroviral-based prevention: Treatment for HIV-positive partners who are in known discordant relationships and have CD4 counts of 350/mm3 or lower (included in prevention since 2011) HIV testing and counseling (included in prevention since 2009)	Mass media communication Community interventions Interpersonal communication *Focal topics:* • Correct and consistent condom use • Multiple concurrent partnerships • Intergenerational and transactional sex • Abstinence and age of sexual debut • Alcohol use • Creating demand for prevention services • VMMC client education • Antiretroviral therapy adherence and education	Reducing stigma and discrimination against PLHIV and marginalized populations Gender inequality and gender-based violence (GBV) Economic empowerment and other multi-sectoral approaches Linkages to HIV and non-HIV health care and treatment services, as well as to non-health services (e.g. legal services) Education

NOTE: Interventions are categorized as described in PEPFAR guidance documents.
SOURCE: (OGAC, 2005a, 2007a, 2009b, 2011a).

The interventions included as a part of PEPFAR's prevention programming have changed over time, in part because the field of prevention science continues to evolve. The need to adapt to and incorporate emerging prevention evidence into program planning, guidance, and implementation is an important challenge and an ongoing process. One example of this process has been PEPFAR's response to the discovery of the prevention benefit of voluntary medical male circumcision, described in Box 5-1.

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BOX 5-1
PEPFAR's Adoption and Scale up of Voluntary Medical Male Circumcision

In 2007, the outcomes of three randomized control trials indicated that voluntary medical male circumcision reduced men's risk of HIV acquisition by 50 to 60 percent (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007). Follow-up of participants at up to 5 years post-trial indicated that the protective effect increased to 68 percent (Kong et al., 2011). This emerging evidence on the effectiveness of VMMC led, in PEPFAR II, to the adoption of this intervention as part of the prevention portfolio and to the scale up of delivery of VMMC.

Following the publication of these study results, PEPFAR initiated an effort to actively incorporate VMMC into its prevention guidance and into the portfolios of partner countries where this intervention would be appropriate, primarily those with high-prevalence generalized HIV epidemics. The U.S. government's commitment to the scale-up of VMMC began with the 2008 Reauthorization Legislation where it was endorsed as a crucial emerging prevention approach.[11] In 2009 PEPFAR introduced a separate budget code within its prevention funding categories designated specifically for programming on VMMC (OGAC, 2008a). In 2011, voluntary medical male circumcision was included as one of the many methodologies that should be used as part of a combination prevention approach in PEPFAR's newly released guidance on the prevention of sexual transmission of HIV (OGAC, 2011a).

PEPFAR-supported activities for VMMC are underway, and implementation scale-up has already begun in some locations. In FY 2009, 14 countries reported budgets for VMMC, totaling $34.9 million. In FY 2011, the number of countries with a VMMC budget was still 14, but the total amount of funding planned was $86.9 million, an increase of almost 250 percent in just 2 years (OGAC, 2010d, 2011f, g).

Interviewees described efforts across partner countries to incorporate VMMC into their prevention portfolios and scale up services (196-12-PCGOV; 116-4-USG; 116-12-PCNGO; 166-4-USG; 272-12-USNGO; 272-17-USG; 272-25-USG; 461-3-USG; 461-8-PCGOV; 934-10-PCGOV). However, these efforts were not without challenges, with a significant one being the process of working to secure the support of partner governments, which was seen as an important step, but could sometimes result in delays (636-16-USG; 116-2-USG; 461-7-PCNGO; 461-13-USACA). Multiple interviewees also highlighted the need to incorporate communication and behavior change activities into VMMC interventions (636-6-USG; 272-12-USNGO; 934-12-CCM).

In addition to these challenges, one important additional limitation to note with respect to the role of VMMC in prevention portfolios is that any HIV prevention benefit for women is at best indirect, resulting from the number of HIV-positive men in the population decreasing over time. There is not yet evidence that among serodiscordant couples circumcision reduces the transmission rate from men to their uninfected female partners (Turner et al., 2007; Wawer et al., 2009).

Although challenges and limitations remain, the roll-out and scale-up of VMMC represents an example of PEPFAR's adaptation to the evolving scientific evidence-base and contains lessons for the program as it incorporates new technologies in the future.

SOURCES: (Auvert et al., 2005; Bailey et al., 2007; Gray et al., 2007; Kong et al., 2011; OGAC, 2008a, 2010d, 2011a, 2011f, 2011g; Turner et al., 2007; Wawer et al., 2009).

[11] *Supra*. Note 1 at §101(a) 22 U.S.C. 7611(a)(14)(A).

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At the level of country programs, the specific portfolio or combination of interventions supported and implemented has varied. A review of annual PEPFAR Country Operational Plans from the countries selected for visits for this evaluation revealed that in most countries, there has been at least one activity supported within each of the modalities listed above. Interviewees in nearly all countries visited described implementation of a broad array of prevention of sexual transmission interventions. A few examples of activities described include media campaigns (166-5-USG; 272-18-PCNGO; 461-10-PCNGO; 461-14-USG), the use of peer educators (331-7-PCNGO; 166-5-USG), increasing the availability of condoms (116-4-USG), community organizing for public health messaging (166-23-USG), school- and sports- based youth programs (272-15-PCNGO), building government capacity to address prevention (272-12-USNGO), and male circumcision (934-10-PCGOV). Indeed, the approach to prevention portfolios in PEPFAR country programs was sometimes diffuse; as one interviewee described, *'The prevention program initially was a 'go everywhere, do a lot of activities' kind of approach.'* (272-17-USG)

Effects of PEPFAR's Prevention of Sexual Transmission Efforts

The committee attempted an assessment of PEPFAR's activities for prevention of sexual transmission using program monitoring data reported annually to OGAC by partner country mission teams (for more information on programmatic reporting see Chapter 11, PEPFAR's Knowledge Management). Of the relevant data requested and received from OGAC, only two prevention indicators had data to document time trends (FY 2004-FY 2009) (OGAC, 2007b):

Indicator 2.1 Number of individuals reached through community outreach that promotes HIV/AIDS prevention through abstinence and/or being faithful

Indicator 5.2 Number of individuals reached through community outreach that promotes HIV/AIDS prevention through other behavior change beyond abstinence and/or being faithful.

In FY 2004 and FY 2005, the number of individuals reached annually with messages that promote HIV/AIDS prevention through abstinence or being faithful was about 24 million. Between FY 2006 and FY 2009, the number of individuals reached annually ranged between 38 and 46 million per fiscal year, an increase that is in part due to the increased number of countries receiving PEPFAR funding and reporting data related to this indicator.

TABLE 5-2 OGAC Indicator 2.1—Number of Individuals Reached Through Community Outreach That Promotes HIV/AIDS Prevention Through Abstinence and/or Being Faithful (in Millions)

	FY04	*FY05*	*FY06*	*FY07*	*FY08*	*FY09*
Total	24.0	24.9	44.9	45.8	38.4	41.4

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2).
SOURCE: Program monitoring indicators provided by OGAC.

Table 5-3 shows a large number of individuals have also been reached with messages regarding HIV/AIDS prevention through behavior change beyond abstinence and/or being faithful. With each successive year of PEPFAR implementation, the number of individuals reached with these messages increased, beginning with 12 million in FY 2004 and ending with

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36 million in FY 2009. Again, there was a large increase in the number of countries funded by PEPFAR and reporting program monitoring data between FY 2004 and FY 2006.

TABLE 5-3 OGAC Indicator 5.2—Number of Individuals Reached Through Community Outreach That Promotes HIV/AIDS Prevention Through Other Behavior Change Beyond Abstinence and/or Being Faithful (in Millions)

	FY04	*FY05*	*FY06*	*FY07*	*FY08*	*FY09*
Total	11.9	17.9	26.0	21.7	32.5	36.2

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2).
SOURCE: Program monitoring indicators provided by OGAC.

In 2009, PEPFAR introduced the Next Generation Indicators (NGIs). Many previous indicators were discontinued and some new program monitoring indicators introduced (the evolution of PEPFAR indicators is discussed in more depth in Chapter 11 on PEPFAR's knowledge management); the two process measures for behavior change activities described above were essentially maintained. There are currently six NGIs, listed in Box 5-2, that attempt to monitor PEPFAR efforts related to prevention of sexual transmission of HIV (OGAC, 2009c). Mission teams began reporting data on these indicators in FY 2010; therefore, longitudinal data to assess PEPFAR's impact using these indicators were not available to the committee.

BOX 5-2
Centrally Reported Next Generation Indicators for Prevention of Sexual Transmission

P8.1.D Number of targeted population reached with individual and/or small group level preventive interventions that are based on evidence and/or meet the minimum standards required.

P8.2.D Number of the targeted population reached with individual and/or small group level preventive interventions that are primarily focused on abstinence and/or being faithful, and are based on evidence and/or meet the minimum standards required

P8.3.D Number of Most-At-Risk Persons reached with individual and/or small group level interventions that are based on evidence and/or meet the minimum standards required

- Disaggregated by population: commercial sex workers, people who inject drugs, men who have sex with men

P5.1.D Number of males circumcised as part of the minimum package of male circumcision for HIV prevention services

- Disaggregated by age: <1, 1-14, 15+

P6.1.D Number of persons provided with post-exposure prophylaxis (PEP)

- Disaggregated by exposure type: Occupational, Rape/Sexual Assault Victims, or Other Non-Occupational

P7.1.D Number of persons living with HIV/AIDS (PLHIV) reached with a minimum package of Prevention with PLHIV (PWP) interventions.

SOURCE: (OGAC, 2009c).

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In addition to the available indicator data, interviewees in countries described some observed successes in the area of prevention of sexual transmission efforts, which they attributed at least in part to the work of PEPFAR. These included a perceived reduction in prevalence (240-3-USG; 331-6-CCM; 272-5-PCGOV; 461-8-PCGOV), a delay in the age of sexual debut for youth (461-8-PCGOV), and increased rates of condom use among youth (272-1-USG) and in the general population (272-5-PCGOV). Output successes were also reported, such as the distribution of large numbers of free condoms (240-9-USG; 240-29-USNGO) and increased awareness of HIV risk prevention (240-35-PCNGO).

Data Limitations for the Assessment of Prevention of Sexual Transmission

While the annual increases in the number of individuals reached by each type of outreach activity are notable, the two process measures presented in Tables 5-2 and 5-3 are not sufficient to provide PEPFAR with an understanding of its programming in this area. These process indicators do not serve to contribute to an overall understanding of the impact of PEPFAR's prevention activities on incidence or infections averted (this is also discussed in greater detail later in the chapter, in the section on analysis of prevention impact). For example, for behavior change interventions, it is not possible through these indicators to assess whether the activities were associated with individual behavior change and risk reduction outcomes. To better understand the effectiveness of its programs for behavior change to prevent sexual transmission, PEPFAR will require more information on the populations in need and a clearer approach to assessing the link between having been reached by a prevention message and resultant change in sexual risk behavior.

Stakeholders interviewed by the evaluation committee echoed this assessment. Although interviewees recognized PEPFAR's support for a range of activities for the prevention of sexual transmission and noted some achievements in this area, many interviewees emphasized that the current PEPFAR prevention indicators do not capture the efforts and outcomes of prevention well, including changes in behavior (587-12-USG; 166-12-USG; 166-23-USG; 461-14-USG; 396-15-USNGO; 935-17-USG). Interviewees highlighted a lack of data available for prevention programming, both in terms of understanding the current epidemic in their country and tracking the outcomes of prevention programs (240; 587; 166; 272-6-ML). One interview described, for example, that '*what little data the country does have on condoms is not being used*' (272-06-ML). However, some interviewees highlighted achievements in the use of data. For example, one participant cited as progress '*transitioning from an emergency, scaled-up approach using general knowledge/awareness focus with little data, to targeting prevention strategies that are informed by data*' (587-12-USG). Interviewees identified several data collection activities that were underway to support these decision-making efforts, and a number of these were supported by PEPFAR (240-08-USG; 587-05-PCGOV; 196-12-PCGOV; 166-05-USG):

> *"PEPFAR-funded programs play a critical role in [this country] being able to report on UNGASS*[12] *and other groups. Especially when it comes to prevention"* (587-25-ML).

Conclusion: Because of a lack of systematically collected information on activities, outputs, and outcomes, PEPFAR is unable to adequately track the implementation of

[12] The UNGASS indicators are a set of national measures (currently 25) used following the 2001 United Nations General Assembly Special Session (UNGASS) on HIV/AIDS to track global progress toward addressing the HIV epidemic. The indicators are typically reported on biannually to UNAIDS (UNAIDS, 2010).

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prevention of sexual transmission, one of the most important components of its prevention programming. The committee was unable to assess the effectiveness or determine the outcomes or impact of PEPFAR's efforts across partner countries to reduce sexually transmitted HIV infections.

Despite the widespread adoption of interventions for the prevention of sexual transmission, outcomes for HIV prevention are inherently difficult to measure. Indeed, there is not clarity in the global community on how to routinely track their implementation and effects, especially for structural interventions, behavior change, and combination prevention. The lack of measurable effects has led to skepticism about the effectiveness of these approaches. For example, several large-scale trials in sub-Saharan Africa addressing the management of STIs, voluntary counseling and testing, individual and community education, intimate partner violence, condom distribution, income generating activities, and combination approaches have had mixed results. While several of these studies recorded significant effects on knowledge and behavior, all failed to detect significant changes in HIV incidence in their respective settings (Corbett et al., 2007; Cowan et al., 2010; Gregson et al., 2007; Jewkes et al., 2008; Kamali et al., 2003; Pronyk et al., 2006; Ross et al., 2007). However, the methodological design of these trials may have limited their ability to demonstrate outcomes because randomized controlled designs may be both unrealistic and inappropriate to evaluate the effectiveness of structural, behavioral, and combination prevention approaches (Laga et al., 2012; Stephenson and Cowan, 2003). Alternative evaluation designs exist, including large-scale cohort studies, non-randomized and quasi-experimental plausibility approaches, and evaluations triangulating across multiple methodologies (Gupta et al., 2008; Laga et al., 2012). PEPFAR's use of these approaches for monitoring, evaluating, and reporting on its non-biomedical prevention efforts is limited. PEPFAR is currently supporting several trials on the effectiveness of combination prevention approaches that address multiple modes of HIV transmission; with respect to sexual transmission, these include biomedical and some limited behavioral interventions (NCV-31-USG) (Essex and DeGruttola, 2012; Kerrigan and Sweat, 2012). While these trials will be an important contribution to the knowledge base and to future program planning, they will not be sufficient to address this fundamental knowledge gap.

Although there is strong foundational knowledge to support the principles and the design of behavioral and structural interventions, persistent gaps in the field include a lack of knowledge on what the appropriate measures are for meaningfully tracking scale-up and coverage of these interventions; a lack of established and agreed-upon behavior change outcome measures and proxy outcome measures; an insufficient understanding of the effectiveness of these interventions when implemented at scale in producing changes in outcomes; and a lack of knowledge of how the rates of change in behavioral and proxy outcomes are associated with rates of change in HIV transmission. However, the challenges of measuring the effects of these interventions and the limited availability of research using appropriately matched methodologies do not mean that they are inherently ineffective. Rather, it is an indication that there is a substantial knowledge gap in this area relative to biomedical prevention modalities, both within PEPFAR and in the greater global health community. This important need was illustrated by the perspective of one interviewee: '*Behavioral interventions cannot be proven as easily. This is also a challenge for scientists to determine how to prove behavioral interventions work*' (272-12-USNGO).

This is an area in which PEPFAR, given the scale of its programs and its commitment to implementation research, has the unique opportunity to contribute to much-needed ongoing

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research in developing and assessing behavioral and structural interventions, building on the methodological approaches that are currently available and in use and supporting innovation where needed. The principle of "know your epidemic, know your response" emphasizes the importance of a country program understanding and responding to the factors that contribute to the epidemic (UNAIDS, 2007). Given that sexual transmission is the primary global driver of HIV infection, effective interventions to address sexual transmission will need to be a central component of any comprehensive national response. Behavioral and structural drivers of the epidemic will not be addressed through biomedical approaches alone, and PEPFAR, along with the international HIV community, has emphasized that the most effective approach is likely to be a combination of interventions designed to reduce high-risk sexual behavior, efforts to modify the structural factors that lead to increased vulnerability, and the use of established and emerging biomedical tools (OGAC, 2011a; WHO, 2011). However, the evidence available for how to best identify, combine, implement, and scale up each of these intervention components is inadequate to guide the response at the global, national, and community levels. An evidence-based response requires responsiveness both to the currently available intervention effectiveness evidence and to the evidence on the epidemiological drivers and other contextual factors that affect the epidemic. Therefore, where intervention effectiveness is lacking for key drivers, efforts to fill that gap are by necessity a part of the response. If PEPFAR is to be able to support programs that are tailored appropriately and effectively to the varied contexts in which it operates, more effort will be needed to advance the field of HIV prevention science, especially for behavioral and structural interventions.

> **Conclusion:** Behavioral and structural interventions, especially those targeted at prevention of sexual transmission, are critical components of a balanced and comprehensive prevention portfolio. Yet, within PEPFAR, there is disproportionately less program monitoring data and rigorous research evidence available on these interventions than on PMTCT and other biomedical prevention programs. Improved monitoring, evaluation, and research methods appropriate to assessing behavioral and structural activities are needed by PEPFAR to enable both OGAC and country implementers to select the most effective interventions and programs and to assess their outcomes once implemented. There is a critical need for improved application of advances in social and behavioral science-based research and evaluation science for prevention to determine the most effective combination of prevention interventions in diverse country contexts. Given the scale of its programs and its commitment to implementation research, PEPFAR can contribute to a more effective HIV response by serving as a platform for innovation to fill the gap in knowledge and availability of effective interventions.

Sex Workers

Background

One population at elevated risk included within PEPFAR's prevention of sexual transmission efforts is people who engage in sex work. Sex work describes a wide range of activities depending on local context. It may be formal or informal, occasional, or a full-time occupation; sex work is sometimes more generically referred to as transactional sex. Sex

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workers may be female, male, or transgendered persons (United Nations Population Fund, 2001). While robust data on the number of persons engaging in sex work and the health status and other outcomes for these individuals are limited, disproportionately high HIV prevalence rates have been documented in persons engaging in sex work as compared to the general adult population in many countries (WHO, 2011).

PEPFAR-Supported Activities for Sex Workers

Legislation The legislation initially authorizing PEPFAR recognized that "the sex industry, the trafficking of individuals into such industry, and sexual violence are additional causes of and factors in the spread of the HIV/AIDS epidemic." [13] The authorizing legislation imposed a restriction on PEPFAR's programmatic activities in a sub-clause stating that "no funds made available to carry out this Act, or any amendment made by this Act, may be used to promote or advocate the legalization or practice of prostitution or sex trafficking"[14] nor "to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking." [15] However, the authorizing legislation also noted that the legislation should not "be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides."[16] The legislation also emphasized that in the required Five-Year Strategy, within prevention efforts a priority should be the reduction of behavioral risks for HIV, in part by "eradicating prostitution, the sex trade, rape, sexual assault and sexual exploitation of women and children." [17]

When PEPFAR was reauthorized in the Lantos-Hyde Act of 2008, the limitation on funds was preserved as previously written in the authorizing legislation. The requirement for a new Five-Year Strategy in the reauthorization specified that the strategy should "make the reduction of HIV/AIDS behavioral risks a priority of all prevention efforts"[18] in part by "educating men and boys about the risks of procuring sex commercially"[19] and by "supporting comprehensive programs to promote alternative livelihoods, safety, and social reintegration strategies for commercial sex workers and their families."[20] Another change in the reauthorization legislation, was an expansion of the list of specific duties of the U.S. Global AIDS Coordinator to include "working with partner countries in which the HIV/AIDS epidemic is prevalent among individuals involved in commercial sex acts to establish, as a national priority, national prevention programs, including education, voluntary testing, and counseling, and referral systems that link HIV/AIDS programs with programs to eradicate trafficking in persons and support alternatives to prostitution."[21]

The application of the law to U.S.-based organizations has been challenged in court, and, under the most recent ruling, the U.S. Second Circuit Court of Appeals held that the pledge requirement violates the First Amendment rights of the nongovernmental organizations that were

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[13] *Supra*. Note 3 at §2(23).
[14] *Supra*. Note 3 at §301(e).
[15] *Supra*. Note 3 at §301(f)
[16] *Supra*. Note 3 at §301(e)
[17] *Supra*. Note 3 at §101(a)(4).
[18] *Supra*. Note 1 at §101(a), 22 U.S.C. 7611(a)(12).
[19] *Supra*. Note 1 at §101(a), 22 U.S.C. 7611(a)(12)(F).
[20] *Supra*. Note 1 at §101(a), 22 U.S.C. 7611(a)(12)(G).
[21] *Supra*. Note 1 at §102(2)(F), 22 U.S.C. 2651(f)(2)(B)(ii)(XI).

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the plaintiffs (*Alliance for Open Society International v. U.S. Agency for International Development*, 2011). As a result, the government is currently prohibited from enforcing the pledge requirement against most U.S.-based recipients of PEPFAR funds.

A subsequent section will further discuss the consequences of the legislation's limitation on funding to organizations, which is often called the "anti-prostitution pledge" and has received strong criticism from global health advocates and some program implementers over concern that it restricts the funding for and provision of evidence-based HIV services and activities for men, women, and transgendered persons engaged in sex work.

Guidance PEPFAR does not issue specific programmatic guidance on activities for sex workers. PEPFAR supports activities for this population primarily within its prevention of sexual transmission portfolio, and sex workers are covered within the guidance documents previously described, as one of the populations to consider when implementing prevention interventions. In addition, although this population is not named explicitly in PEPFAR's documentation of its gender strategy (OGAC, 2012d), there is an increasingly articulated intersection with PEPFAR's gender-focused efforts and activities, as evidenced by the inclusion of sex workers in USAID's recent technical documents focused on integration of gender strategies into HIV programs for populations at elevated risk (USAID, 2011b) and on integrating multiple PEPFAR gender strategies to improve HIV interventions (USAID, 2011a).

It is also worth noting that in some partner country settings there are high rates of injecting drug use among sex workers, and there are efforts to provide them PEPFAR-supported services for people who inject drugs (injection drug use is discussed later in this chapter). In addition, individuals who engage in sex work who are HIV-positive are also in need of HIV care and treatment services, which in many partner countries are supported by PEPFAR. The USAID technical document on integrating gender strategies recommends providing comprehensive services to this population, emphasizing that "addressing the particular challenges sex workers face is essential to slowing the epidemic in many communities. Sex workers, regardless of the illegality of their work or status in a country, require comprehensive, stigma-free, and safe services. Moreover, comprehensive services should support, where possible, sex workers' access to alternative livelihoods." It notes that "few services such as HIV care and treatment, HIV testing and counseling, and legal protection are available" to sex workers and that "as a result, in many communities, both the supply of and demand for sex work play a significant and unchecked role in spreading the epidemic for all members of the community, including sex workers themselves, their male clients, the wives of these men, and the other partners of both men and women" (USAID, 2011a, p. 11).

Effects of PEPFAR-Supported Activities for Sex Workers

In nearly all PEPFAR partner countries visited interviewees identified female sex workers most frequently but, in some cases also men and transgendered persons, as important focus populations for the HIV response (240-09-USG; 331-07-PCNGO; 587-07-PCGOV; 196-08-ML; 116-01-USG; 166-05-USG). In many cases it was also emphasized that individuals could be a part of multiple populations at elevated risk; in particular, sex workers who also inject drugs and MSM who are engaged in sex work were identified as populations with distinct needs (240-09-USG; 331-07-PCNGO; 396-27-PCGOV; 396-37-USNGO; 196-25-PCNGO). In some cases it was described as a challenge to get all stakeholders, and in particular partner country governments, to recognize the vulnerability of sex workers as part of the HIV response and to garner the political will to include appropriate efforts

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for them. Some stakeholders preferred instead to focus on the general population or on children and youth (542-9-PCGOV; 587-ES; 166-5-USG).

Education activities and peer outreach targeted at sex workers were important components of PEPFAR's efforts; focusing on engaging with and educating pimps, brothel owners, clients, and other non-paying sexual partners was also emphasized as important (331-14-USG; 396-36-PCGOV; 196-10-PCGOV; 196-19-PCNGO; 196-24-PCNGO; 196-25-PCNGO; 542-9-PCGOV; 166-27-PCNGO). As one interviewee noted, '*most female sex workers now know about transmission and condoms but are not empowered to bargain for condom use*' (196-10-PCGOV). Multiple interviewees described efforts to improve sex worker's negotiation skills and empower them to request the use of condoms with their clients as well as to provide more general skills training and empowerment (196-23-PCNGO; 396-36-PCNGO; 587-21-PCNGO; 240-22-PCNGO). One challenge identified was that low-cost or free condoms are not sufficiently available or accessible (396-36-PCGOV; 196-06-USG). Program implementers were working to address this limitation in access to prevention services, such as one example, where condom distribution was brought closer to the brothels in which sex workers operated (196-06-USG). Another frequently noted challenge was that sex workers are highly mobile and often don't have stable housing, making consistent access to services difficult (196-24-PCNGO; 196-25-PCNGO).

Across countries, some successes were described as a result of the efforts of civil society organizations and other partners that work with sex workers, including sex workers who are now successfully negotiating condom use and have started buying condoms when free condoms are not available; interviewees also described seeing declining HIV prevalence and fewer deaths from HIV in sex worker communities (396-36-PCGOV; 396-37-USNGO; 196-19-PCNGO; 542-9-PCGOV). Several local civil society organizations, many that were established and run by sex workers, noted the positive role of PEPFAR in supporting and empowering them to provide assistance and services to sex workers as well as to engage with local governments and influence policy (396-8-PCNGO; 196-19-PCNGO; 196-24-PCNGO; 196-25-PCNGO). Operational challenges for civil society organizations, including limits in the opportunities available for civil society organizations to be funded through partner country government mechanisms was described as a difficulty; as a result, these organizations were entirely dependent on external donors or other sources of revenue (542-9-PCGOV; 196-10-PCGOV; 196-ES; 396-ES).

While activities for sex workers are organized under PEPFAR's prevention portfolio, individuals who engage in sex work also need other services, and PEPFAR-supported program implementers in several countries have been responsive to this through referrals, mobile testing clinics, building networks and relationships with facilities, and direct provision of health services to this population, including STI services, ART services, and PMTCT services (196-10-PCGOV; 196-19-PCNGO; 196-21-PCGOV; 196-24-PCGOV; 166-27-PCNGO), although unmet needs for reproductive health and STI services were also noted (396-36-PCGOV). Programs to offer vocational training and other income training activities for persons engaged in sex work to find alternate sources of income are also supported by PEPFAR; though, one challenge identified was providing these successfully enough to match even the very low income levels beneficiaries were able to derive from sex work (196-9-USNGO; 166-27-PCNGO; 935-16-USNGO; 166-27-PCNGO).

Interviewees across countries described stigma or discrimination against sex workers, leading to experiences such as harassment and violence and rejection by their families (587-21-PCNGO; 166-05-USG; 196-24-PCNGO; 542-9-PCGOV). Accessing health services was highlighted by interviewees in several countries as a key challenge for sex workers (196-9-USNGO; 587-21-PCNGO; 396-37-USNGO), and one reason given for this barrier was stigmatization, which made clients less likely to come in to a facility (587-21-PCNGO; 196-09-USNGO).

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One major challenge, not specific to PEPFAR, is that there is very little data on this population. As a result, it is difficult to determine whether their HIV prevention, treatment, and care needs are being adequately covered, and the lack of information was sometimes used a rationale for not supporting additional activities (396-24-USNGO; 636-6-USG). Interviewees lamented the lack of reliable population size estimates, and the high mobility of this population, in addition to discrimination and stigma, were noted as contributing to the limited availability of epidemiological data on sex workers in general and on sex workers with overlapping risk, particularly people who inject drugs and MSM (166-05-USG; 396-24-USNGO; 240-09-USG; 331-07-PCNGO; 396-37-USNGO). In some countries PEPFAR has supported or is supporting special studies or surveys to try to address this gap and to help target interventions and influence policy and planning for activities targeted to sex work as part of the response (196-24-USNGO; 935-16-USNGO; 542-9-PCGOV; 116-8-USG; 396-24-USNGO). Within PEPFAR there is also very little data. PEPFAR's program monitoring system includes few indicators that are relevant for supported activities for this population; none that are centrally reported to OGAC. There is also little available data on outcomes to assess the effectiveness of the activities supported by PEPFAR.

Interviewees described the previous requirement to allocate a specified proportion of prevention funding to "abstinence" and "be faithful" programs as a former limitation, and highlighted the inherent mismatch between an abstinence/be faithful approach and programs for individuals engaged in sex work (396-39-USG; NCV-24-USNGO). Interviewees acknowledged that the lifting of the required budgetary allocation earmark in the reauthorization legislation afforded country programs and implementing partners greater flexibility in planning prevention portfolios and providing programs for this population, whether as part of the effort to address the major drivers in a concentrated epidemic or as an important population to target for interventions and services within generalized epidemics (396-39-USG).

> **Conclusion:** There is recognition in PEPFAR of the important role of efforts for sex workers as a part of the national response in both concentrated and generalized epidemics. There are some examples of success as a result of PEPFAR-supported activities for this population, and increased flexibility for prevention programming with the elimination of the budget earmark for abstinence and be faithful programs in PEPFAR II has enabled country programs to more readily plan activities for sex workers.

Consequences of the Legislative Limitation on PEPFAR Funds

A major issue that is often raised in relation to PEPFAR's efforts for sex workers is the legislative limitation on providing funding to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.[22] Although PEPFAR has supported programs and partner organizations in efforts for sex workers, nonetheless there is concern that the legislative limitation on funding has been an impediment to PEPFAR's work on prevention of HIV transmission for this population (NCV-22-USNGO; NCV-24-USNGO). This committee's assessment was limited to the activities and efforts for sex workers that PEPFAR has funded, consistent with the congressional mandate to evaluate the "efforts that are supported by United States

[22] *Supra*. Note 3 at § 301(e).

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funding."[23] Therefore, although the committee recognized the important issues and concerns raised by the legislative limitation, given the entirety of the scope to be covered in this evaluation, it was not feasible to conduct the data gathering and analysis for the kind of complex, comprehensive assessment in policy, legal, stakeholder perspective, and health outcomes domains that would be needed to draw conclusions about the effects on the HIV response and HIV epidemic in partner countries of the legislative restriction and of what PEPFAR has not funded as a result.

Nonetheless, the committee reflects here in this report the concerns that have been expressed in the global health community, where there has been strong criticism of the legislation and the resulting implementation and enforcement of it through USAID and Department of Health and Human Services policies ((CHANGE), 2008; Brennan Center for Justice, 2012; Evertz, 2010; Law Students for Reproductive Justice, 2012; UNDP, 2012) Focusing on the public health effects of the legislative limitation, there is concern that the restriction has meant that organizations created by sex workers themselves, that could be providing services and are uniquely positioned to access this population, have been excluded from PEPFAR's efforts, as have activities to limit the severity of criminal penalties for sex workers, penalties that can interfere with HIV-related services and outcomes. These efforts have been restricted even though their inclusion would not necessitate a direct link to promoting the legalization of prostitution. This exclusion is seen by a range of stakeholders in the global health community as impeding access to HIV services for sex workers and as a missed opportunity for PEPFAR to more effectively contribute to the HIV response in partner countries and to the reduction of HIV transmission ((CHANGE), 2008; Brennan Center for Justice, 2012; Evertz, 2010; Law Students for Reproductive Justice, 2012; UNDP, 2012).

Men Who Have Sex with Men

Included within PEPFAR's prevention of sexual transmission efforts is another population that is at elevated risk and bears a disproportionate burden of HIV disease, men who have sex with men. HIV prevalence for men who have sex with men is significantly higher as compared to the general population in all regions of the world (Beyrer et al., 2012). There are several factors that contribute to the increased rate of HIV infection in MSM, including increased biological risk of HIV transmission via unprotected anal sex and behavioral risk factors and lack of access to services, both of which are compounded by stigma and discrimination, socio-cultural norms, and national laws and policies.

PEPFAR has supported some activities for this population since its inception. From 2004 to 2010, information on activities for HIV prevention with MSM was incorporated into overarching guidance documents and the annual Country Operational Plan guidance, where MSM were identified as one of many populations that may be at elevated risk of HIV acquisition through sexual transmission (OGAC, 2004a, 2005a, c, 2006b, 2007a, 2008b). In 2011, as a supplement to the updated prevention of sexual transmission guidance discussed previously, OGAC also released its *Technical Guidance on Combination HIV Prevention for Men who have Sex with Men* (OGAC, 2011e). This document articulated a new, six-part comprehensive prevention approach to be applied going forward: "community-based outreach; distribution of condoms and condom-compatible lubricants; HIV counseling and testing; active linkage to

[23] Supra. Note 1 at § 101(c), 22 U.S.C. 7611(c)(2)(A)(ii).

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health care and antiretroviral therapy; targeted information, education and communication; and sexually transmitted infection prevention, screening and treatment" (OGAC, 2011e, p. 1).

As noted above, there were no PEPFAR programmatic indicators required to monitor prevention of sexual transmission efforts specifically for MSM until 2010 when, as a part of the Next Generation Indicators process, a new required measure for the number of persons reached with individual and/or small group level interventions with disaggregation by population at elevated risk was introduced. As a result, longitudinal program monitoring data on activities and outputs for this population are not available.

Data from semi-structured interviewees provided insight into the types of prevention activities supported by PEPFAR for MSM and some of the effects of these activities. Multiple interviewees described general prevention efforts for MSM as components of their programs (240-9-USG; 331-14-USG; 331-18-USNGO; 166-5-USG; 396-5-USNGO), including activities to increase access for MSM to condoms (331-14-USG; 196-25-PCNGO), behavior change campaigns (331-14-USG; 166-5-USG), support prevention programs for male sex workers (196-25-PCNGO), and encouraging HIV testing and addressing stigma in local communities (331-07-PCNGO; 196-25-PCNGO). Across different types of services, the use of peer educators was highlighted as a key positive element of many MSM outreach activities (331-07-PCNGO; 331-14-USG; 166-5-USG; 196-25-PCNGO) as was PEPFAR support for local civil society and nongovernmental organizations working with this population (331-22-PCNGO; 331-32-PCNGO; 196-25-PCNGO).

One major challenge noted by interviewees is that there is also very little data on this population. Similar to its efforts for sex workers, PEPFAR has responded to this challenge in several countries where it has supported or is planning to support special studies, surveillance activities, and pilot studies to obtain better population size estimates and other country-specific information on MSM, as well as to increase attention to MSM in the planning and implementation of the national HIV response (331-ES; 240-ES; 396-ES; 196-ES; 240-09-USG; 166-5-USG; 396-09-PCGOV). For example, in Ghana, PEPFAR partnered with the University of California, San Francisco to support the Ghana Men's Study, and similar efforts are under consideration in Ethiopia (PEPFAR/Ethiopia, 2010; UCSF, 2012).

As with all populations at elevated risk, the needs of MSM cut across not only prevention programming but also other categories of services supported by PEPFAR including access to HIV care and treatment. A more comprehensive discussion of PEPFAR's support for policy, programs, and data collection for MSM can be found in Chapter 8, Gender. PEPFAR has recently included MSM in its comprehensive framing for addressing the role of gender in the HIV epidemic and response, emphasizing that "gender norms around masculinity and sexuality also put men who have sex with men (MSM) at increased risk for HIV by creating additional stigma and discrimination that can prevent them from seeking and accessing services" (OGAC, 2012d).

Conclusion: Over time, PEPFAR has increasingly supported data collection efforts and prevention programming for men who have sex with men, which PEPFAR has recently codified in programmatic guidance. Men who have sex with men are recognized as an important population for prevention and other PEPFAR-supported programming.

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PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

Background

UNICEF has estimated that of the 115 million annual births in low- and middle- income countries, approximately 1.5 million are to HIV-infected women (UNICEF, 2008b). It was estimated that in 2009, 370,000 infections in children were attributable to mother-to-child transmission, down from 500,000 in 2001 (UNAIDS, 2010).

In 1994, the results of the first clinical trial demonstrating that antiretrovirals, specifically zidovudine (AZT), could reduce mother-to-child transmission (MTCT) of HIV-1 became available (Connor et al., 1994). In 1998, UNICEF created 11 pilot programs using AZT for the prevention of mother-to-child transmission (UNICEF, 2008a), and by 1999 it was demonstrated that a single dose of nevirapine administered to a woman in labor and a single dose of nevirapine administered to the newborn could successfully diminish transmission of HIV-1 from women to their infants by approximately 47 percent (Guay et al., 1999). Around the same time, work supported by the U.S. Centers for Disease Control (CDC) in Thailand also demonstrated the efficacy of a short course of zidovudine for reducing HIV-1 MTCT (Shaffer et al., 1999). Implementation of the results of these trials marked the beginning of successful interruption of MTCT of HIV in developing countries, and in the 1990s, support from the private sector and nonprofit organizations led to some of the first PMTCT efforts in the developing world (Spensley et al., 2009).

In the United States, it was feasible to rapidly implement testing of pregnant women for HIV and utilize recommended ARVs beginning with AZT in l994. Data from the CDC (Figure 5-2) demonstrate the rapid decline in reported pediatric AIDS diagnoses attributable largely to the successful prevention of mother-to-child HIV-1 transmission (Centers for Disease Control and Prevention (CDC), 2012), with fewer than 200 cases per year of pediatric AIDS reported in the U.S. since 1999. This striking decline demonstrates that even with the earliest ARV regimens, it was possible to prevent most MTCT. Over time, PMTCT has been done more efficiently and safely, employing more complex antiretroviral regimens.

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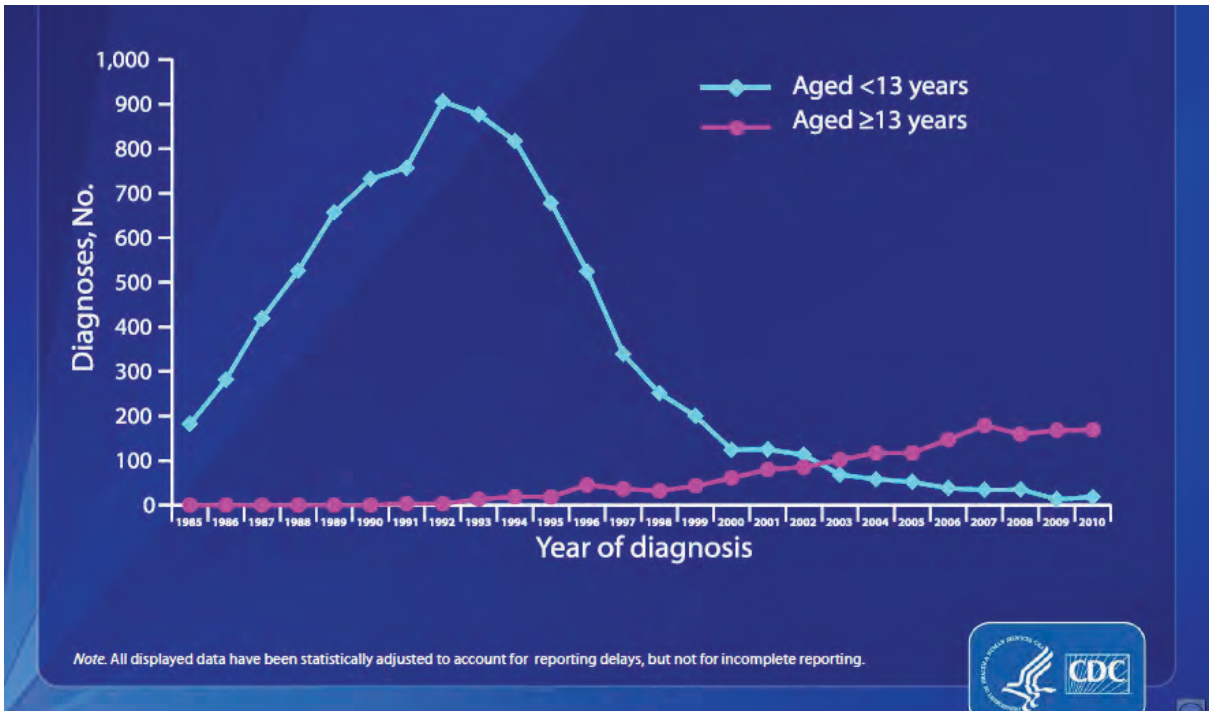

FIGURE 5-2 AIDS diagnoses among perinatally infected persons, 1985–2010, United States and six U.S. dependent areas.
SOURCE:(Centers for Disease Control and Prevention (CDC), 2012).

Randomized, controlled clinical trials have shown that, in the absence of any antiretrovirals, approximately 40 percent of infants born to HIV-positive mothers are infected with HIV (Nduati et al., 2000). Approximately 12 percent of HIV infection occurs prior to 36 weeks gestation, 29 percent from 36 weeks to delivery, 20 percent during delivery, and 39 percent postpartum when breast feeding occurs for 18-24 months (Kourtis et al., 2006); breast feeding is responsible for approximately one-third of all infant HIV infections. Antepartum, intrapartum, and postpartum regimens with AZT have all been shown to reduce transmission of HIV from mother to infant (Connor et al., 1994; Guay et al., 1999; Lallemant et al., 2000; Petra Study Team, 2002; Shaffer et al., 1999). Administration of a shorter antepartum course (4-6 weeks) is effective but less so than longer courses (Lallemant et al., 2000). When the antepartum course is shorter (4 weeks), the addition of AZT/3TC[24] increases effectiveness (Chaisilwattana et al., 2002; Chaix et al., 2004; Dabis et al., 2005; Mandelbrot et al., 2001). Adding single-dose nevirapine to short-course AZT improves efficacy in breast-fed and formula-fed infants (Chaix et al., 2004; Dabis et al., 2005; Moodley et al., 2003; Shapiro et al., 2006; Thior et al., 2006), and single dose nevirapine plus AZT has better efficacy than nevirapine alone (Taha et al., 2003; Taha et al., 2004). Either administration of antiretrovirals to the breast feeding infant or treatment of the HIV-infected mother can also greatly reduce transmission during breastfeeding (Chasela et al., 2010; Kumwenda et al., 2008; Six Week Extended-Dose Nevirapine Study et al., 2008).

[24] Zidovudine and lamivudine

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WHO Recommendations to Prevent MTCT of HIV

In 2010, WHO revised its 2006 recommendation for prevention of mother-to-child transmission and care of mothers (WHO, 2010a), increasing the CD4 count threshold of those who require antiretroviral therapy from <200/mm^3 to <350/mm^3 or clinical stages 3-4. The 2010 WHO PMTCT guidelines recommended that all infants born to women receiving ART should receive either AZT or nevirapine for 4-6 weeks and those mothers who do not need ART for their own health, should start ARV prophylaxis as early as 14 weeks of pregnancy, replacing the initiation at 28 weeks in the 2006 recommendations. The 2010 guidelines also recommended two options for prevention of mother-to-child transmission, Option A and Option B.[25] The guidelines placed the responsibility on national authorities to decide whether mothers should breastfeed and receive ARVs or avoid all breastfeeding with the goal of achieving maximum HIV-free survival for the child, not just the initial prevention of infection. When breastfeeding is the best option, it should be exclusive for the first 6 months and then continued with appropriate complementary foods until the infant is 12 months of age or older (WHO, 2010a). In 2012, the WHO released a programmatic update to its 2010 guidelines that included a new third option called option B+. Option B+ includes the same recommendations for prophylaxis but suggests that ARV treatment for women be continued beyond pregnancy regardless of CD4 count (WHO, 2012a).

PMTCT Coverage

UNAIDS has estimated that increasing coverage to 90 percent of HIV-positive women with WHO recommended regimens could decrease the number of children infected annually to fewer than 150,000 (WHO, 2011). PMTCT programs have expanded over time and are present in most low- and middle-income countries. A UNICEF cluster survey with respondents representing 81 million deliveries in 58 countries estimated that only 10 percent of the world's HIV-positive women had access to PMTCT services in 2004 (UNICEF, 2009). The subsequent scale-up in global resources contributed to an increase in PMTCT coverage, and in 2010 an estimated 35 percent of pregnant women in low- and middle-income countries received HIV testing and counseling, with coverage of counseling and testing for pregnant women increasing from an estimated 35 percent to 42 percent between 2009 and 2010 in sub-Saharan Africa (WHO, 2011). In 2009, an estimated 53 percent of pregnant women living with HIV in low-and-middle-income countries received antiretroviral medication to prevent mother-to-child transmission of HIV versus an estimated 45 percent in 2008 (WHO, 2010b).

There are few countries that have reached the international target of providing access to services for 80 percent of pregnant women articulated in the commitment document released following the 2001 UNGASS session (United Nations General Assembly, 2001). The challenges to reaching this goal include establishing services in health systems not optimally staffed and that

[25] Option A includes AZT antepartum, with nevirapine/AZT/3TC during labor and delivery. AZT/3TC should then be continued for 7 days postpartum. The infant, if breast fed, should receive nevirapine from birth until 1 week after exposure to breast milk has stopped. Non-breastfeeding infants should all receive either daily infant nevirapine or single dose nevirapine with AZT for 4-6 weeks.
Option B includes AZT/3TC/LPV/r or the substitution of A/B/C or EFV for LP/r starting from 14 weeks gestation until delivery or until 1 week after exposure to breast milk has stopped if breastfeeding. Alternatively TDF/3TC (or FTC)/EFV could be used. In Option B, all infants should receive NVP or AZT for 4-6 weeks.
In both Option A and B, women should be treated according to existing WHO guidelines for treatment initiation. (WHO, 2010a)

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experience a lot of turnover of trained personnel; ensuring a reliable supply chain for diagnostics and ARVs; and having the essential funds to support the necessary costs of implementation. The knowledge of how to virtually eliminate pediatric HIV transmitted from mother-to-child currently exists; the greatest gap is in providing access to services. Figure 5-3 illustrates the cascade of services that, if available and accessible to pregnant women, can maximize child HIV-free survival and improve maternal health (Stringer et al., 2008).

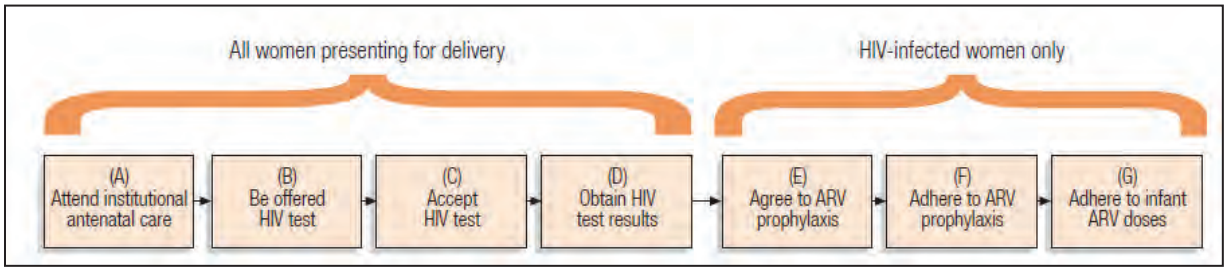

FIGURE 5-3 PMTCT cascade.
SOURCE: (Stringer et al., 2008). Used with permission.

PEPFAR's PMTCT Efforts

Building on the success of the MTCT initiative started by President Bush in 2002, the 2003 authorizing legislation emphasized that mother-to-child transmission of HIV was largely preventable and directed PEPFAR to support activities for this purpose,[26] with the aim of "meeting or exceeding the goal to reduce the rate of mother-to-child transmission of HIV by 20 percent by 2005 and by 50 percent by 2010."[27] In 2008, the reauthorizing legislation added the goal of helping "partner countries in the effort to achieve goals of 80 percent access to counseling, testing, and treatment"[28] for PMTCT. This is articulated with the aims of "reaching 80 percent of pregnant women for prevention and treatment of mother-to-child transmission of HIV in countries in which the United States is implementing HIV/AIDS programs by 2013" and promoting "infant feeding options and treatment protocols that meet the most recent criteria established by the World Health Organization."[29]

PEPFAR's PMTCT activities have evolved with the changing evidence base and PEPFAR has endorsed the adaptation of the updated 2010 WHO PMTCT guidelines described above into their programming (OGAC, 2011d). PEPFAR defers to the WHO normative guidelines and only issues its own PMTCT-specific operational guidance. Implementing partners implement option A or option B, and in some pilot sites, including several in Malawi, option B+ has been rolled out, with initial evaluations confirming the feasibility of implementing this approach in certain settings (Chirwa, et al., 2012; PEPFAR, 2012).

In the context of supporting the scale-up of PMTCT and pediatric HIV services, PEPFAR currently organizes its activities around addressing three distinct aims mandated by the reauthorization legislation: "a) support HIV testing and counseling for 80% of pregnant women

[26] *Supra*. Note 3 at §301(a)(2), 22 U.S.C. 2151(d)(1)(E).
[27] *Supra*. Note 3 at §312(b)(1).
[28] *Supra*. Note 1 at §101(a), 22 U.S.C. 7611(a)(4)(D)
[29] *Supra*. Note 1 at §301(c)(1)(E), 22 U.S.C. 2151b-2(d)(1)(F)(ii).

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in countries most affected by HIV/AIDS; b) support antiretrovirals (ARVs) for PMTCT and/or their own health as medically indicated for 85% of HIV-positive pregnant women in those countries; and c) ensure that the proportion of children receiving care and treatment meets their proportion of the HIV-infected individuals in each country" (OGAC, 2010b, p. 1). In order to accomplish these goals, PEPFAR not only supports efforts in partner countries but also works in concert with international partners, such as through its support of the UNICEF Inter-Agency Task Team and through PEPFAR's contribution to the 2011 *Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive* (OGAC, 2011d). The centrality of PMTCT activities to PEPFAR's overall prevention programming was reinforced as part of the recent "AIDS-Free Generation" goals articulated by the U.S. Government (OGAC, 2012c).

PEPFAR's Contribution to Scale-Up and Coverage of PMTCT Services

Two centrally reported programmatic indicators requested and provided to the committee by OGAC serve to assess PEPFAR's contribution to the scale-up and delivery of PMTCT services. These indicator data show that, in the 31 countries that are the focus of this evaluation, the number of pregnant women who received PEPFAR-supported HIV counseling and testing for PMTCT and received their test results has increased from approximately 600,000 in FY 2004 to just over 7.3 million in FY 2009. The number of pregnant women who received PEPFAR-supported antiretroviral prophylaxis for PMTCT has increased from nearly 48,000 in FY 2004 to just over 600,000 in FY 2010.

The indicator for the number of pregnant women tested was no longer reported after 2009 as a result of the Next Generation Indicator revision process in 2009; instead, a revised indicator reports the number of pregnant women with known HIV status, including women who were tested for HIV and received their results, as well as pregnant women with already known HIV status who attended antenatal care (ANC) services (OGAC indicator P1.1D) (OGAC, 2009c). Rather than a measure of HIV testing provided to pregnant women, this provides a measure of the pregnant women known to be in need of PMTCT. Going forward, this can serve as denominator to assess the coverage in PEPFAR-supported programs of pregnant women who receive ARV prophylaxis for PMTCT. However, this indicator was added too recently to provide an assessment of coverage over time for this evaluation.

As a broad assessment of PEPFAR's contribution to the national coverage of PMTCT services in partner countries, Figure 5-4 shows PMTCT coverage in the 31 countries included as the focus this evaluation from 2006 to 2009 (the years for which the best data were available at the time of the committee's assessment). The annual figures for national coverage, inclusive of PEPFAR, and PEPFAR's contribution to overall coverage were obtained by combining the PEPFAR programmatic indicator for pregnant women who received ARV prophylaxis for PMTCT (OGAC indicator 1.3) with two publicly available indicators from the UNAIDS UNGASS reporting system: the national number of HIV positive pregnant women receiving antiretroviral prophylaxis for PMTCT and the national estimated number of HIV positive pregnant women. However there were several inconsistencies in these two measures. In some cases, the national PMTCT coverage and the estimated national prevalence were lower than the reported PEPFAR PMTCT coverage. In other cases, the reported UNGASS indicators were missing altogether. In an effort to make the three indicators internally consistent, the committee made the following adjustments to the values:

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- When the reported PEPFAR PMTCT coverage exceeded the reported national PMTCT coverage, the committee set the reported national PMTCT coverage equal to the reported PEPFAR PMTCT coverage.
- If the estimated national prevalence or the national PMTCT coverage were missing, the committee created an estimate on the basis of surrounding years' non-missing UNGASS indicator values.

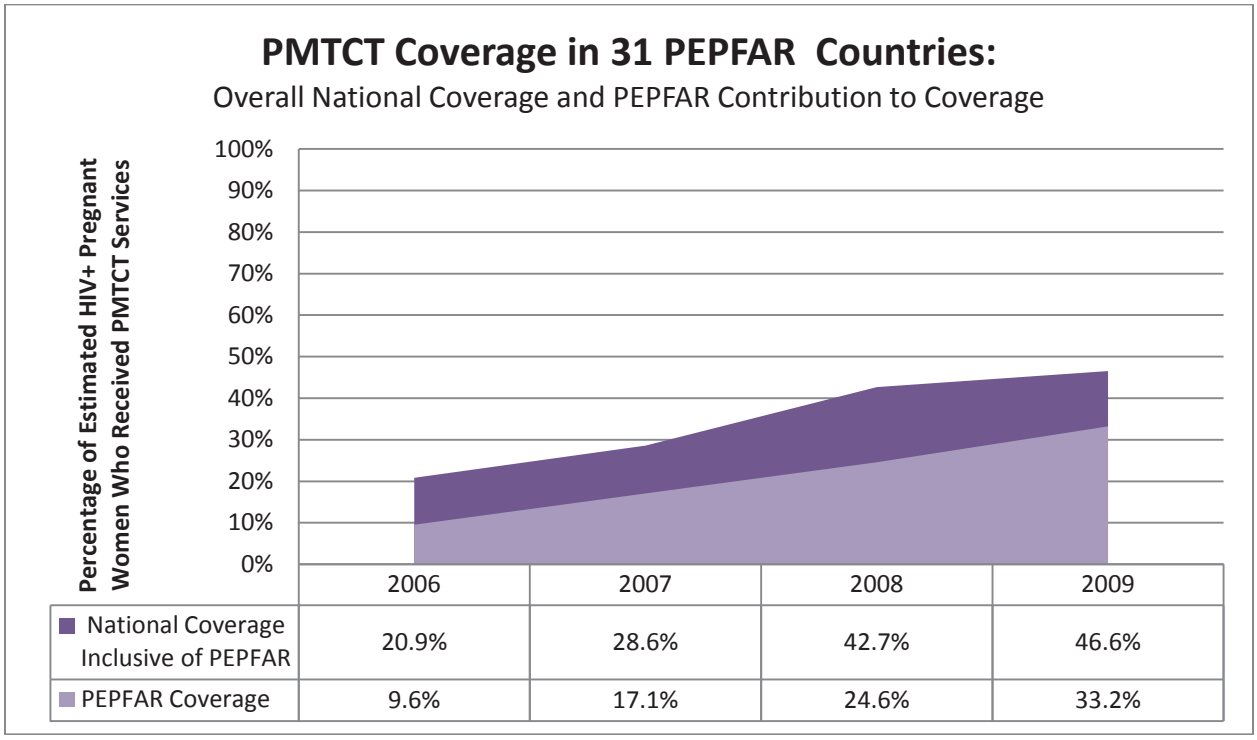

FIGURE 5-4 PEPFAR's contribution to PMTCT coverage, 2006 to 2009 (aggregate data from 31 countries).
NOTE: This figure represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2).
SOURCE: Program monitoring indicators provided by OGAC; (UNAIDS, 2012a).

On average, more than half of all PMTCT services provided each year are supported by PEPFAR, and in 2009 PEPFAR contributed to supporting about 71 percent of all women receiving ARV for PMTCT in these partner countries (Table 5-4).

TABLE 5-4 Number of HIV+ Pregnant Women Receiving ARV Prophylaxis for PMTCT (PEPFAR and National) (in Thousands)

Year	*Estimated # of HIV+ pregnant women (National)*	*# HIV+ pregnant women receiving ARV prophylaxis for PMTCT (National)*	*# HIV+ pregnant women receiving ARV prophylaxis for PMTCT (PEPFAR)*	*PEPFAR Contribution to Overall PMTCT Services*
2006	1,541.7	321.5	147.3	46%
2007	1,436.6	410.9	245.5	60%
2008	1,563.0	667.3	384.4	58%
2009	1,534.2	714.3	509.8	71%

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2).
SOURCE: Program monitoring indicators provided by OGAC; (UNAIDS, 2012a).

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Estimated and observed results from several studies conducted in PEPFAR partner countries have demonstrated not only successful efforts to scale up PMTCT services, but also a positive impact of PMTCT on the reduction of HIV transmission to infants, including in operational settings. Studies in Kenya, Swaziland, and Zambia have highlighted the feasibility and effectiveness of implementing PMTCT programs in under-resourced settings (Azcoaga-Lorenzo et al., 2011; Bancheno et al., 2010). In Nigeria, a retrospective review of records of 702 mother-infant pairs enrolled in PMTCT programs across six health facilities found that mothers who received ARVs were eight times less likely to transmit HIV to their children than those who did not receive treatment (Anoje et al., 2012). Another study in Haiti used mother-infant pair records from the primary HIV testing and treatment center and found that in the group of those who completed the PMTCT program, mother-to-child transmission was 9.2 percent, significantly lower than Haiti's historical transmission rate of 27 percent (Deschamps et al., 2009). Additional studies of PMTCT program effectiveness in South Africa, Angola, and Zambia have found that these programs led to reduced vertical transmission rates in real settings that are consistent with results of clinical trials using similar drug regimens (Coetzee et al., 2005; Colvin et al., 2007; Lussiana et al., 2012; Torpey et al., 2010). A recent population-based study evaluated PMTCT coverage and HIV-free infant survival in 26 communities throughout Cote D'Ivoire, South Africa, Cameroon, and Zambia using community surveys and testing to collect data on 7,985 mother-infant pairs. It found that community PMTCT coverage was moderately correlated with HIV-free survival of 24 month old children, and that a potent ARV regimen was the co-factor most strongly associated with the prevention of vertical transmission and child survival at 24 months (Stringer et al., 2013).

Interviewees from country visits consistently noted the increase in PMTCT services over time and the impact of this on reducing HIV transmission to infants, and emphasized PEPFAR's contribution to this achievement (240-13-PCGOV; 331-38-USPS; 587-2-USG; 587-5-PCGOV; 636-2-USG; 636-9-USACA; 636-16-USG; 272-22-USG; 272-24-USG; 461-4-USG; 461-17-PCNGO; 934-17-PCGOV).

> **Conclusion:** PEPFAR support for scale-up of services for prevention of mother-to-child transmission has made a major contribution to meet the need in partner countries.

Even with the major increase over time in pregnant women receiving services, the data in Figure 5-4 and Table 5-4 also show that overall coverage for PMTCT is still well below the need in PEPFAR partner countries. Overall coverage of PMTCT services from all actors in the response was less than 50 percent in 2009 in the 31 countries under review, well below PEPFAR's stated goal of supporting the provision of ARV prophylaxis for PMTCT for 85 percent of eligible women by 2013. This is consistent with the reality that, given the current rate of global scale-up, the world is not on track to meet the global target of 80 percent coverage in the near future.

Indeed, despite the large scale-up and increase in access to PMTCT, challenges remain with PMTCT service delivery and access. Studies on PMTCT services in PEPFAR partner countries have identified sub-optimal coverage and follow-up rates, and noted contributing factors such as socio-economic factors, staff shortages, adherence, and other service delivery factors (Azcoaga-Lorenzo et al., 2011; Bancheno et al., 2010; Colvin et al., 2007; Doherty et al., 2005; Lussiana et al., 2012). Challenges with access and service delivery were also highlighted by interviewees across countries. In many locations, part of this challenge was due to women

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being more likely to seek prenatal care in places other than at an antenatal clinic or hospital, which then limits access to PMTCT if it is provided only in those facilities. The cultural practice of having children at home was identified as one driver of this decision (240-12-USG). In several countries, interviewees highlighted difficulties in reaching pregnant women in geographically remote regions (587-5-PCGOV) and noted distance and transportation as challenges for women to access PMTCT services (240-2-USG; 240-13-PCGOV; 240-19-USACA; 240-24-USG; 636-2-USG; 461-7-PCNGO; 396-42-PCGOV). Lack of road infrastructure (461-7-PCNGO) and topographical barriers such as mountains prevented patients from reaching facilities. Additionally, participants noted that the cost of obtaining transportation and staying overnight near services were prohibitive for women to deliver in settings other than their homes (240-24-USG; 461-7-PCNGO). Other challenges identified included staffing (587-5-PCGOV, 116-18-PCNGO) and the quality of PMTCT services, service providers, and facilities (240-5-PCGOV; 240-13-PCGOV; 240-19-USACA; 240-24-USG; 461-7-PCNGO)—for example, unclean facilities that were not perceived as patient friendly (240-5-PCGOV).

Gender-related issues, including gender-based violence, emerged as a theme among participants for their effects on access of women and infants to services. Gender dynamics, including their intersection with access and service delivery, are discussed in greater detail in Chapter 8, but the following quote is revealing:

> *"The culture is very machismo here. [. . .]And you'll see a lot of women who are victims of domestic violence. They get HIV through that. They are very scared to disclose. And wouldn't protect their baby because of that, or wouldn't use replacement feeding because of those reasons. But you hear a lot of this anecdotally and through the healthcare workers. And so those are very complex issues to address. And we've only like touched on them"* (587-05-PCGOV)

Interviewees offered a variety of potential solutions to address the limitations in PMTCT access. Interviewees in multiple countries noted the approach of creating demand for PMTCT services through communication and behavior change messaging, which has been supported by PEPFAR (240; 331; 636). Others stated that it was seeing the success of PMTCT itself and the impact within communities of seeing a baby born HIV-negative that influenced women's decisions to seek access to services (396-21-USG; 934-17-PCGOV). Other approaches included allowing maternal and child health (MCH) nurses to provide ARVs to pregnant women (166-29-PCGOV) and using mobile clinics to reach pregnant women in remote regions (587-5-PCGOV). Another approach developed by UNICEF has been to offer pre-packaged PMTCT drugs and materials for women to take home at their first visit; this accommodates the fact that women typically only attend a single ANC visit during their pregnancy (Kelland, 2010; UNICEF, 2012).

Challenges and Successes of Integration of PMTCT with Other Services

As a part of the campaign for scaling-up universal access to PMTCT services, the WHO recommends that "[n]ational programmes should establish the necessary links to ensure large-scale access to a comprehensive package of services defined according to local context, including epidemiology and available resources" (WHO, 2007, p. 15). WHO places special emphasis on integrating family planning services into HIV prevention and care programs in order to maximize the potential health benefits of these activities (WHO, 2007). Evidence

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supporting improved health outcomes as a result of PMTCT integration is limited, but several studies comparing service uptake in integrated versus stand-alone care have shown positive results (Tudor Car et al., 2012).

PEPFAR has endorsed the WHO recommendations, and in 2011, articulated a goal of increasing activities related to integration, with the release of *Guidance on Integrating Prevention of Mother-to-Child Transmission of HIV, Maternal, Neonatal, and Child Health and Pediatric HIV Services* (OGAC, 2011b). PEPFAR reaffirmed this intention in the *FY 2012 Country Operational Plan Guidance* (OGAC, 2011c). The guidance recognizes that the evidence base for integration methods and outcomes is still emerging, but recommends an integrated package of services for women, including voluntary family planning, provider-initiated HIV testing and counseling, routine ANC, malaria and tuberculosis services, nutrition counseling, prophylaxis for women who test HIV positive through completion of breast feeding for PMTCT, and ARV treatment for women who are eligible (OGAC, 2011b). For children up to age 5 the package includes essential newborn care, counseling and testing, ARV therapy for those eligible, and social services for OVC (OGAC, 2011b).

Interviewees in several different partner countries described the integration of PMTCT activities into other health service delivery platforms. The most common of these was antenatal care (240-2-USG; 636-16-USG; 116-4-USG; 272-24-USG) and maternal and child health (587-5-PCGOV; 166-10-USNGO; 396-21-USG), however other examples included family and children's health (240-3-USG; 331-44-USNGO), tuberculosis (636-17-PCGOV), and the overall health system (587-10-USG, 587-12-USG, 396-21-USG). Participants noted that integration was associated with health systems strengthening and sustainability (331-02-USG; 587-06-CCM; 636-09-USACA; 396-21-USG), including improvements in infrastructure to integrate PMTCT into antenatal care and MCH (240-19-USACA, 166-10-USNGO).

Specific examples of successes related to the integration of PMTCT in other health services included '*strong commitment from the government to integrated HIV services for children*' (240-24-PCGOV) and increasing '*the capacity of maternal and child health*' (396-21-USG) Capacity building occurred through training of health workers in skills in maternal and child health, as well as in referral of children to care and treatment services (587-5-PCGOV; 166-10-USNGO; 396-21-USG; 396-42-PCGOV; 934-17-PCGOV; 587-5-PCGOV, 166-10-USNGO). Incorporation of PMTCT training into training for healthcare workers was also important, including the development of manuals and curricula (240-24-USG, 587-5-PCGOV):

> *"And then integrated in the sense that there are a lot of people trained in MCH. There are general nurse that are also trained in PMTCT. And then we're administratively integrated into MCH."* (587-5-PCGOV)

Additionally, improving the patient experience (934-15-PCGOV) and meeting obstetric needs (934-44-PCACA) were offered as successes:

> *"I think it's been positive because what has often happened is with the integration of HIV services within health centers, within district hospitals, it becomes very difficult to isolate someone who comes for obstetric needs or services from someone who comes for purely HIV needs. Obstetrics is a good one because everybody then goes through evaluation of the PMTCT program."* (934-44-PCACA)

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Several interviewees cited the challenges of integration of PMTCT services (240-24-USG, 587-2-USG; 587-5-PCGOV; 196-8-ML; 636-9-USACA; 461-18-USG). '*PEPFAR is being implemented in a system that is far from perfect*' noted one (587-02-USG), and another noted that stand-alone PMTCT sites still exist necessitating referrals to other health facilities (587-5-PCGOV) and that integration with family planning was difficult (240-24-USG). Another concern expressed was the potential decline in quality of services for both MCH and PMTCT after integration:

> *"Yeah, there have been concerns, obviously. That sometimes when you integrate the quality of care, yeah, may actually diminish. When you have a specialized person who is focusing on PMTCT, the person does a better job [...]. So people are a bit worried in terms of how well will be the quality."* (934-10-PCGOV)

Finally, the integration of PMTCT data collection into existing, often administratively divided, systems was identified as a challenge that had to be addressed, with some success attributed to PEPFAR's efforts (196-8-ML; 461-14-USG; 587-05-PCGOV), for example, through support for revised and standardized registers that integrate tracking of information for both general ANC and PMTCT (587-05-PCGOV).

> **Conclusion:** Integration of PMTCT into maternal and child health is occurring and is a sign of evolution of the program. However, integration at the facility level with other services is variable, and the link between PMTCT and ART for both women and children is still a challenge.

The linkages from PMTCT to ART services are also discussed in Chapter 6, Care and Treatment, and service integration, including that of PMTCT, is further discussed in Chapter 9 on health systems strengthening.

INJECTION DRUG USE

Background

The United Nations Office on Drugs and Crime (UNODC) estimates that approximately 205 million people use drugs illegally with more than 10 percent of users meeting the criteria for drug dependence (UNODC, 2008). Use of injection as the primary mode of drug consumption introduces specific health risks, such as venous collapse and ulcers, hemorrhage due to inadvertent injection into the artery, increased risk of blood-borne infections including HIV and viral hepatitis, and bacteremia and septicemia (World Health Organization Regional Office for South-East Asia, 2009). The link between injection drug use and HIV infection is particularly significant and has motivated a robust response from the international health community.

HIV transmission among people who inject drugs occurs primarily through the sharing of used needles and other injection equipment contaminated with HIV, although sexual transmission between drug users and their partners—who may or may not themselves be injectors—is also common and of concern. Because injection drug use is illegal nearly everywhere, it is difficult to measure the prevalence of this behavior, which limits the ability to

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determine the prevalence (and incidence) of HIV among people who inject drugs. However, in 2008 it was estimated that of the approximately 16 million people who injected drugs, one fifth were likely to be HIV positive (Mathers et al., 2008). In regions where injection drug use is the primary driver of the epidemic, HIV prevalence in people who inject drugs may be as high as 40 percent (Mathers et al., 2011). Outside of sub-Saharan Africa, transmission via injection drug use is responsible for an estimated 30 percent of all new HIV infections (WHO, 2009a). Given the substantial health and economic burden caused by HIV, addressing the risks of drug dependency is a key focus for global health programs operating in countries with concentrated HIV epidemics, and an increasing focus in countries where illicit drug use is emerging as a driver of HIV transmission within generalized epidemics.

Harm Reduction

In the 1990s, polymerase chain reaction (PCR) testing detected HIV on used needles and syringes (Heimer et al., 1992), and mathematical modeling of the circulation of HIV-contaminated syringes used by people who inject drugs (Kaplan and Heimer, 1994) added evidence for advocates and public health practitioners to press governments to permit legal implementation of harm reduction strategies as a way to prevent HIV transmission among people who inject drugs. However, UNAIDS estimated that only 19 percent of individuals at risk of injection drug use–related HIV acquisition had access to harm reduction interventions in 2001 (Global HIV Prevention Working Group, 2003), and the adoption of harm reduction approaches has remained politically and culturally controversial and has varied among countries (Auerbach, 2009).

Harm reduction strategies may include sterile needle and syringe exchange programs, the relaxation of drug paraphernalia and possession laws, and the provision of medication for substitution therapy (Hunt, 2003). This harm reduction approach emphasizes the public good in limiting the transmission and acquisition of infectious blood-borne pathogens (i.e., HIV and hepatitis C virus) even while individuals might not be able to successfully stop using drugs altogether, with or without referrals for addiction and substance abuse treatment, although both the UNODC and WHO identify drug dependence as a disease that should be addressed with evidence-based treatment options (UNODC, 2008; WHO, 2009a).

Medication-assisted treatment (MAT) is the provision of a daily dose of methadone or buprenorphine to people who are addicted to opiates. Methadone and buprenorphine are synthetic agents that affect the brain receptors that are responsive to heroin and other opiates and block the sedative effect of these drugs, reducing cravings and alleviating the symptoms of opiate withdrawal (Centers for Disease Control and Prevention (CDC), 2002; Kumar, 2012). MAT has been shown to be effective in reducing the extent and frequency of injection and in reducing HIV risk behaviors among people who inject drugs (IOM, 2007b). WHO Guidelines state that provision of methadone as a part of maintenance therapy for people who inject drugs is the minimal acceptable standard for national opioid treatment programs, though ideally both buprenorphine and opioid antagonists should also be made available (WHO, 2009a). MAT also increases patient adherence to antiretroviral treatment (WHO, 2009a).

In addition to voluntary treatment for drug dependence or addiction and detoxification programs that assist or medically monitor patients who stop using drugs and experience withdrawal symptoms, the WHO has also recognized the effectiveness of sterile needle and syringe exchange programs in reducing transmission of HIV (WHO, 2004). Despite this recognition, WHO has yet to release comprehensive international guidelines on incorporating

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these strategies into national policies. In places where expanded sterile syringe access was implemented, HIV epidemics where transmission is concentrated among IDU have been significantly reduced (Hurley et al., 1997).

PEPFAR's Activities for Prevention with People Who Inject Drugs

The 2003 PEPFAR authorizing legislation was the original document that instructed the program to include activities in its prevention portfolio aimed at addressing "substance abuse and intravenous drug use that can lead to HIV infection."[30] In response to this legislative authorization, activities focused on people who inject drugs were first incorporated into the "Condoms and Other Prevention" annual budget request narrative (OGAC, 2004a). Early prevention activities for this population included peer- and community-based outreach and education, especially focused on encouraging people who inject drugs to access voluntary counseling and testing; support to reduce needle-sharing; evidence gathering and research; and technical assistance to support policy change and development (PEPFAR/Vietnam, 2004, 2005).

Guidance for the Prevention of HIV for People Who Inject Drugs

The first formal guidance on PEPFAR activities specifically targeting HIV Prevention among people who use drugs was released in 2006 (OGAC, 2006d). The guidance document acknowledged the important role that the use of injection drugs played in the HIV epidemic, and outlined a three-part strategy of activities that could be supported by PEPFAR. The strategy included tailoring existing prevention of sexual transmission and counseling and testing activities to people who inject drugs; supporting substance abuse programs including medication-assisted treatment; and providing individuals with comprehensive HIV treatment services (OGAC, 2006d). Notably, this guidance prohibited the use of PEPFAR funds for sterile needle and syringe exchange programs (OGAC, 2006d).

The guidance was updated in 2010 in the document *Comprehensive HIV Prevention for People Who Inject Drugs, Revised Guidance*, which endorsed a modified three-component strategy that included community-based outreach programs, sterile needle and syringe exchange programs, and treatment for drug dependence, such as opioid substitution therapy (OGAC, 2010a). The shift in policy about supporting needle and syringe exchange programs followed a change in U.S. law, when Congress removed the prohibition in 2009. In 2011, the ban on the use of foreign assistance for needle and syringe exchange was included by Congress in the budget resolution for fiscal year 2012, halting the scale-up of these programs for a second time (Harm Reduction International, 2011). Of note, these changes to PEPFAR guidance and U.S. law occurred during the course of the study's data collection period, and the committee interpreted the available data in light of this evolution.

Communicating the content and intent of changes in this guidance and policy to the field remains a persistent challenge for OGAC and may potentially limit the effectiveness of program implementation. Interviewees in several countries visited, as well as advocates and OGAC headquarters staff, highlighted instances in which a lack of clarity about changes in the guidance led to confusion (396-56-USNGO; 396-59-USG; NCV-19-USG; NCV-24-USNGO). There was awareness of the change in PEPFAR policy related to needle and syringe exchange programs (196-11-USNGO; 396-07-PCGOV; 935-17-USG), but also concerns about difficulties due to the lack of clarity on whether scale-up would be able to proceed (196-11-USNGO; 396-02-USG).

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[30] *Supra*. Note 3 at § 301(a)(2), 22 U.S.C. 2151b (d)(1)(G).

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> *"…the guidance on needle syringe programming for [this country] is not 100 percent clear. Are we allowed to do it? We were informed […] that perhaps procurement is still not cleared in the latest congressional budget. You know it's a very different epidemic […] so we really need to understand what the guidance is on that. And of course when there's a change in administration things change."* (396-57-USG)

PEPFAR-Supported Services for People Who Inject Drugs

Due in part to the recentness of the introduction of indicators and a dedicated budget code, it is difficult to determine the scope of PEPFAR's activities for people who inject drugs over time. Of the 15 original focus countries, 6 described activities that included efforts, beyond improved measurement, for people who inject drugs in their country operational plan narratives in at least one year during the first phase of PEPFAR (PEPFAR/Kenya, 2006; PEPFAR/Mozambique, 2006; PEPFAR/Nigeria, 2006; PEPFAR/South Africa, 2006; PEPFAR/Tanzania, 2006; PEPFAR/Vietnam, 2006). In 2009, planned funding for activities for this population was disentangled from other prevention efforts and a new budget code titled Injecting and Non-injecting drug use was created and ten countries planned activities under this budget code in FY 2009 and FY 2010 (OGAC, 2010d, 2011f). In FY 2011, 12 countries (Cambodia, China, Guyana, India, Indonesia, Kenya, Mozambique, Russia, Tanzania, Thailand, Ukraine, Vietnam) and the Central Asian Region, included specific budgets for activities for people who inject drugs in their HIV prevention programming portfolio (PEPFAR, 2011a). This reflects an expansion of PEPFAR's efforts in this area, from an initial focus on implementing programs primarily in concentrated epidemics, to the development of pilot programs in some countries with generalized epidemics where injection drug use is emerging as an important HIV transmission risk (Nieburg and Carty, 2011). Because these efforts are still in pilot stages, there were no data available for the committee to include them in its assessment of the impact of PEPFAR's activities. To expand access to HIV services, current PEPFAR prevention efforts for people who inject drugs include support for activities in an increasing variety of facility and community settings. Services supported include ART and treatment for co-morbidities including hepatitis B and C; education on safer sexual practices and condom provision; and medication-assisted treatment, which is stated as a critical priority for PEPFAR (OGAC, 2011d).

Injection drug users were identified as a vulnerable or at-risk group in most countries visited by the evaluation team, regardless of national epidemic type (331-14-USG; 587-7-PCGOV; 196-7-PCNGO; 166-5-USG; 272-6-ML; 935-14-USG; 461-1-USG; 542-8-ML; 396-1-USG). Interviewees described numerous ongoing activities supported by PEPFAR for both HIV prevention and treatment for people who inject drugs. Prevention efforts include the use of peer educators (166-5-USG; 935-17-USG), the provision of condoms (196-6-USG; 196-21-PCGOV), counseling and testing services (196-6-USG; 196-11-USNGO; 196-17-PCGOV), and activities for people who inject drugs in prisons (331-14-USG; 542-6-ML; 196-11-USNGO). As described above, interviewees noted limitations and challenges regarding the use of PEPFAR funds for needle and syringe exchange (935-17-USG; 196-12-PCGOV; 396-56-USNGO; 396-59-USG; 196-11-USNGO; 396-07-PCGOV; 396-02-USG; 396-57-USG). PEPFAR is also supporting substance abuse treatment services in several countries, including through efforts to increase access to methadone (196-11-USNGO; 196-14-PCGOV; 542-6-ML; 935-17-USG; 542-8-USNGO) and the provision of a safe space for services (166-5-USG), as well as ART for people who inject drugs who are HIV positive (542-8-USNGO).

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Importance of the National Policy Context for Efforts for Prevention for People Who Inject Drugs

The policy environment, which includes the USG policies described above, as well as a partner country's own laws and policies related to drug users, has been a crucial driver of the response to HIV in PEPFAR-supported countries where transmission among people who inject drugs is a major driver of the epidemic. Criminalization of injection drug use and types of enforcement mechanisms vary greatly in PEPFAR partner countries with concentrated epidemics (Chiu and Burris, 2011). Given the sensitive nature of providing services for people who inject drugs, the policy context within which PEPFAR provides these services can affect program impact. For FY 2012, mission teams were expressly tasked with supporting national governments and NGO's to "address policies that serve as barriers (criminalization for seeking health-care, policy to not initiate ART until patient has stopped using drugs, etc.) or facilitators (use of case managers for service coordination, promotion of drug treatment over criminalization, etc.) to drug-using populations accessing HIV-related services" (OGAC, 2011d, p. 56).

Interview data reflect the effect that the national policy context has had over time on PEPFAR's efforts to provide HIV prevention services for people who inject drugs. Although there were differences in the specific effects due to differences in national and local legislation, legal and policy issues were highlighted across countries as a challenge to implementing services for people who inject drugs (196-12-PCGOV; 542-06-ML; 396-02-USG; 396-57-USG). Some interviewees identified that different laws within a country were often in conflict with each other, and this conflict among laws sometimes affected service delivery in these locations (396-02-USG; 542-06-ML; 196-ES). As a result, some interviewees identified the need for PEPFAR to work beyond the Ministry of Health, noting that many other agencies are involved in or have the ability to affect the provision of harm reduction services (396-02-USG; 396-23-USG).

Effects of PEPFAR's Activities for Prevention Among People Who Inject Drugs

PEPFAR indicators to monitor activities for people who inject drugs were not defined or part of required reporting until FY 2010, when a Next Generation Indicator was introduced: number of IDU on opioid substitution therapy (OGAC, 2009c). OGAC programmatic indicator data provided to the committee showed that in FY 2010, four countries (China, Tanzania, Ukraine, and Vietnam) and one region (Central Asia) in which injection drug use is a key driver of the HIV epidemic, reported targets for this indicator and only two, Ukraine and Vietnam, reported results toward achieving this goal. The committee's ability to interpret effect size or health impact from these data was extremely limited, but in the future, should this indicator continue to be collected consistently, PEPFAR should be able to assess trends in the scale-up of its opioid substitution therapy services and evaluate the impact of this important component of the HIV response.

Declining HIV prevalence among people who inject drugs was described by interviewees in PEPFAR partner countries (196-12-PCGOV; 542-06-ML; 396-12-USG), and was directly attributed to the use of opioid substitution therapy and sterile needle and syringe exchange programs (542-06-ML; 396-12-USG). A range of other achievements, both specific to PEPFAR and for people who inject drugs in general, were identified by interviewees. These included acknowledgment that PEPFAR's work on harm reduction programs had been innovative; successful awareness and advocacy work with key stakeholders; provision of technical assistance to national counterparts; and recognition that PEPFAR had established a reputation of being '*well respected*' in its work with populations

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at elevated risk in the country (196-11-USNGO; 542-06-ML; 396-23-USG; 196-08-ML). Interviewees in multiple countries highlighted the work of external partners, including PEPFAR, in contributing to positive shifts in the approach of the national government response (396-12-USG; 396-39-USG; 542-06-ML). One implementing partner noted that *"It is because of PEPFAR, frankly, that even some of these issues get discussed,"* including the government's willingness to discuss a *"really good spectrum of services for injecting drug users that goes from like this intervention of reducing initiation but then also addiction counseling, job placement for them, methadone. This is all PEPFAR"* (396-15-USNGO). Another interviewee described the importance of successful pilot studies supported by PEPFAR in influencing national governments:

> *"the truth is that in multiple ways whether it's for delivery of ARV or substitution treatment, which PEPFAR has funded…showing that something is possible and that nothing bad will happen has been enormously influential in getting national governments to relax and to allow things to proceed and in some cases to fund it themselves. So again, taking the example of substitution treatment even though it was a very long and labored process and even though the absolute numbers of people on substitution treatment in [one country] remain small, I think it is very clear that without PEPFAR there would be (a) no one on substitution treatment, and (b) no national targets for the government to scale up substitution treatments."* (NCV-24-USNGO)

Despite these successes, services for people who inject drugs remain inadequate in many countries in which PEPFAR works. Interviewees noted remaining unmet need for harm reduction services (196-13-OGOV; NCV-24-USNGO), skills training (196-17-PCGOV), HIV services, including for female drug users (542-3-USG), and, in some cases, for other health services, such as support for treatment for hepatitis C (542-11-PCNGO). Need for continued work regarding restrictive national policies that limit access to services for people who inject drugs was also identified (NCV-24-USNGO). Globally, while the number of countries reporting data is limited, a 2012 UNAIDS report noted that most country programs provide fewer than 100 needles per year per person who injects drugs resulting in sterile injecting equipment being used for only 5 percent of injections globally (UNAIDS, 2012b). Additionally, access to HIV counseling and testing services is low, with fewer than 40 percent of individuals on average in urban areas reporting having received an HIV test in the past year (UNAIDS, 2012b). Inadequate information on people who inject drugs was also identified by interviewees as a global challenge that affected the implementation of PEPFAR's programs (331-15-USG; 196-8-ML; NCV-24-USNGO; NCV-7-USG). Efforts, some PEPFAR-supported, were underway in several countries to address this (331-14-USG; 196-11-USNGO; 935-14-USG; 461-1-USG), ranging from IBBS surveys (331-24-PCGOV; 196-12-PCGOV), to surveillance systems (935-14-USG; 461-1-USG), to the production of peer-reviewed literature (196-11-USNGO).

Conclusion: PEPFAR has been instrumental in facilitating and supporting some harm reduction approaches in countries with epidemics for which injecting drug use is a major or emerging driver. Notwithstanding restrictive U.S. and partner country policy and legal environments, a positive effect of these activities and

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programs is being seen in countries in which PEPFAR works, but substantial unmet need remains for harm reduction and other services for this population.

BLOOD AND MEDICAL INJECTION SAFETY

Blood safety is a critical element of a comprehensive approach to HIV prevention. In 2003, WHO estimated that 5-10 percent of HIV infections were acquired though transfusion-related transmission (OGAC, 2004b). Voluntary, non-remunerated blood donors have the lowest rates of infectious disease, including HIV, and thus the WHO recommends that 100 percent of blood and blood products used for transfusion come from this type of donor by 2020 (WHO, 2009b). In order to meet national need, it is estimated that approximately one percent of a country's population must be regular blood product donors (WHO, 2008). While this target has been met in most developed countries, as of 2010 there were still 70 developing countries falling short of this goal (World Health Assembly, 2010).

Blood and medical injection safety have been components of PEPFAR's prevention efforts since the program's inception in 2003. The authorizing legislation included "assistance to ensure a safe blood supply and sterile medical equipment"[31] among the prevention activities supported by the program, and the 2008 reauthorization legislation reiterated support for these prevention areas.[32] PEPFAR has never released guidance specific to either topic, but the first 5-Year Global HIV/AIDS strategy defined blood and injection safety as two critical components of the prevention portfolio that should be rapidly scaled-up (OGAC, 2004b). PEPFAR's primary type of activity around blood safety is the provision of technical assistance and capacity building (OGAC, 2011d). USG staff and partners have worked with national governments over time to implement activities related to both blood and injection safety (OGAC, 2011d).

Several challenges related to the implementation of blood safety activities were mentioned in partner countries visited by the evaluation committee. These included measuring and tracking the need for blood and blood products (331-15-USG), issues with the infrastructure of blood banks (166-11-USG), and the out-of-pocket cost of blood critically needed for obstetric care (934-17-PCGOV). Despite these challenges, participants identified blood safety work as a PEPFAR success in several countries (935-3-USG; 166-11-USG; 934-18-PCGOV; 935-7-USG; 935-17-USG; 240-9-USG; 240-7-PCGOV). One participant noted that before PEPFAR's efforts in that country, blood testing processes were less rigorous, but more recently, improvements have been seen (166-11-USG). Interviewees also described how capacity in the national blood safety system had been built with PEPFAR support (240-9-USG; 240-7-PCGOV; 935-3-USG).

In the first five years of implementation, PEPFAR's program monitoring indicators tracked the number of activities related to improving blood safety, but did not measure outcomes on blood safety at the programmatic level. Currently, there are four PEPFAR blood safety indicators; central reporting to OGAC is not required for any of them (OGAC, 2009c). Although available PEPFAR programmatic data are limited, during the time of PEPFAR's implementation some improvements were seen based on globally reported data. In all but one of the 15 original PEPFAR focus countries, the number of blood units screened for HIV in centers or laboratories that followed basic quality assurance processes increased between 2007 and 2009 (UNAIDS,

[31] *Supra*. Note 3 at § 301(a)(2), 22 U.S.C. 2151b (d)(1)(F).
[32] *Supra*. Note 1 at § 101(a), 22 U.S.C. 7611(a)(14)(D).

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2012a). Additionally, as of 2009, 12 PEPFAR-funded countries reported screening 100 percent of donated blood (UNAIDS, 2012a).

Achieving the goal of universal access to safe blood and blood products for transfusion in PEPFAR countries is inseparable from health systems strengthening and policy development efforts. Many of the challenges are similar to those identified for other components of the health system (see Chapter 9 for further discussion of health systems strengthening). The Melbourne Declaration highlights the importance of leadership from national governments as they work to build blood safety systems focused on quality, sustainability, and effective monitoring (WHO, 2009b).

While smaller than the blood safety program, support for safe medical injection practices and prophylaxis in the event of exposure has also been a component of PEPFAR's prevention portfolio since 2004 (OGAC, 2003). From FY 2004 to FY 2011, across all countries in which it operated, PEPFAR obligated $180 million for medical injection safety (OGAC, 2005b, 2006c, 2007c, 2008c, 2010d, 2011f, g), which PEPFAR defined as "policies, training, waste-management systems, advocacy and other activities to promote (medical) injection safety, including distribution/supply chain, cost and appropriate disposal of injection equipment and other related equipment and supplies" (OGAC, 2006b, p. 55). From 2004 to 2009, one indicator tracking the number of individuals trained in medical injection safety was required to be reported to OGAC (OGAC, 2007b). In 2009, as a part of the Next Generation Indicators, use of this indicator was discontinued and a new measure was added requiring countries to report on the number of individuals provided with PEP, disaggregated by exposure type (occupational, rape/sexual assault, and non-occupational) (OGAC, 2009c).

HIV COUNSELING AND TESTING

Counseling and testing serves many functions within an effective response to HIV. Initially, voluntary HIV testing programs were primarily intended to increase the number of people aware of their HIV status and to serve as an entry point for counseling and for prevention services, for those who were both HIV-positive and HIV-negative, with the aim of reducing HIV transmission and infection. With the introduction of more widespread care and treatment services, HIV testing now serves as a crucial gateway to enrollment of those who are HIV-positive in services for HIV treatment, care and support, and the prevention of vertical HIV transmission, while the function of providing counseling and an entry point to prevention services also remains. HIV counseling and testing as a direct prevention tool was supported by early evidence suggesting positive reductions in sexual risk behavior after testing and post-test counseling (OGAC, 2006a; Weinhardt et al., 1999). Today, the potential impact of counseling and testing on directly reducing HIV incidence is unclear, with studies showing both decreases and increases in sexual risk behavior following counseling and testing and the knowledge of one's serostatus (Corbett et al., 2007; OGAC, 2011d; Sherr et al., 2007; Sweat et al., 2000; The Voluntary HIV-1 Counseling and Testing Efficacy Study Group, 2000; Weinhardt et al., 1999).

From the start of PEPFAR through FY 2008, the budget for counseling and testing activities was captured as a part of the larger technical area of HIV Care (OGAC, 2005b, 2006c, 2007c, 2008c). In FY 2009 the budget code was relocated to the technical area of Prevention, and as a result, funding for counseling and testing has since been included by PEPFAR in overall spending on HIV prevention efforts (OGAC, 2010d, 2011f, g). PEPFAR's 2006 *Guidance for a Preventative Care Package for Adults* included "services and counseling to prevent the

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transmission of HIV to others" and "HIV counseling and testing of family members and other contacts" as key components of its care approach. The goal of these elements was to connect HIV infected persons with prevention messages and with needed medical care and treatment and aid in early identification of other HIV-positive family members and sexual partners (OGAC, 2006a). Thus, the aim of linking to prevention interventions, especially for those identified as HIV-positive, were from the beginning a component of PEPFAR's counseling and testing activities, with a special emphasis on promotion of condom use for PLHIV (OGAC, 2008b). PEPFAR has also more recently stated that it is heightening its efforts to implement modified case management approaches with individuals who test HIV negative (OGAC, 2010c). When PEPFAR updated its guidance on the prevention of sexually transmitted infections in 2011, it incorporated counseling and testing as one of its recommended biomedical approaches to prevention.

Evidence regarding effective and appropriate counseling and testing modes and settings has expanded over time, and the activities that PEPFAR supports have subsequently evolved as well. Currently, in line with WHO recommendations, PEPFAR funds both client- and provider-initiated voluntary counseling and testing, primarily in clinic settings, but is increasingly investing in home and community-based approaches, to varying degree across countries (OGAC, 2011a; WHO, 2012b).

Counseling and testing continues to play an important gateway role for entry into different prevention activities, most notably for identifying individuals eligible for VMMC and PMTCT (OGAC, 2011d), while many behavior change-based prevention methods, such as condom use, are effective regardless of whether individuals are aware of HIV serostatus. Moving forward, the increasing focus on interventions aimed at serodiscordant couples and the prevention benefits of antiretroviral therapy, discussed in greater detail below, will also rely on the linkages between testing and prevention services.

The committee recognized the important role that counseling and testing plays as a part of both the effective implementation of HIV prevention services and the effective implementation of care and treatment services. However, the data collection for the committee's evaluation revealed that there is little information on the coverage or quality of the implementation of the counseling activities for risk reduction supported by PEPFAR as part of counseling and testing or on the effects of these efforts on HIV risk behavior. There is also little information regarding linkages for individuals who test HIV negative to appropriate prevention services. Program monitoring indicators for counseling and testing are focused on documenting the number of people who access this service and receive their results (OGAC, 2007b, 2009c), and interview data were most robust on the role of testing within PEPFAR for linking individuals who test HIV-positive to ART and other care and treatment services. Therefore, the primary discussion of PEPFAR's achievements and ongoing challenges in counseling and testing can be found in Chapter 6, Care and Treatment.

ANALYSIS OF PREVENTION IMPACT

PEPFAR's support for the scale up of HIV prevention activities across prevention modalities has been an achievement and a contribution to the response to the epidemic in partner countries. However, given the various data challenges described in this chapter, the committee was limited in the extent to which it could draw conclusions about the overall impact of PEPFAR's HIV prevention programs on HIV transmission and on population incidence of HIV

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infection in the countries in which it operates. The committee recognized the difficulty of assessing prevention impact both for PEPFAR and in general, given the complexity of interventions, the shifting landscape in which PEPFAR has been operating over time, and limitations in the field of prevention science to systematically monitor and evaluate prevention outcomes and impact.

When considered in the context of the program impact pathway that guided this evaluation, the inputs (such as funding and guidance) for prevention interventions are documented within PEPFAR across the various prevention modalities. However, information about other steps in the impact pathway varied considerably depending on the modality. For PMTCT, it was possible to document and understand the scope of PEPFAR's contribution to inputs and activities in terms of the specific funding for PMTCT and the services PEPFAR supports, as well as the output of these activities in terms of the number of pregnant women who have received PMTCT services. It was also feasible to reasonably assess coverage as one outcome of this contribution. In addition, there is well-established evidence for the effectiveness of PMTCT that supports a credible conclusion that PEPFAR's successful contribution to outputs and outcomes has contributed directly to reducing vertical transmission of HIV. For other modalities, such as VMMC and certain elements of harm reduction approaches for people who inject drugs, the committee was able to document PEPFAR's support for scale-up of specific activities related to these interventions. The committee also anticipates that in the future PEPFAR's program monitoring system will provide some estimates of intervention outputs and coverage, which will allow for reasonable conclusions to be drawn about the expected prevention impact of such interventions, although the committee was limited in doing so at this time because relevant indicators were only recently added.

Behavioral and structural interventions for prevention of sexual transmission were the modalities with the least information available to draw conclusions along the steps of the program impact pathway. The committee was able to document over time which activities PEPFAR has recommended to be funded through a review of guidance. Semi-structured interviews and a review of Country Operational Plans from the partner countries visited for this evaluation indicated that there has been implementation of activities across the range identified in the guidance. However, these data sources revealed a wide and diffuse range of activities, and it was difficult to gain a comprehensive understanding of how PEPFAR's support has been distributed among different activities and what the outputs of those activities have been. This is because there is a lack of useful, centrally-reported process indicators, as well as other systematically collected and synthesized information, as an alternative to indicators. In addition, there is very limited information on the outcomes of these activities that could be used to support conclusions about their likely contribution to impact on HIV transmission or population incidence.

The challenges in monitoring and evaluating prevention interventions are not unique to PEPFAR. Indeed, there is not clarity in the global community about how to routinely track their implementation and effects. Behavioral and structural interventions in particular are difficult to measure and evaluate because they are affected by many individual, interpersonal, and contextual factors and because their practical implementation as part of programs does not lend itself readily to controlled, random assignment evaluation designs. However, the challenges of measuring the effects of these interventions do not mean that they are inherently ineffective. Rather it is an indication that there is a substantial knowledge gap in this area relative to biomedical prevention modalities, both within PEPFAR and in the greater global health

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community. Although there is strong foundational knowledge to support the principles and the design of these interventions, the persistent gaps in the field include a lack of knowledge on what the appropriate measures are for meaningfully tracking scale-up and coverage of behavioral and structural interventions, a lack of established and agreed-upon behavior change outcome measures and proxy outcome measures, an insufficient understanding of the effectiveness of these interventions when implemented at scale in producing changes in outcomes, and a lack of knowledge of how the rates of change in behavioral and proxy outcomes are associated with rates of change in HIV transmission.

This is an area in which PEPFAR, given the scale of its programs and its commitment to implementation research, has the opportunity to contribute to much-needed ongoing research and development for assessing behavioral and structural interventions, building on the methodological approaches that are currently available and in use. These include, for example, large-scale cohort studies, non-randomized and quasi-experimental plausibility designs, and evaluations triangulating across multiple methodologies. PEPFAR's use of these approaches for monitoring, evaluating, and reporting on its non-biomedical prevention efforts is currently quite limited. The benefits of investing in closing this knowledge gap would not be limited to prevention programs, but also would apply to programmatic approaches in areas such as gender, orphans and vulnerable children and nonclinical care for people living with HIV. In addition, there is an ongoing need to assess the effectiveness of biomedical preventions when implemented at scale, and advances of this kind would contribute to assessing and addressing behavioral aspects that are critical elements of uptake, access, adherence, and quality for biomedical prevention interventions, as well as for care and treatment programs and services.

In addition to understanding the effects of prevention programs on intermediate outcomes and on HIV transmission, the ultimate goal of any prevention intervention is to affect incidence rates in the target population. Incidence rates cannot yet be easily measured directly. Therefore, an accepted method used to attempt to capture the impact of prevention programming across prevention modalities is incidence modeling. Several approaches, each with its own limitations, have been developed to model the impact of prevention activities and estimate HIV infections averted, including coverage-based, behavior-based, and disease modeling (Heaton et al., 2008). The coverage-based approach relies on an estimate of the efficacy of the intervention on incident HIV infection but two critical inputs (the coverage and the relative risk) are important sources of uncertainty with this approach (Heaton et al., 2008). The behavior-based approach relies on a model that describes how HIV infection is mediated by behavior, incorporating evidence of the effects of behavior change on incident HIV infection and the change in prevalence of the high-risk behaviors resulting from the intervention. A key limitation of this method is the lack of reliable behavioral data in many developing countries. The third approach of disease modeling is based on a comparison of observed HIV incidence trends with the expected or baseline HIV incidence trends. However, few countries have been able to collect true population-level incidence data and there have been difficulties with measuring incidence using measures such as BED immunoassays[33] (Hallett et al., 2008; Murphy and Parry, 2008). Indirect strategies for estimating HIV incidence include models, such as the Estimation and Projection Package and the Spectrum software, developed at UNAIDS, have been used by some researchers to predict HIV

[33] The BED-CEIA (HIV-1 subtype B, CRF_01AE, and subtype D–Capture Enzyme Immunoassay) is a commercially available product designed specifically for the purpose of indentifying HIV-1 infections that were recently acquired—using the three specific peptides to cover much of the extent of antigenic diversity to overcome some of the subtype differences associated with the "detuned" assays (Murphy and Parry, 2008).

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prevalence. Comparisons of the observed trends with the modeled or expected trends have been used to estimate infections averted.

PEPFAR uses a model produced by the U.S. Census Bureau to estimate the overall number of infections averted in partner countries and measure progress towards its congressionally mandated targets (IOM, 2007a), however, the results of these modeling estimates are not publicly available (OGAC, 2012b). The Census Bureau model (known as, RUPHIVAIDS) follows a disease-modeling approach in which expected or baseline HIV incidence estimates are developed with data prior to 2005 and compared to re-estimated trends in HIV incidence from new surveillance data available after 2004. The difference in the number of new infections, based on this comparison approach, is used as the number of infections averted. The model incorporates estimates of HIV prevalence from the Estimation and Projection Package to project HIV incidence and applies various assumptions in relation to sex distribution of HIV infection, sex ratios of new infections, rate of mother-to-child transmission, and disease progression as recommended by the UNAIDS Reference Group on Estimates, Modelling and Projections (Bureau, 2010).

PEPFAR does release publicly the number of estimated infant infections averted through its PMTCT programs; these estimates use a different methodology. PEPFAR calculates infant infections averted by "multiplying the total number of HIV+ pregnant women who received ARV prophylaxis [supported by PEPFAR] by 19 percent, reflecting a consensus estimate that current interventions (which vary by country and site) are reducing transmission, on average, from a background of 35 percent to 16 percent. Countries with more effective interventions (e.g. Botswana) are likely averting more infant infections than [the estimate reports]" (OGAC, 2009a). At the completion of the first phase of PEPFAR in 2008, the program estimated that its support for PMTCT activities had averted nearly 240,000 infant HIV infections (PEPFAR, 2008). The committee did not conduct any additional modeling of its own for this study.

> **Conclusion:** There are limitations to measuring the effects of prevention programs across modalities, and in particular for behavioral and structural interventions. These limitations are not unique to PEPFAR and a substantial increase in attention and effort will be required to address them, yet more comprehensively identifying and understanding the outputs, coverage, and outcomes of prevention interventions would be of immense value in accurately assessing and documenting the impact of prevention efforts. Across modalities, measuring and achieving key intermediate outcomes for prevention efforts is as important a goal for PEPFAR as achieving estimated impact on the number of infections averted.

INTERVENTIONS ON THE HORIZON FOR PREVENTION STRATEGIES

As noted throughout this report, PEPFAR has evolved over time, adapting itself to changes in science, politics and policy, and the nature of the HIV epidemic itself. Going forward, programmatic agility will be required as PEPFAR attempts to incorporate a number of important scientific developments that have occurred in just the past few years. Many of these

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developments relate to HIV prevention technologies, including oral pre-exposure prophylaxis (PrEP), topical microbicides, and ART for prevention of transmission.

In the summer of 2010, a key development in HIV prevention methods for women occurred, when the CAPRISA 004 study found that a vaginal microbicide of 1 percent tenofovir gel reduced risk of HIV infection among women in South Africa by 39 percent (Abdool Karim et al., 2010). Although it achieved a less than optimal level of efficacy, the trial did establish proof of concept of an ART-based vaginal microbicide that women could control. Confirmatory trials were quickly designed to see if the efficacy results could be replicated and improved, as required by regulatory bodies. The VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial was initiated to determine whether a woman's daily application vaginal gel or taking a daily tablet containing either 1 percent tenofovir or Truvada®[34] would be effective methods of prevention of sexual transmission of HIV. Following a midterm review, the tenofovir arms of the intervention were discontinued due to lack of evidence of effectiveness, however the evaluation of Truvada® was maintained and results are expected to be released in 2013 (Microbicide Trials Network (MTN), 2012b). The FACTS 001 (Follow-on African Consortium for Tenofovir Studies) trial began in 2011 and is studying the same tenofovir gel regimen as the CAPRISA 004 study in 2,200 women across South Africa; results from this trial are not expected to be available until 2014 (Microbicide Trials Network (MTN), 2012a). Clinical trials of other microbicidal products and routes of administration (e.g., time-release medication in vaginal rings) are also underway, with results expected in the next few years (AVAC, 2010). One study has also demonstrated the efficacy of vaginal tenofovir gel for use as a rectal microbicide, and several trials are currently underway to evaluate the safety, acceptability, and adherence for this product (Microbicide Trials Network (MTN), 2012a).

In the autumn of 2010, another HIV prevention milestone was achieved when the iPrEX study found that daily, PrEP with Truvada® reduced risk of HIV acquisition among gay and other MSM in the Americas, Asia and Africa by 42 percent (Grant et al., 2010). In 2011, two additional trials of heterosexual HIV-serodiscordant couples and individuals in a number of African countries (Partners PrEP and TDF2) also showed that daily, oral PrEP with Truvada® reduced risk of HIV infection by 62 percent to 73 percent (Baeten et al., 2012; Thigpen et al., 2012). However, a third study in Africa (FEM-PrEP) showed no efficacy of oral, daily PrEP on HIV infection in women (Van Damme et al., 2012). In all of these studies, the key factor in the level of the product's efficacy was adherence: the more individuals adhered to the prescribed drug regimen, the higher the level of efficacy found. In iPrEX, for example, drug level tests showed that those who took their pill every day as prescribed reduced their risk of HIV acquisition by over 70 percent (HHS, 2010).

HIV treatment with ART leads to significant reductions in viral load (Coetzee et al., 2004), and several studies that have analyzed the relationship between viral load and heterosexual transmission have found that reduced viral load was associated with reduced HIV transmission among serodiscordant couples (Attia et al., 2009; Donnell et al., 2010; Quinn et al., 2000). In the recent multisite HPTN 052 study published in 2011, 1,763 HIV-serodiscordant couples at 13 sites in 9 countries were enrolled either in an early treatment of HIV infection with ARV group (individuals with a CD4 count of 350 to 550) or in a delayed-therapy group where ARV was initiated at a CD4 count of 250 or after the development of an AIDS-related illness. Couples enrolled in the study were predominantly heterosexual (97 percent) and married (94 percent). Couples were required to have had a stable relationship for at least 3 months and to be

[34] Truvada® is a fixed-dose combination of tenofovir disoproxil fumarate and emtricitabine.

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willing to disclose their HIV status to their partners. During the trial, 12 additional HIV-uninfected partners were enrolled as the result of a new relationship and the original partner was released from the study. As part of the study protocol, both groups were provided with ongoing couples counseling on risk reduction, condoms, and adherence counseling at three monthly visits after enrollment, followed by quarterly visits. Adherence to the study treatment regimen (as measured by pill count) of at least 95 percent was observed in 79 percent of participants in the early-therapy group and in 74 percent of those in the delayed-therapy group.

In the initial trial design, the authors anticipated a total of 188 incidences of transmission. In the trial results, a total of 39 HIV transmission events were observed during the study period (a median follow up of 1.7 years); 35 in the delayed-therapy group and 4 in the early-therapy group. Of 39 total transmissions, 28 were confirmed to be linked virologically to the HIV-infected partner in the study, of which 27 occurred in the delayed-therapy group and one occurred in the early-therapy group. The investigators concluded that early initiation of antiretroviral therapy significantly reduced HIV transmission from HIV-infected individuals to their HIV-uninfected partners (Cohen et al., 2011). The study authors noted that the population of stable serodiscordant couples in the study may not be representative of the general population and that the provision of ongoing counseling and condoms likely contributed to the low incidence of HIV infection. They also reported more adverse events related to antiretroviral therapy in the early therapy group than in the delayed-therapy group.

In combination with the PrEP trials, this study added to the existing evidence that antiretrovirals can play a role in HIV prevention and the HPTN 052 results have influenced the direction of current HIV prevention efforts both globally and in PEPFAR. Ongoing efforts continue to contribute to the knowledge base on the likely effectiveness and contribution of antiretrovirals as a part of the prevention component of the HIV response. For example, a recent retrospective cohort analysis in China included over 38,000 serodiscordant heterosexual couples and analyzed the annual rate of HIV infection in the HIV-negative partners, stratified by whether the HIV-positive partner had received ART or was treatment naïve. The authors found a 26 percent relative reduction in HIV transmission for the cohort receiving treatment (Jia et al., 2012).

Despite emerging evidence and enthusiasm for the potential of treatment of HIV-infected persons for secondary prevention of transmission to their sexual partners, the cost, complexity, and clinical and public health implications of implementing this as a long-term approach at scale outside of trial conditions are not fully understood. Incorporating this as a prevention approach will not eliminate the need for effective primary prevention interventions delivered to uninfected persons at elevated risk of sexual HIV exposure (Hallett et al., 2011).

Given the potential of these and future new prevention technologies to markedly reduce HIV transmission and acquisition globally, it will be important for PEPFAR to quickly determine how best to incorporate them into the programs it supports; the committee understands that PEPFAR is already taking these scientific advancements into consideration. This will involve engaging and supporting social science research and implementation science (or operations research) to answer questions about the desirability, feasibility, cost-effectiveness, and impact of scaling-up new prevention methods in various countries, settings, and health care delivery and community-based service systems.

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SUMMATION

Making strong global and national commitments to HIV prevention, with commensurate resources, expertise, and research, is critical to any balanced attempt to change the course of the HIV epidemic. The 2001 UN's Declaration on Commitment on HIV/AIDS stated that "Prevention must be the mainstay of our response" (United Nations General Assembly, 2001). Not only does this continue to be a central tenet of the global HIV/AIDS response, PEPFAR was directed by its reauthorization legislation to prioritize HIV prevention going forward, and this expectation is being passed on to partner countries as part of the emphasis for sustainable management of HIV responses. As a common theme during country visit interviews, the committee also heard that prevention must be a mainstay of an HIV response and that many stakeholders felt that their countries' HIV prevention efforts need to be strengthened.

With the evolution of PEPFAR's prevention programming and changing priorities, prevention has developed into a "catch all" term for many disparate concepts and activities that have not been clearly oriented around a strategic objective. Over time, OGAC has provided more guidance and technical support documentation, including population-specific guidance. In addition, PEPFAR has recently articulated a commitment to overarching goals for prevention (Clinton, 2012; OGAC, 2012a; PEPFAR, 2011b). However, despite these developments, ambiguity remains about the operational objectives and targeted outcomes for prevention as well as the best ways to develop, implement, and monitor a comprehensive prevention portfolio across all modalities that reflects country context and incorporates the ongoing evolution of the evidence base.

For prevention activities to be maximally effective program planners must have access to appropriate data that will inform which combinations of prevention activities and interventions are most effective and best suited for implementation for specific populations, epidemiological contexts, and a variety of settings including different geographic areas, governmental and nongovernmental sectors, facilities, and communities. Despite remaining knowledge gaps for monitoring and evaluating prevention interventions, PEPFAR has supported a variety of data collection for prevention planning, especially at the country level.

> **Overall Conclusion:** PEPFAR's support for the scale-up of HIV prevention activities across prevention modalities has been an achievement and a contribution to the response to the epidemic in partner countries. Within PEPFAR, there has been an evolution in prevention programming, from an initial focus on a limited number of behavioral and biomedical interventions, to an expansion of prevention portfolios to reflect both existing and emergent evidence-based approaches. Although PEPFAR has articulated a commitment to overarching goals for prevention, PEPFAR lacks clear target outcomes and objectives across all prevention modalities; this is especially the case for behavioral and structural interventions for prevention of sexual transmission, the primary global driver of HIV infection. To achieve its overall goal of reducing new infections and stopping the spread of the epidemic, PEPFAR will need a more comprehensive and balanced approach, with greater clarity in its operational guidance and mechanisms to support the development, implementation, monitoring, and evaluation of prevention portfolios in country programs that are aligned with the drivers of epidemics and the needs for prevention services.

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Greater attention to developing appropriate approaches to assess the effectiveness of prevention interventions across all modalities and modes of transmission would contribute to this more balanced and comprehensive operational approach.

Recommendation 5-1: To contribute to sustainable management of the HIV epidemic in partner countries, PEPFAR should support a stronger emphasis on prevention. The prevention response should prioritize reduction of sexual transmission, which is the primary driver of most HIV infections, while maintaining support for interventions targeted at other modes of transmission. The response should incorporate an approach balanced among biomedical, behavioral, and structural interventions that is informed by epidemiological data and intervention effectiveness evidence. PEPFAR should support advances in prevention science to expand the availability of effective interventions where knowledge is lacking.

Further considerations for implementation of this recommendation:

- PEPFAR has made a commitment to overarching goals for prevention and for achieving an AIDS-Free Generation, but this does not constitute a long-term prevention strategy that clearly states prevention objectives and the pathways to achieving them. The following elements will be critical for a more comprehensive strategy to achieve successful execution of prevention programs:
    - PEPFAR should continue to enhance its efforts to involve partner country stakeholders and incorporate country-specific epidemiology, context, and priorities in planning appropriately-matched prevention programs that achieve a balanced approach to HIV prevention across the available modalities. To provide greater technical and operational clarity, OGAC should provide mechanisms to support the development, implementation, and monitoring of comprehensive prevention portfolios; including how to determine what populations need which directed prevention activities in which settings. Areas of prevention where current interventions are successful and effective, such as PMTCT, should be continued and scaled up to ensure access, coverage, and quality. As new PEPFAR-supported prevention activities are adopted, OGAC should communicate their objectives and the methods for introducing or scaling up with specified populations.
    - OGAC should improve mechanisms to collect and incorporate evidence on the effectiveness of prevention activities implemented in partner countries. The key components for future assessment and evaluation of HIV prevention should include need, coverage of need, quality of services provided, and behavioral and epidemiological outcomes. OGAC should provide clearly defined process and outcome measures as well as impact assessment methods to evaluate progress.
    - PEPFAR's prevention strategy should include balanced support for innovation, research, and evaluation to contribute to the evolving evidence base and advance understanding of the effectiveness of interventions within all prevention modalities. To define and ensure this balance, OGAC

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should, through its existing mechanisms, convene and use expertise spanning behavioral, structural, and biomedical prevention intervention approaches. PEPFAR-supported research and evaluation activities should employ appropriate methodologies and study designs, without unduly emphasizing random assignment designs. PEPFAR should support innovations in prevention science methodologies where needed to achieve its programmatic research aims (see also Recommendation 11-1).

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6
Care and Treatment

Main Messages

HIV Counseling and Testing

- PEPFAR's efforts have led to a considerable achievement in increasing availability of and access to HIV testing, counseling, and diagnosis. As a result, many more individuals have learned their HIV status and, if positive, been linked to clinical services. However, challenges remain in achieving adequate coverage of testing services, especially in scaling up and improving access to testing for infants and children and for testing for pregnant women who do not attend antenatal care or deliver in health facilities. For those who test positive, challenges also remain in consistently ensuring they are linked to care and treatment as well as prevention services to reduce HIV transmission. Overcoming these challenges and continuing to make progress in HIV counseling and testing will be a critical factor in achieving a successful comprehensive response to HIV.

HIV Care and Treatment Services

- PEPFAR has made a major contribution to increasing the number of people living with HIV who are in care and on antiretroviral therapy (ART) through the expansion of the number and geographic distribution of care and treatment sites, the training of providers, the procurement and delivery of drugs, improvements in laboratory services, and support for the adoption and implementation of national policies and guidelines in partner countries. Support for care and treatment programs is a success that has contributed to saving lives and improving the quality of life for people living with HIV in PEPFAR partner countries.
- Retention and adherence are critical and persistent challenges in PEPFAR-supported HIV care and treatment programs. Understanding the factors that contribute to the lack of retention and the most effective strategies to improve it are needed to fully maximize the role of care and treatment in a sustainable HIV/AIDS response.
- PEPFAR has made a tremendous contribution to a wide variety of clinical and nonclinical care and support services, beyond provision of antiretroviral therapy, through scale-up of services and programs in facilities and communities and through support for partner country policies, guidelines, and protocols. However, for the area of nonclinical care and support in particular, services span a diffuse range of activities across countries and it is difficult to assess their effects. Information is lacking on the distribution of services, the intended outcomes, how well the services are matched to population and subpopulation needs, and the effectiveness of these services.
- The particular importance of efforts to address HIV and tuberculosis (TB) is well-recognized within PEPFAR and in partner countries, given that TB is a common co-infection and leading cause of death for people living with HIV. PEPFAR has increasingly supported integration and coordination of screening, diagnosis, and referrals or other linkages to treatment for both infections. PEPFAR has also made a notable contribution in its support for advancing policies and systems for TB/HIV integration in partner countries. However, progress in this area has come more slowly than in other clinical services for HIV, and challenges persist in achieving adequate coverage of both HIV screening for TB patients and TB screening for HIV patients, as well as in ensuring and monitoring subsequent referral and retention in treatment for both infections. Concerted efforts in this area will be critical for reducing mortality from TB/HIV as part of an effective response to HIV.

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- The expansion of treatment has an ancillary effect of increasing drug resistance. The earlier ART programs were implemented in a region, the more drug resistance is present. With the limited availability of second line antiretroviral drugs in resource-limited settings, as drug resistance increases, the need for an expanded pharmaceutical arsenal for effective treatment intensifies. The emergence of HIV drug resistance is cause for greater efforts to improve the effectiveness and expand the implementation of adherence support, treatment failure and drug resistance monitoring strategies, and treatment options in resource-limited settings.
- The ability to assess the impact of PEPFAR-supported care and treatment programs across countries and partners is restricted by limitations in the available data. The available program-wide output measures provide a sense of the growth of PEPFAR supported treatment programs over time but do not provide an understanding of the distribution of those services in populations of interest and do not provide a measure of effectiveness and outcomes. It was a missed opportunity not to invest more resources earlier in standardized, realistic, and useful monitoring of outcomes.

Ongoing Challenge of Coverage

- Despite progress in the availability of and access to HIV services, there remains a large unmet need for care and treatment in PEPFAR partner countries. Intrinsic limitations of the health system infrastructure continue to be barriers to delivery of care treatment services including clinical care, clinical and laboratory monitoring, and antiretroviral therapy.
- Treatment of infants and children remains a persistent challenge across the continuum of care. The main barriers, especially for infants, come at the stages of testing and diagnosis, linkages to care and treatment, and timely initiation of therapy. Limitations in health systems for support of pediatric HIV services are also a major factor. PEPFAR has contributed to increasing pediatric treatment, but the coverage of pediatric HIV remains proportionally much lower than coverage for adults, despite the goal in the reauthorization legislation to provide care and treatment services in partner countries to children in proportion to their percentage within the HIV-infected population.

Sustainability of HIV Treatment

- The large numbers of currently enrolled patients who need to be maintained, those currently eligible but not yet enrolled, and the potential for expansion of eligibility if changing WHO guidelines are adopted and implementedare fundamental challenges for achieving adequate coverage and for the sustainability of care and treatment across PEPFAR partner countries. Intrinsic limitations in the health system and other systems involved in the response continue to be barriers to delivery of services, as do the realities of resource constraints, especially with the possible flattening or decreasing of external resources. the most critical challenge for the future is for PEPFAR to work with partner countries and global partners to sustain the gains made, to continue to make progress, and to ensure the ongoing quality of services provided and programs implemented. Given that this challenge must be confronted while facing limited resources, contributing stakeholders will need to allocate resources with a strategic and ethical balance among coverage priorities.

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Recommendations Presented in this Chapter

Recommendation 6-1: To improve the implementation and assessment of non-clinical care and support programs for adults and children, including programs for orphans and vulnerable children,[1] the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.

Further considerations for implementing this recommendation (Chapter 6):

- Outcomes for consideration should reflect the aims of care and support programs, which are to optimize quality of life, promote health, slow the progression of AIDS, and reduce HIV-related complications and mortality. Other outcomes of importance for the performance and effectiveness of care and support programs include measures of quality of services and equitable access to services.
- PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to assess country-specific needs and select a subset of the core key outcomes to focus on when planning, selecting, and developing evidence-informed activities and programs for implementation.
- OGAC should provide general guidance for country programs on continuous program evaluation and quality improvement to measure and monitor achievement of the key outcomes. This may include, for example, template evaluation plans and methodological guidance. To allow for comparability across countries and programs, evaluation plans should include (but not be limited to) the defined indicators or other measures of the core key outcomes. Evaluations should emphasize the use of in-country local expertise (e.g., local implementing partners/subpartners and local academic institutions) to enhance capacity building and contribute to country ownership. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11).
- PEPFAR should develop a system for active dissemination and sharing of evaluation outcomes and best practices both within and across countries that is driven as much by country-identified needs for information as by opportunities for exchange of information identified by headquarters-level leadership and Technical Working Groups. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11).

[1] The discussion of programs for orphans and vulnerable children leading to this aspect of this recommendation can be found in Chapter 7.

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Recommendation 6-2: To contribute to sustainable care and treatment programs in partner countries, PEPFAR should build on its experience and support efforts to develop, implement, and scale up more effective and efficient facility- and community-based service delivery models for the continuum of adult and pediatric testing, care, and treatment. These efforts should aim to enhance equitable access, improve retention, increase clinical and laboratory monitoring, ensure quality, and implement cost efficiencies.

Further considerations for implementation of this recommendation:

- This recommendation should be implemented in coordination with recommendations and considerations discussed in Chapter 9, Health Systems Strengthening.
- PEPFAR should develop a system for active dissemination and sharing of best practices in service delivery both within and across countries. (See also recommendation for PEPFAR's Knowledge Management in Chapter 11).

Recommendation 6-3: To assess PEPFAR-supported HIV care and treatment programs and to evaluate new service delivery models, the Office of the U.S. Global AIDS Coordinator should support an enhanced, nested program monitoring effort in which additional longitudinal data on core outcomes for HIV-positive adults and children enrolled in care and treatment are collected and centrally reported from a coordinated representative sample across multiple countries and implementing partners.

Further considerations for implementation of this recommendation:

- This activity would serve as a targeted, nested evaluation within routine program monitoring systems to allow for long-term operational assessment of performance and outcomes for care and treatment across a representative sample of PEPFAR-supported programs. The aim would be to focus on key areas for evaluation and improvement of programs going forward, including as PEPFAR supports innovations in service delivery and as PEPFAR-supported programs transition to new models of implementation.
- Data collected and reported for this sample should be harmonized with existing data collection whenever possible, including data already collected by implementing partners but not centrally reported (for example, see the discussion of Tier 3 data in the implementation considerations for Recommendation 11-1A). Collaborative opportunities may be feasible with existing or new large-scale national and multicountry samples.
- This data collection effort should be designed by first identifying and prioritizing the key questions that require longitudinal data and then focusing on relevant key outcomes with measures that are standardized across the sample. Priorities should include core outcomes related to clinical care and treatment, including adherence and retention; outcomes related to the reduction of HIV transmission through biomedical and behavioral prevention interventions for people living with HIV; quality measures; and program measures, such as the costs of services, that can help inform strategies for efficiencies, sustainable management, and resource planning for the trajectory of need.
- There may also be opportunities for an established data collection effort of this kind to serve as a synergistic platform for targeted implementation research studies in subset samples to assess innovations and advance best practices with maximal readiness for translation for scale-up.
- In addition to implementing this approach prospectively, OGAC should explore working with and coordinating Track 1.0 partners to pool data for retrospective outcome analyses.

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6

Care and Treatment

One of the cornerstones of PEPFAR has been a major investment in meeting the tremendous challenge of supporting and scaling up services for HIV care and treatment in countries with limited resources and infrastructure and a high burden of disease. The congressional charge for this evaluation, as laid out in the Lantos-Hyde Act of 2008, requested an evaluation of the impact of treatment and care efforts on health, including an assessment of progress toward treatment and care targets and an evaluation of the effects of treatment and care programs on survival rates, drug adherence, and the emergence of drug resistance.[1]

This chapter describes the committee's assessment of PEPFAR's support for testing, care, and treatment services together, as part of a continuum of HIV-related services (Figure 6-1) (Eldred and Malitz, 2007; Gardner et al., 2011). All along this continuum there are interventions and efforts supported by PEPFAR: testing and diagnosis as the entry point into care and treatment services; referrals and linkages to care services; provision of clinical care services, nonclinical support services, and monitoring for those not eligible for antiretroviral therapy (ART); initiation of ART when eligible; maintenance and retention on ART with continuation of non-ART clinical care and nonclinical support services; and monitoring for treatment failure with initiation of second-line treatment as needed. This chapter describes the committee's assessment of PEPFAR's efforts, focused on its activities to support the scale up of service delivery, in each of the components of this continuum sequentially, providing for each some brief background and then following the program impact pathway framework of inputs, activities, and, to the extent possible, outcomes and impact of PEPFAR's efforts.

[1] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008) , §101(c), 22 U.S.C. 7611(c)(2)(A)(i-ii).

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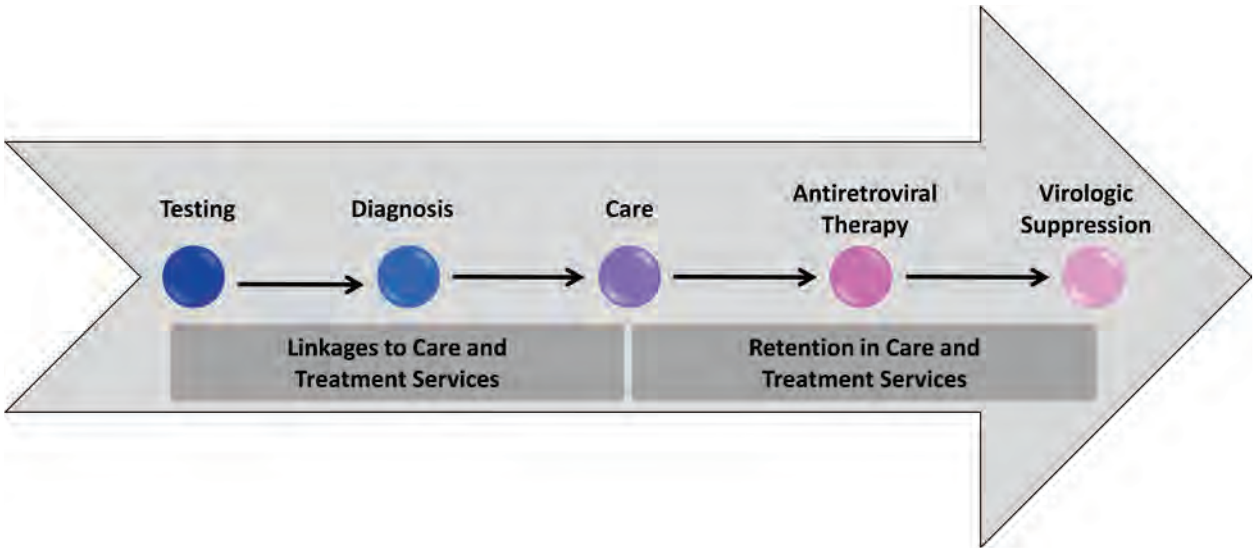

FIGURE 6-1 Implementation cascade for the continuum of care.
SOURCE: Adapted from (IOM, 2012) and (Das, 2011).

The continuum of care described here is directed toward virological suppression and improved health, wellbeing, and survival for individuals who are HIV positive; however, another ultimate goal of the HIV response is a population-level reduction of the burden of HIV and of mortality due to HIV/AIDS. The contribution of PEPFAR to this aim, to the extent that it can be assessed, is discussed at the end of this chapter.

Although this chapter will focus on PEPFAR's support for the provision of testing, care, and treatment services, it is also important to note that this continuum for care and treatment intersects with other services that are supported by PEPFAR programming and other opportunities where PEPFAR has a role in facilitating an effective response, as well as where interrelated challenges that affect care and treatment can arise. These other program areas are discussed elsewhere in this report, including prevention services (Chapter 5), programs for orphans and vulnerable children (Chapter 7), and efforts to address gender-specific aspects of HIV (Chapter 8). Along with the intersection with these other services, care and treatment programs also are inextricably linked to elements of the health system, including infrastructure, commodities and supply chain, workforce, management, leadership, and financing that are required to support service delivery; these areas are touched upon only briefly in this chapter, while the primary discussion can be found in Chapter 9 on health systems strengthening. Finally, a multisectoral response to HIV also relies on other, non-health systems and operates in the broader context of the economic, social, cultural, and political environments, which are all part of the broader context of a multisectoral response to HIV. This broader context both contributes to and poses challenges to the effectiveness of the HIV response.

HIV COUNSELING AND TESTING

Early in the HIV epidemic, voluntary HIV testing programs were intended to increase the number of people aware of their HIV status and to serve as an entry point for counseling and other prevention services, for those who were both HIV positive and HIV negative, with the aim of reducing HIV transmission and infection. Early programs faced challenges such as fear of

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stigma and discrimination, complex laboratory methods, and a lack of available care and treatment services (Marum et al., 2012). With the introduction of more widespread access to care and treatment services and support for laboratory and other related services, HIV testing now serves as a crucial gateway to HIV treatment, care and support, and the prevention of mother-to-child transmission (PMTCT), while the initial intent of providing counseling and an entry point to prevention services also remains (Mahungu et al., 2009; Medley et al., 2004). Access to testing early in the course of HIV infection is of particular importance given that people living with HIV/AIDS (PLHIV) who receive treatment later in their disease consequently have poorer outcomes (WHO, 2012c).

The following section presents the committee's assessment of PEPFAR-supported HIV counseling and testing programs, with information on PEPFAR's funding history and activities as well as the effects of these activities, including achievements and challenges. This section focuses primarily on testing services because it was difficult to comprehensively assess the effects of counseling services that are intended to accompany testing, including discussions that take place before and after an HIV test to increase knowledge, convey prevention and risk reduction messages, provide supportive counseling, and facilitate referrals to services. There is very little available information to track this component of counseling and testing in terms of how PEPFAR-supported activities have been implemented and what the outcomes of these activities have been.

PEPFAR Funding History for Counseling and Testing

PEPFAR's funding for counseling and testing is captured in a single budget code. Figure 6-2 shows the funding over time in this budget code in both the dollar amount and as a proportion of all PEPFAR funding. The total for this budget code increased substantially over time during the first phase of PEPFAR, leveling off starting in FY 2008 at just over $200 million per year.

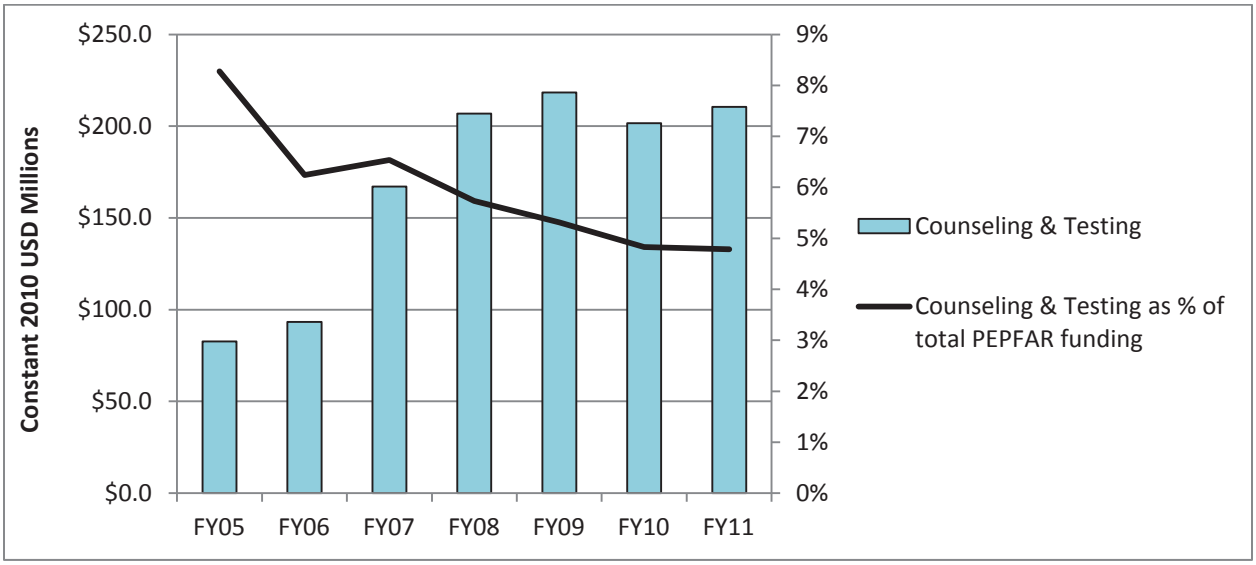

FIGURE 6-2 Planned/approved funding over time for counseling and testing services (by fiscal year).
NOTE: This figure represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by

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programmatic area. Data are presented in constant 2010 USD for comparison over time. Currently, funding for testing and counseling in the context of PMTCT can be included under the PMTCT budget code or the Counseling and Testing budget code, and so some investment in testing in that context may not be reflected here. Similarly, funding for testing and counseling in the context of TB services is under the TB budget code and is not reflected here (OGAC, 2011). See Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding.
SOURCE: (OGAC, 2005, 2006c, 2007b, 2008, 2010c, 2011d, 2011e)

PEPFAR Guidance for Supported Activities for Counseling and Testing

PEPFAR does not issue specific programmatic guidance on counseling and testing, but refers programs to World Health Organization (WHO) standards and provides operational guidance in its annual Country Operational Plan (COP) guidance, which describes counseling and testing activities in a range of health-facility- and community-based settings that include HIV testing and counseling provided through both client-initiated approaches and provider-initiated approaches (OGAC, 2011b). HIV counseling and testing is part of the package of services in a range of PEPFAR technical areas including medical male circumcision, prevention with positives, preventing mother-to-child transmission, services for populations at high risk, adult treatment, care and support, pediatric treatment, and tuberculosis (TB) services.

The COP guidance instructions include examples of settings, including health facilities (e.g., antenatal clinics, TB clinics, outpatient clinics) and other settings such as counseling and testing through home-based, mobile, and outreach efforts including special events, campaigns, and promotional activities for demand creation. Other related activities may include training or refresher training in areas such as retesting recommendations, couples counseling and testing, and quality assurance; strengthening and monitoring referrals and linkages, including tracking or follow-up of HIV-positive individuals not enrolling in care or treatment services; and activities for quality assurance of both testing and counseling. For planning activities through different partners, the guidance also instructs that target populations should be specified including, if known, the HIV prevalence and testing coverage in those populations and specifying the linkages between testing and services in other technical areas.

Effects of PEPFAR-Supported HIV Testing

PEPFAR Testing Indicator Data: Targets and Results

PEPFAR has limited central reporting of indicators to reflect the performance of its testing programs. The primary indicator is an overall output indicator capturing the number of individuals who received counseling and testing for HIV and received test results. Table 6-1 shows that the number tested with the support of PEPFAR has increased notably over time, and after the initial year of implementation the annual target has been consistently met or exceeded.

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TABLE 6-1 Number of Individuals Who Received Counseling and Testing for HIV and Received Test Results (in Millions)

	FY04	*FY05*	*FY06*	*FY07*	*FY08*	*FY09*	*FY10*
Actual	1.3	2.5	5.1	9.3	16.4	21.2	32.7
Target	--	2.6	4.8	6.1	9.0	13.2	25.8
% of Target	--	96	106	153	182	160	127

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Results and targets correspond to OGAC indicator 9.2 (direct)/ P11.1.D.
SOURCE: Program monitoring indicators provided by OGAC.

Monitoring of Testing Services

The monitoring of testing services is affected by a number of challenges. One prominent challenge in tracking the number of individuals who have received testing services is the potential for double counting of testing clients, some of whom may be accessing testing services repeatedly, either due to a lack of confidence in the results or because they have tested negative but are accessing periodic testing to due to high, ongoing, or new risk exposure. The lack of unique patient identifiers poses a generally recognized challenge for monitoring counseling and testing services, and was also identified as a challenge by interviewees in several countries who described that patients will decide to test more than one time (587-18-PCGOV; 587-02-USG; 587-09-USG), to go to more than one community to be tested (331-23-USNGO), or to hide previous testing (461-16-USG).[2] The lack of unique identifiers for the people tested prevents the adjustment of these numbers (461-16-USG; 587-02-USG). In addition, without unique identifiers it is difficult to track whether individuals are being successfully referred for additional services following their test results; the data are largely cross-sectional and do not allow for longitudinal individual follow-up. Other challenges identified by interviewees in some countries that interfere with collecting quality data on testing services included the use of different counseling and testing reporting systems by PEPFAR and the national system (587-09-USG) and the practice of only registering in patient tracking databases those who test positive (272-21-PCNGO).

Challenges with accurate monitoring of testing services and outcomes affect planning and management not only for testing services but also for other target areas that are dependent on estimates of the numbers of people identified as living with HIV.

PEPFAR Achievements in Scale-Up of Testing

The implementation of PEPFAR-supported services has resulted in a considerable expansion of service delivery and in an increase in the numbers and proportion of individuals in PEPFAR partner countries, and indeed globally, who are aware of their HIV status (WHO, 2012e; WHO et al., 2011). Consistent with this, across countries visited for this evaluation, interviewees noted that before PEPFAR there was no counseling and testing program, or, if

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[2] Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Non-country Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO

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available, only on a small scale with few facilities to provide this service, and uptake of counseling and testing was low (240-02-USG; 396-23-USG; 116-16-PCGOV). Challenges related to HIV testing remain, as will be discussed further below, but overall interviewees considered PEPFAR's efforts in testing a success that has led to increased access to testing and counseling, with the result that many more individuals have learned their HIV status and, if positive, been linked to clinical services.

PEPFAR helped partner countries to initiate counseling and testing and scale up the number of facilities and other venues to provide this service (461-14-USG; 396-23-USG; 116-16-PCGOV; 272-ES; 331-32-PCNGO; 935-17-USG; 240-02-USG). As a contribution to this scale-up PEPFAR has not only supported testing services but has also helped develop guidelines related to counseling and testing, promoted the implementation of innovative approaches and emergent testing methods, and advocated for more aggressive policies for HIV testing in the setting of not only high-prevalence countries but also concentrated epidemics (196-11-USNGO; 396-23-USG; 272-13-USG; 542-08-USNGO; 396-23-USG; 331-18-USNGO). PEPFAR's contribution through the activities it has supported related to scale-up of testing has also increased public awareness of both HIV and the availability of HIV counseling and testing in partner countries. Awareness efforts have involved a diversity of strategies and settings, such as hotlines, national testing initiatives, drop-in centers, health fairs, posters, media channels, and engaging peer educators, worksites and employers, community service organizations, and faith based organizations (587-14-PCGOV; 166-05-USG; 331-07-PCNGO; 331-22-PCNGO; 396-32-PCGOV; 196-20-PCNGO; 166-14-PCNGO; 240-02-USG; 272-24-USG; 587-08-PCGOV; 636-06-USG; 636-17-PCGOV; 331-38-USPS; 934-17-PCGOV; 331-22-PCNGO; 396-12-USG; 396-44-PCGOV; 196-23-PCNGO).

Evolution of Testing Approaches Over Time

In scaling up testing services, PEPFAR has supported both client-initiated approaches and, increasingly over time, provider-initiated approaches. Initially most PEPFAR-supported testing was client-initiated testing based in facilities (935-17-USG). In the beginning of the program, client-initiated testing was implemented mostly in separate facilities, but later the need for integration of testing with other key services was recognized as a way to facilitate access to and provide a less stigmatized environment for HIV testing; efforts were made towards more integration with, for example, antenatal care, child health programs, primary health care, and TB services (272-24-USG; 331-28-PCGOV; 272-24-USG; 587-05-PCGOV; 636-17-PCGOV; 396-18-USG). As another avenue to increase access to and availability of HIV testing, PEPFAR moved to implement more client-initiated testing services outside of facilities. These approaches include home-based testing, testing in community settings, and mobile clinics (116-12-PCNGO; 116-13-PCNGO; 331-11-PCNGO; 461-07-PCNGO; 461-24-PCNGO; 35-17; 116-12-PCNGO; 935-17-USG; 116-13-PCNGO; 240-02-USG). Interviewees identified these approaches as ways to expand testing, allow for earlier detection of HIV, and facilitate access to testing and referrals to services for specific populations at high risk (166-13-PCGOV; 542-11-PCNGO; 935-17-USG; 542-14-PCGOV). Home-based counseling and testing has been more recently implemented on an increasing scale in several countries, and the initial achievements of adopting a home-based approach were highlighted as an indication of its potential to better integrate HIV treatment and prevention and to reach more couples, especially male partners (935-17-USG; 461-07-PCNGO; 116-12-PCNGO). Mobile clinics were viewed as a particularly useful strategy to offer testing services to populations at high risk who are also highly mobile or transient (396-44-PCGOV; 196-25-PCNGO).

In addition to expanding client-initiated testing services, as the adoption of provider-initiated counseling and testing emerged globally (Marum et al., 2012; WHO and UNAIDS, 2007) PEPFAR widely supported its implementation in partner countries in both outpatient and

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inpatient health facilities (935-17-USG; 116-12-PCNGO; 240-08-USG; 272-24-USG; 240-24-USG). This approach was encouraged as another means to increase access to testing and improve coverage in facility-based testing in general, and also to reduce missed opportunities to test those patients who present to health facilities under circumstances where there is reason to consider them at high risk for HIV, such as TB patients or patients hospitalized with illness that could be due to opportunistic infections (196-11-USNGO; 196-17-PCGOV). In addition to supporting provider-initiated counseling and testing (PICT) in PEPFAR-supported service delivery, interviewees also noted PEPFAR's contribution to the inclusion of PICT in the national strategy, the scaling up of training for PICT to the national level, and the development of training guidelines (196-11-USNGO; 636-06-USG).

Targeted Testing

Interviewees highlighted several efforts to target vulnerable or difficult to serve populations for counseling and testing. In addition to the use of targeted community-based and mobile testing to reach populations at high risk described above, some other examples of specific counseling and testing efforts included a campaign to offer counseling and testing services in locations and at times that guarantee privacy for men who have sex with men, night-time mobile testing services to reach sex workers and their clients, a referral system for sex workers to increase their access to testing, efforts to improve referrals and access to testing services specifically for women who inject drugs, and mobile outreach services including testing for street children (935-17-USG; 935-16-USNGO; 331-22-PCNGO; 542-11-PCNGO; 196-24-PCNGO; 542-14-PCGOV). PEPFAR's support for services for these populations is discussed in more depth in Chapter 5, Prevention and Chapter 8, Gender.

Another population with special consideration for testing is pregnant women; reaching this population ideally provides an entry point into both services for prevention of mother-to-child transmission and care and treatment services for women who are HIV positive. Interviewees noted PEPFAR's achievements in the effort to reach pregnant women with HIV testing, especially in antenatal clinics and at delivery in health facilities. Interviewees affirmed that pregnant women were increasingly likely to be offered and accept testing for HIV when receiving antenatal care, particularly during their first antenatal visit (166-05-USG; 331-28-PCGOV; 166-27-PCNGO; 166-05-USG; 166-27-PCNGO; 587-5-PCGOV; 636-22-PCNGO; 636-01-USG; 636-06-USG). Despite the relative success and progress in testing for this population, interviewees emphasized that coverage gaps do remain, especially for pregnant women who do not make a visit to antenatal care clinics or to facilities for delivery (240-ES; 240-2-USG; 240-13-PCGOV; 240-19-USACA; 240-24-USG; 636-2-USG; 461-7-PCNGO; 396-42-PCGOV; 587-5-PCGOV; 636-06-USG). Issues related to access to testing and PMTCT services for pregnant women are discussed in more depth in Chapter 5, Prevention. There are also gaps in linking testing for pregnant women with testing for their male partners; PEPFAR has supported efforts around engagement of male partners in PMTCT services (331-27-PCGOV; 587-9-USG; 636-9-USACA; 116-15-USNGO).

Infants and children are another critical and challenging population with respect to HIV testing; efforts for this population are discussed in depth later in this section of the chapter.

In some cases the targeting of testing services was described as resulting in some conflict and lack of alignment with national priorities and planning in partner countries. In these cases, typically generalized testing was a priority for the partner government, while PEPFAR was advocating that the most strategic use of available resources for testing would be to prioritize identified high risk populations or higher prevalence geographic areas (587-22-USG; 240-02-USG; 396-23-USG).

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Other Efforts Related to Testing

In addition to the delivery of counseling and testing services to clients, other areas are critical for testing in which PEPFAR has supported activities in partner countries at the level of health systems. These are noted briefly here; health systems strengthening is discussed in more depth in Chapter 9.

Interviewees across countries described PEPFAR's contribution to testing through the construction of laboratories, strengthening central laboratory services to receive district samples, and capacity building of technical staff (935-08-PCGOV; 542-08-USNGO; 396-25-PCGOV; 934-05-USG). Beyond training laboratory staff, other workforce activities funded by PEPFAR with respect to testing have included the training of counselors in counseling and testing, the training of supervisors on PICT, and the training of health care workers to do HIV rapid testing (272-13-USG; 116-12-PCNGO). The training of non-laboratory workers to do testing was described by one interviewee as having a '*huge impact*'[3] (272-13-USG), but in other cases this approach has encountered policy barriers related to scope of work that limited the ability of programs to expand home-based testing and testing in facilities without laboratory staff (935-ES). PEPFAR has also supported the supply chain for counseling and testing through the provision of test kits as well as through transportation solutions for delivery of samples (935-08-PCGOV; 935-13-PCGOV). Other examples include PEPFAR support for the strengthening of information systems (396-36-PCGOV) and providing access to electronic tools to track samples and to register the positive cases tested (935-17-USG).

Interviewees also mentioned several examples of PEPFAR introducing counseling and testing quality assurance strategies to ensure providers maintain quality services (935-17-USG; 272-13-USG; 934-05-USG). These efforts included setting up quality assurance programs at the national level (461-18-USG), the use of the HIVQUAL system through the U.S. Centers for Disease Control and Prevention (CDC) and Ministry of Health (587-09-USG), and training supervisors on PICT and HIV testing and counseling (116-12-PCNGO). At the same time, in some countries challenges were noted with quality assurance, due for example to the lack of a system to measure the quality of HTC services and issues with standardization for counseling and testing services (166-05-USG; 272-25-USG).

Ongoing Challenges with Coverage of HIV Testing

Despite the achievements in the scale-up of HIV testing in PEPFAR partner countries, challenges with adequate coverage remain, with low rates of testing and low knowledge of HIV serostatus (particularly among HIV-infected persons) and the need to achieve coverage goals of HIV treatment and prevention programs (Gilliam et al., 2012; OGAC, 2011c). This limits the ultimate success of testing services as part of the continuum of HIV prevention, care, and treatment services as part of a comprehensive response to HIV. Several interviewees on country visits remarked that, although the progress in testing coverage since the initiation of PEPFAR has been a notable achievement, there continue to be large numbers of people who do not know their HIV status (196-14-PCGOV; 331-10-PCGOV; 240-09-USG; 935-08-PCGOV; 636-11-PCNGO; 166-13-PCGOV). As one interviewee put it, a *'key challenge is getting more people access to counseling and testing'* (166-13-PCGOV). Interviewees noted a host of factors that, in their experience supporting the implementation and delivery of these services, affect whether people access counseling and

[3] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

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testing services. In most cases these are barriers that PEPFAR's efforts to date have aimed to overcome and, as described above, PEPFAR's contribution has led to remarkable progress. Nonetheless, this ongoing challenge of coverage remains an important factor to address as it will otherwise hinder efforts to further advance PEPFAR's efforts and to achieve future HIV-related goals.

Many of the factors affecting coverage had to do with how readily available testing services are, which is affected by geographic location; necessity of referring to another site for testing; distance and transportation issues; client socioeconomic status; long wait times; availability of trained counseling and testing and laboratory personnel; and availability of laboratory equipment and commodities such as test kits and reagents (240-02-USG; 396-25-PCGOV; 587-05-PCGOV; 396-21-USG; 934-05-USG; 272-13-USG; 196-24-PCNGO; 196-27-USG; 166-05-USG; 166-15-USACA; 196-10-PCGOV; 461-14-USG; 461-10-PCNGO;587-05-PCGOV; 636-22-PCNGO; 935-17-USG; 935-24-USNGO; 935-14-USG; 461-14-USG; 166-10-USNGO; 272-25-USG; 116-20-USNGO; 636-17-PCGOV; 196-17-PCGOV; 542-08-USNGO). Other factors described by interviewees had more to do with the engagement of individuals in accessing these services, which they described as affected by stigma, concern about discrimination, cultural norms about accessing health services, fear of experiencing violence or separation from a spouse or partner, and fear of losing family support (636-11-PCNGO; 331-07-PCNGO; 935-15-ONGO; 166-05-USG; 240-ES; 166-27-PCNGO; 331-06-CCM; 166-05-USG).

These interviewee perspectives on barriers affecting a lack of coverage of HIV testing are consistent with the research literature, which has documented that even when HIV testing is available discrepancies persist between intention to be tested and actually being tested (Obermeyer and Osborn, 2007) and has similarly shown that engagement in testing is affected by complex factors such as awareness of and accessibility to testing and health care and perceived risk, stigma, fear, discrimination, and threat of violence (Bartlett et al., 2008; Medley et al., 2004; Padian et al., 2011). Women are particularly vulnerable to stigma, domestic violence, and abandonment related to testing outcomes (Visser, 2012; WHO, 2006a), yet are more likely to report having had an HIV test than men (WHO, 2011a). The increased likelihood of testing among women is in large part associated with their participation in antenatal care (WHO, 2012c).

The fear of violence or abandonment as a result of an HIV diagnosis was raised in several countries as a salient and critically important issue for some women, and is discussed in more depth in Chapter 8, Gender, along with additional discussion of cultural norms and gender differences in accessing HIV and other health services.

HIV Testing for Children

PEPFAR has supported activities for the identification and diagnosis of children as part of its PMTCT and pediatric HIV programs since early in the program, but it was not until the second PEPFAR Five-Year Strategy that a specific goal was articulated, that of ensuring by 2014 that every partner country with a generalized epidemic reach a threshold of 65 percent coverage for early infant diagnosis at the national level, and testing of 80 percent of older children of HIV-positive mothers, along with increased referrals and linkages to care and treatment (OGAC, 2009d). PEPFAR's activities include efforts to increase early identification of HIV exposure and infection status in children. However, HIV testing for infants and children is a particularly challenging area.

HIV Testing for Infants

Early infant diagnosis (EID) has been a focus of increasing attention over time in PEPFAR-supported programs. In the FY 2009 annual report to Congress, PEPFAR reported its

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support for "expanding polymerase chain reaction (PCR) testing to identify the presence of HIV" including "country-level policy change to allow PCR-based dried blood spot testing" to reduce the cost and burden of infant diagnosis (OGAC, 2009a). Centrally reported indicators to monitor testing do not reflect performance specific to scale up of EID, but the introduction in the Next Generation Indicators (NGIs) of an EID indicator should serve to improve monitoring of this programmatic goal at the country program level (OGAC, 2009c).

Interviewees in partner countries described PEPFAR's support for programs to implement and scale up EID by using strategies such as integration of EID into other services and improving laboratory access and capabilities, including technology and training for the use dried blood spot (DBS) collection to obtain samples for testing. Wider access to these specialized laboratory services has led to improved diagnostic efforts, including in some countries improved turnaround time for lab results (240-02-USG; 240-21-PCGOV; 240-24-USG; 396-21-USG; 636-17-PCGOV; 116-19-PCGOV). Despite this progress, PEPFAR-supported programs and partner country HIV programs remain unable to achieve goals for infant testing and consequently for pediatric HIV treatment (240-02-USG; 240-21-PCGOV; 935-ES). One interviewee described the consequences of failing to improve infant diagnosis by noting that '*so many infants were not recruited for treatment, even though treatment was available'* (240-21-PCGOV).

The chain of steps necessary to the process of EID include identifying the HIV-exposed infants in maternal and child health services, obtaining and sending the specimen to the lab, performing the test, getting the results returned to clinic, and finally getting the results to the family. Several steps in this chain can pose challenges to the successful implementation of EID, starting with documentation of the mother's status; ideally, the mother's HIV status and her status with respect to receipt of appropriate antiretroviral (ARV) drugs for PMTCT should be apparent on the infant's medical record so that a blood sample can be obtained from the infant at about 6 weeks of age for diagnosis when it is known that mother is HIV positive. Interviewees described that, even as a country is slowly building its laboratory and technical capacity to do the appropriate test, there remain geographic areas without access to testing, and even in areas where testing is available difficulties in the logistics of transport of specimens and conveying the results also cause delays in diagnosis and initiation of treatment (240-24-USG; 240-21-PCGOV; 396-21-USG; 331-28-PCGOV; 636-17-PCGOV; 461-18-USG). Providing technical expertise and assisting in the country development of a national implementation plan for EID is important but implementation at scale takes time, and in the meantime infected infants continue to be undiagnosed and consequently untreated in the first year of life.

As a result of these challenges to the scale up of EID services, availability is far from universal in most low- and middle-income countries. WHO recently estimated that among 65 reporting countries only about 28 percent of infants born to mothers living with HIV received an HIV test within the first two months of life (WHO et al., 2011). This lack of or delay in diagnosis in this age group represents an important problem because early initiation of treatment in infants is critical for survival. Based on evidence from across regions in Africa, without treatment 50 percent of HIV infected infants die by age 2 years (Brahmbhatt et al., 2006; Newell et al., 2004; Taha et al., 1995). A study in South Africa showed that early diagnosis and early initiation of antiretroviral therapy reduced early infant mortality by 76 percent and HIV progression by 75 percent (Violari et al., 2008). Given the urgency and importance of early diagnosis and the reality that it will take time for universal access to testing to be instituted and successfully implemented, there appears to be a relative lack of parallel emphasis in PEPFAR on supporting

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alternative means to diagnose young infants, despite an evidence base for presumptive diagnosis based on clinical presentation, serology, and CD4 (Grundmann et al., 2011).

HIV Testing for Older Children

Older HIV-infected children in need of treatment are also often identified late in the course of their disease. Although children older than 2 years may be tested for HIV by the standard rapid serological test, few interviewees in PEPFAR partner countries indicated that routine provider initiated HIV testing of ill and hospitalized children was being performed (461-13-USNGO; 542-3-USG). One reason offered for this was a lack of training among providers to readily recognized HIV symptoms in children, thus underscoring the need to educate general pediatricians and other providers caring for children about detecting HIV in children (396-42-PCGOV; 396-43-ML). In addition, for the most part, routine provider initiated testing of all children in the families of adults receiving care and treatment was not being done. Testing the children of identified adults with HIV is an avenue to identify a large number of infected children. Alternative strategies such as outreach testing have also been supported by PEPFAR to identify HIV infected children and adolescents, including specific populations at elevated risk, such as street children (542-4-USG; 542-14-PCGOV; 240-24-USG).

Linkages from HIV Testing to Care and Treatment

Getting patients who have accessed testing services and been found to be HIV positive successfully enrolled in care treatment is essential to improve HIV outcomes; indeed the availability and awareness of successful care and treatment is one of the contributing factors to the successful scale up of testing. In the words of one interviewee,

> *'Before, people were afraid to get tested, but now there are known advantages of getting tested: linkages to care and support, as well as treatment.'* (240-09-USG)

To this end, PEPFAR supported counseling and testing is implemented with a strong emphasis on linking with care and treatment (OGAC, 2011b). Interviewees in the countries visited described not only the importance of linking to HIV care and treatment but also to other services such as appropriate antenatal care, reproductive health and family planning, STI services, TB services, and for injecting drug users, community based rehabilitation and ongoing harm reduction services and counseling.

Despite the intent to establish these linkages, there is concern about the actual success of referrals to link HIV testing to care and treatment. A lag between testing and enrollment in care and treatment can delay early therapy for those already eligible for ART. Patients can also be lost entirely to follow-up in this gap, falling almost immediately off the continuum of services for people living with HIV. The available literature shows that reasons for the loss of patients in this period are related to the low risk perceived by asymptomatic patients; the little therapeutic care that may be provided at this point in the course of the disease; and the effort and investment required by patients to attend health care facilities for follow-up (Long et al., 2011).

These challenges are consistent with the perspectives of interviewees in PEPFAR partner countries. Interviewees described that patients face several challenges after testing, such as insufficient emphasis on referrals in some testing programs, a lack of facilities to be referred to,

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long distances to reach facilities, long waiting times and the need for return trips to receive their results for CD4 counts to determine the need for ART, stigma, and denial or non-acceptance of HIV positive status (636-06-USG; 461-14-USG; 461-07-PCNGO;272-13-USG; 542-11-PCNGO; 331-11-PCNGO; 587-12-USG).

The lack of a system and of unique patient identifiers to help track whether people reach care and treatment programs after being tested was also raised as a challenge to assessing and addressing the loss of patients (116-09-PCNGO; 587-03-USG; 461-07-PCNGO; 587-13-USG; 396-21-USG). As one interviewee observed, there is a *'disconnect between testing and care and treatment because there is no name-based reporting for testing—it is hard to track patients from testing to care'* (587-13-USG). Another interviewee underscored the problem of not being able to account for the gap in HIV-positive patients being linked to treatment: *'We do not know why they are not seeking treatment'* (396-21-USG).

There have been PEPFAR-supported efforts to address this problem of linkages and referrals to care and treatment services, including home-based and community-based programs and efforts to improve linkages among different health services which will be described later in this chapter. In a comprehensive example from one country, the lessons learned from a pilot program using referrals included: using lay persons for testing, addressing supply chain management issues for testing commodities, involving people living with HIV and local leaders, and multiple strategies for community mobilization (461-07-PCNGO). Providing testing and treatment services under one roof was also described as a solution to link positive patients to treatment (196-11-USNGO; 935-20-PCNGO; 396-25-PCGOV; 396-32-PCGOV). In some cases, special effort has been made to link marginalized populations to the services they need at facilities known to be accepting (331-14-USG; 396-25-PCGOV; 196-ES; 331-22-PCNGO; 331-44-USNGO).

Conclusion: PEPFAR's efforts have led to a considerable achievement in increasing availability of and access to HIV testing, counseling, and diagnosis. As a result, many more individuals have learned their HIV status and, if positive, been linked to clinical services. However, challenges remain in achieving adequate coverage of testing services, especially in scaling up and improving access to testing for infants and children and for testing for pregnant women who do not attend antenatal care or deliver in health facilities. For those who test positive, challenges also remain in consistently ensuring they are linked to care and treatment as well as prevention services to reduce HIV transmission. Overcoming these challenges and continuing to make progress in HIV counseling and testing will be a critical factor in achieving a successful comprehensive response to HIV.

CLINICAL CARE AND NONCLINICAL SUPPORT SERVICES

Overview of Program Guidance and PEPFAR-Supported Activities for Care and Support

Care and support services, considered here separately from antiretroviral treatment, are an important component of programs for people living with HIV/AIDS as the step in the continuum of care after testing and diagnosis for those who are HIV-positive and not yet eligible for ART, and as an important ongoing component of care and treatment once ART is initiated. The Lantos-Hyde Act of 2008 set the target of supporting care for 12 million people infected with or affected by HIV/AIDS (including 5 million children orphaned or made otherwise

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vulnerable by HIV/AIDS, discussed more in Chapter 7). The legislation emphasizes promoting a "comprehensive, coordinated system of services to be integrated throughout the continuum of care."[4]

PEPFAR defines care and support services as "the wide range of services other than ART offered to people living with HIV/AIDS (PLHIV) and other affected persons, such as family members" (OGAC, 2009a), p. 16). For adults, this includes facility-based and home/community-based activities. For pediatric care and support, this category includes services for children when provided at a facility, while community and home-based services for children living with HIV, including some of the same services included in care and support when not provided in facilities, are implemented under the programmatic area category of programs for orphans and vulnerable children (discussed in full in Chapter 7). Both adult and pediatric care and support activities are aimed at "extending and optimizing quality of life for HIV-infected clients and their families throughout the continuum of illness" by providing clinical care services, psychological, spiritual, and social support services, and prevention services (OGAC, 2010a). These services are ultimately intended to promote health for people living with HIV/AIDS (PLHIV), slow the progression of AIDS, and reduce HIV-related complications and mortality.

The PEPFAR-issued guidance for care and support services, *Guidance for United States Government In-Country Staff and Implementing Partners for a Preventive Care Package for Adults*, describes a menu of preventive care services for adults (OGAC, 2006a). There is also guidance for preventive care for children (0–14 years) with a similar menu of services (OGAC, 2006b); care and support services for children are also discussed in Chapter 7. The categories of preventive care services are summarized in Figure 6-3; the types and combinations of interventions in a preventive care menu vary by country and implementing partner. Clinical care includes prevention and treatment of TB and other opportunistic infections and HIV/AIDS-related complications, including malaria and diarrhea, by providing pharmaceutical prophylaxis, insecticide-treated nets, safe water interventions and related laboratory services; pain and symptom relief; and nutritional assessment and support including food. Psychological and spiritual support may include counseling, end-of-life care, and bereavement services. Social support may include social and legal protection, training and support of caregivers, vocational training and income-generating activities. Prevention services may include behavioral counseling and counseling and testing of family members (OGAC, 2010a). Efforts to integrate care and support services with other health and development programs, such as voluntary family planning and reproductive health services, are also a key component of PEPFAR II (OGAC, 2009a).

A review of annual PEPFAR Country Operational Plans from the countries selected for visits for this evaluation revealed implementation of a broad and widely ranging array of care and support activities; this was similarly described by interviewees across countries. PEPFAR's care and support activities are implemented across levels of stakeholders in the response, from national and local governments to facilities to communities. Given the breadth of services, PEPFAR uses a wide range and types of partners, including local community and nongovernmental partners. In addition, these services require involvement of stakeholders across more than the health sector. Interviewees in partner countries reflected that collaboration is therefore essential since partnering with agencies and programs across sectors and levels, down to the community, enables the offering of cross-cutting interventions (240-15-USG; 331-05-ML).

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[4] *Supra*., note 1 at §101(a), 22 U.S.C. 7611(a)(4)(C).

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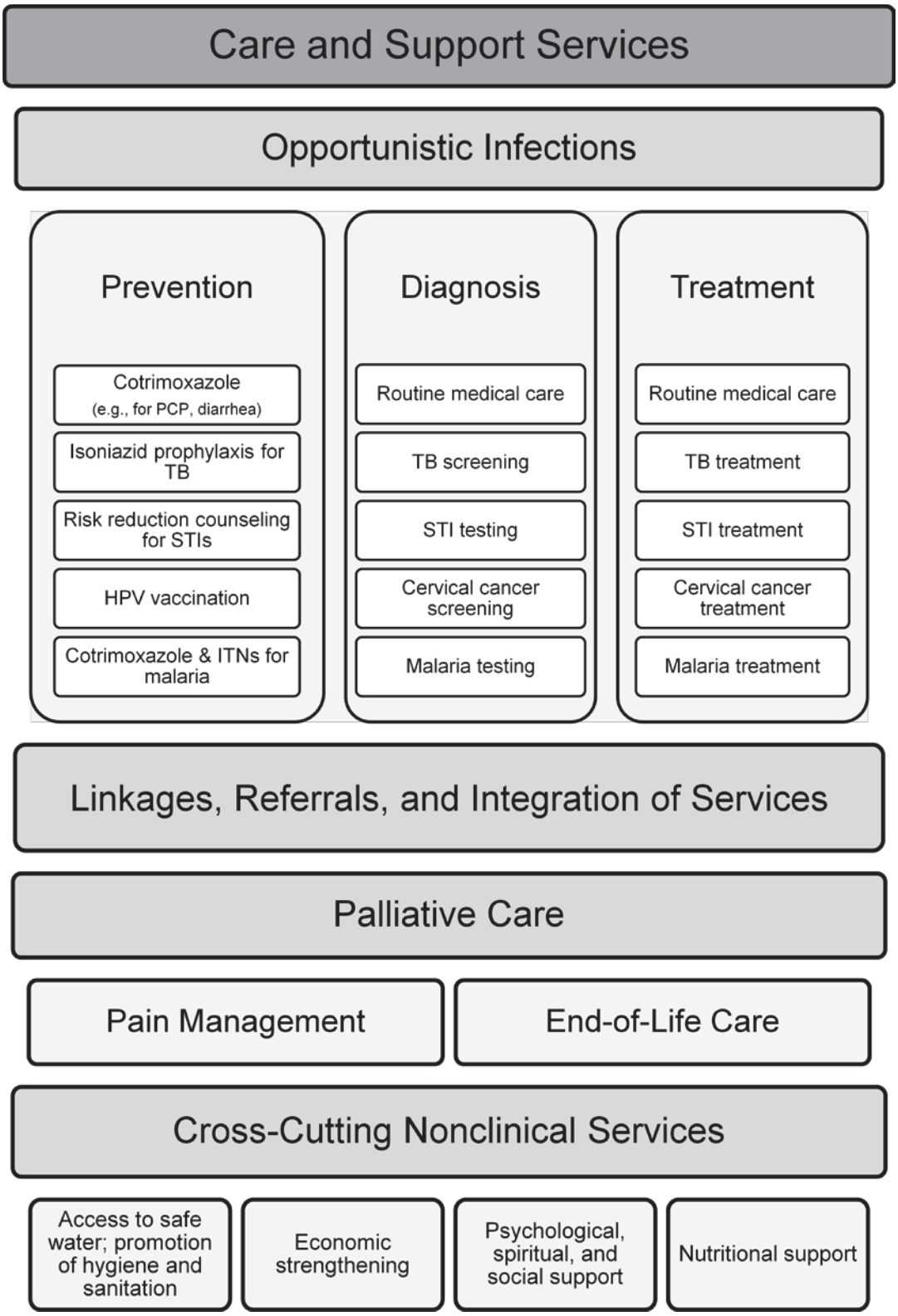

FIGURE 6-3 PEPFAR care and support services.
NOTES: HPV = human papillomavirus; ITNs = insecticide-treated nets; PCP = *Pneumocystis jiroveci* pneumonia; STI = sexually transmitted infections; TB = tuberculosis.
SOURCE: (IOM and NRC, 2010).

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Funding History for PEPFAR Care and Support Activities

PEPFAR's activities for care and support are implemented with funding captured within several budget codes: Adult Care and Support, TB/HIV, Pediatric Care and Support, and OVC (funding for OVC is also discussed in more detail in Chapter 7). Figure 6-4 shows the funding over time in these budget codes in both the dollar amount and as a proportion of all PEPFAR funding. The total across these budget codes has increased since the beginning of PEPFAR, leveling off starting in FY 2009 at just less than $900 million per year. Care and support has represented about 20 percent of all PEPFAR funding across the duration of the initiative. Since the pediatric care and support budget code was introduced, it has been a relatively constant proportion of care and support funding.

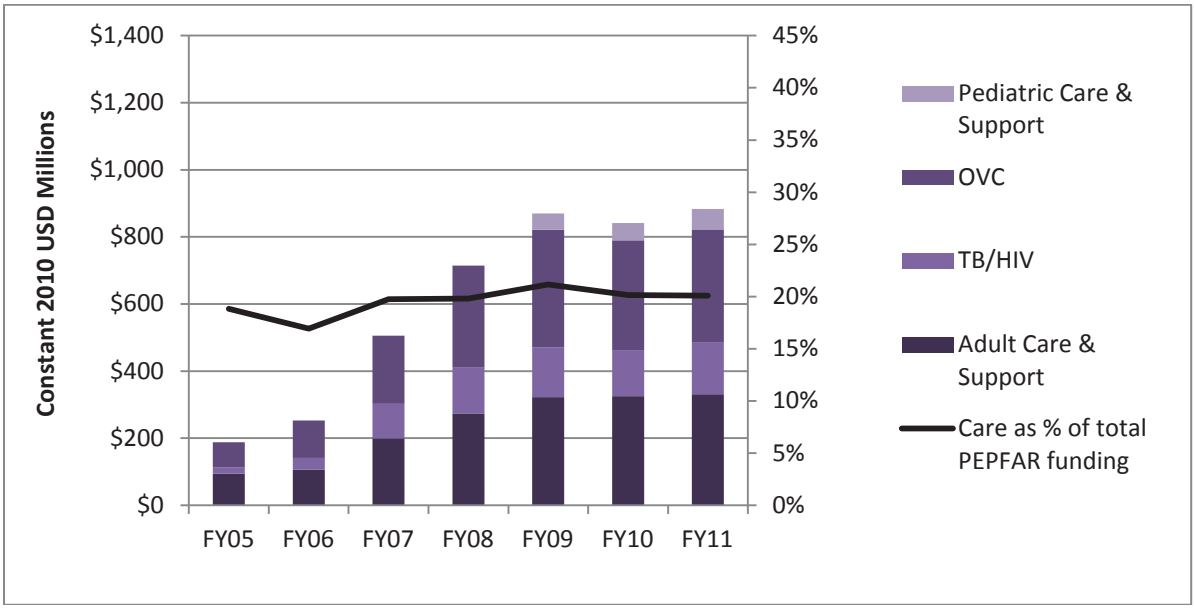

FIGURE 6-4 Planned/approved funding over time for care and support services.
NOTE: This figure represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by programmatic area. Data are presented in constant 2010 USD for comparison over time. As defined in the FY 2011 COP Guidance, PEPFAR funding for Care includes budget codes for Adult Care & Support and Pediatric Care & Support, TB/HIV, and OVC. The TB/HIV budget code includes funding for all TB activities, including commodities and laboratory as well as pediatric TB/HIV services (OGAC, 2010a). Funding for Pediatric Care & Support was not reported separately until FY 2009. See Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding.
SOURCES: (OGAC, 2005, 2006c, 2007b, 2008, 2010c, 2011d, 2011e).

Overview of Effects of PEPFAR Care and Support Activities

Overall Care and Support Indicator Data: Targets and Results

To reflect the performance of PEPFAR's care and support programs, PEPFAR has an overall output indicator reported centrally, capturing the number of individuals provided with HIV-related care. This was revised in the Next Generation Indicators to be the number of eligible adults and children provided with a minimum of one care service. To count under this indicator, individuals must receive a minimum of one service. However, guidance from PEPFAR programs

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is that the aim should be to provide a comprehensive set of support and clinical services appropriately tailored to the status of the individual or family, including linkages among partners (OGAC, 2009c). As of the NGI revision, this overall care indicator is reported with disaggregation by age, with the grouping of less than 18 years of age replacing the previous OVC indicator (see Chapter 7). This indicator serves to track the overall legislative target of reaching 12 million people with care services.

TABLE 6-2 Number of Individuals Provided with Care (in Millions)

	Number of individuals provided with HIV-related care[a]						**Number of eligible adults and children provided with a minimum of one care service[b]**
	FY04	**FY05**	**FY06**	**FY07**	**FY08**	**FY09**	**FY10**
Actual	0.5	1.2	2.3	3.4	5.3	7.4	11.4
Target	--	1.0	1.7	2.4	4.4	6.4	12.4
% of Target	--	119	134	144	122	115	91

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2).
[a] Results and targets correspond to OGAC indicator 6.2 (direct): Total number of individuals provided with HIV-related palliative care (including those HIV-infected individuals who received treatment for tuberculosis). This indicator is defined to represent the total number of unique individuals receiving palliative care from facilities and/or community/home-based organizations. Clients may include HIV-infected individuals and family members. How much care is needed in order to count within the indicator is currently left to national standards. All persons served during the reporting period will be counted once by a unique program regardless of frequency (OGAC, 2007a).
[b] Results and targets correspond to OGAC indicator C1.1.D: The number of eligible individuals who received at least one care service from facilities and/or community/home-based organizations. Individuals eligible for care services include people living with HIV/AIDS (PLHIV); family members, caregivers, or other household members living with an HIV-positive individual; children orphaned by HIV (<18 years old); children made vulnerable due to HIV (<18 years old); and infants born to HIV-infected mothers (OGAC, 2009c).
SOURCE: Program monitoring indicators provided by OGAC.

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Following the implementation of the NGIs in 2009, another centrally reported indicator is a subset of the overall care indicator that is specific to clinical care. This indicator is available with disaggregation by sex and by two age groups, under 15 or >15 (see Table 6-3). A greater number of females than males received at least one clinical care service in FY 2010, with females representing 64 percent of the total and males 36 percent of the total. Of the total number provided with clinical care services, 10 percent were children under the age of 15.

TABLE 6-3 Number of HIV-Positive Adults and Children Receiving a Minimum of One Clinical Service (in Millions)

Disaggregated by Sex						
FY2010	Male		Female		Total	
	Result	Target	Result	Target	Result	Target
	2.1	2.1	3.8	3.2	5.9	5.5
Disaggregated by Age[a]						
FY2010	<15 Years Old		15+ Years Old		Total	
	0.6		5.3		5.9	

NOTES: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Data correspond to indicator C2.1.D (Number of HIV-positive adults and children receiving a minimum of one clinical care service [subset of C1.1.D]). "Clinical services may be provided in facilities, the community, or in the home, and may include both assessment of the need for interventions (for example assessing pain, clinical staging, eligibility for Cotrimoxazole, or screening for tuberculosis) and provision of needed interventions: prevention and treatment of TB/HIV, prevention and treatment of other opportunistic infections (OIs), alleviation of HIV-related symptoms and pain, nutritional rehabilitation for malnourished PLHIV" (OGAC, 2009c).
[a] OGAC did not provide age-specific targets for this indicator.
SOURCE: Program monitoring indicators provided by OGAC.

A small number of other centrally reported output indicators for TB/HIV, cotrimoxazole, and food/nutrition services were also available to the committee and will be presented in the sections that follow on specific sub-areas of activities within care and support. There are no centrally reported indicators for isoniazid preventive therapy; insecticide treated nets; testing and treatment for malaria; prevention, testing, and treatment for sexually transmitted infections and other infections; safe drinking water, basic hygiene, and sanitation; pain management services and policy efforts; economic strengthening services; or psychological and social support.

Many country programs and partners also collect additional indicators on intervention areas within care and support that are not routinely reported centrally. However, even with the additional data that may be available at country and program level, there are major limitations to the utility of the program monitoring data for fully understanding the effects of PEPFAR's programs. Monitoring of PEPFAR's care and support activities is complicated by changes in indicators over time during PEPFAR, i.e., 14 of the essential PEPFAR indicators for care have changed significantly, have been dropped, or are new.[5] This limits the possibility of examining longitudinal trends for some data. The lack of unique identifiers for each participant in most PEPFAR activities constitutes a major methodological challenge. Care and support programs are offered within different settings in which eligible clients may receive multiple services from different providers and partners. Therefore, there is a risk of an individual being counted several

[5] Essential indicators are those for which OGAC requires PEPFAR mission teams to track data to monitor PEPFAR's progress (OGAC, 2009c).

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times ("double counting"), thus potentially over-representing the number receiving services. This also makes it difficult to track the scope of services received by an individual client and to track that client through programs and services over time. In addition, aggregated data reported to OGAC provide limited insight about the types of populations accessing care. The lack of disaggregation by sex, populations (including those at elevated risk), and age range subgroups within children under 15 years old also makes it difficult to assess how services are distributed across identified populations and to assess progress toward goals for equitable service delivery across the whole of PEPFAR. Finally, most of these indicators do not reflect outcomes for the clients who received services and therefore do not inform an assessment of the effectiveness or quality of PEPFAR-supported care and support programs.

Overall Effects of PEPFAR Care and Support Activities

Achievements and challenges in specific areas of PEPFAR's care and support activities are described in the sections that follow; a few examples of overall achievements are described here. Interviewees described a diversity of PEPFAR-related achievements that they associated with the provision of HIV-related care and support. One major area highlighted by interviews was improvements in availability of and access to care. These improvements resulted from what interviewees noted as an often-remarkable increase in the number of sites offering HIV-related care since the initiation of PEPFAR, including facilities, community-based sites, and workplace programs (196-1-PCGOV; 240-02-USG; 587-06-CCM). In addition, some interviewees described access as improving through new models for care and integration of services. Although HIV services continue to be widely offered separately from other health services, some partner countries have initiated complete integration of all HIV-related service provision, co-location of services, referral systems, and new models of care such as family-centered approaches (166-11-USG; 934-15-PCGOV; 934-16-PCGOV; 396-41-PCGOV; 587-13-USG). Service integration is discussed in depth in Chapter 9, Health Systems Strengthening. Another factor identified across interviews and countries as contributing to access to care is the use of community- and home-based care primarily provided by volunteers and community health workers, many of whom are PLHIV (272-7-USG; 272-32/35-PCNGO; 166-23-USG; 396-31-PCGOV; 461-13-USACA; 240-15-USG; 240-2-USG; 272-18-PCNGO; 331-14-USG; 331-16-USG).

In addition to support for service delivery, PEPFAR has also contributed to systems-level efforts in partner countries. PEPFAR facilitated the initiation or modification of partner country national policies, guidelines, protocols, and standard operating procedures related to care and support (166-13-PCGOV; 461-18-USG; 166-09-ML; 272-07-USG; 240-02-USG; 272-7-USG; 396-29-PCGOV; 461-13-USACA). Examples of this included supporting partner country government efforts to define a comprehensive care package (272-07-USG), to decentralize comprehensive HIV services (240-0- USG), to establish or take over coordination and ownership of home-based care/community health worker programs (272-7-USG; 396-29-PCGOV), to develop national policies on community/home-based care and palliative care (461-13-USACA; 166-09-ML), to develop training manuals related to care and support (166-09-ML), other efforts to provide technical assistance and to build capacity and structures to improve access to care (166-08-USG; 272-32,35-PCNGO; 586-18-PCGOV; 396-12-USG), and strengthening public-private partnerships regarding care and support (240-02-USG). The increasing provision of comprehensive services was described by one interviewee as leading to increased access and quality of services (116-04-USG).

Interviewees from PEPFAR-funded partners reported government and community advocacy as part of their efforts to improve and provide care and support, particularly around issues such as palliative care, pain control, treatment access, or leadership training for PLHIV,

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especially women (331-09-PCNGO; 196-07-PCNGO; 116-13-PCNGO; 396-44-PCGOV; 272-07-USG). In one partner country, the findings of a PEPFAR-supported care and support evaluation '*came to conclude that there are huge gaps,'* which was used as an advocacy tool (272-07-USG).

Building on this overview across PEPFAR's care and support efforts, the following sections will describe in more depth the efforts and effects, including achievements and challenges, in specific components of care and support programs, including TB services, other clinical care services, and home- and community-based services.

Screening, Diagnosis, and Treatment of Tuberculosis

Tuberculosis infection in people living with HIV is one of the most common co-infections and has devastating consequences. Globally, TB is the leading cause of death for PLHIV; it is estimated that about a quarter of all HIV-related deaths are attributable to tuberculosis. HIV infection increases the risk of active TB disease more than 20-fold (WHO, 2012d). WHO has identified three major objectives in its guidelines for TB and HIV. The first objective is to establish and strengthen collaborations between HIV and TB-control programs to deliver integrated services; for example, through the creation of an HIV/TB coordinating body that functions at the district, regional, local, and facility levels that is responsible for determining and monitoring the prevalence of HIV in TB patients and vice versa as well as integrating the delivery of services through joint planning. The second objective is to reduce the burden of tuberculosis in people with HIV by intensifying casefinding for TB among those who are HIV positive and providing TB treatment and early initiation of antiretroviral therapy; by introducing isoniazid preventive therapy (IPT), which has been shown in randomized controlled trials to reduce active tuberculosis in HIV-positive patients; and by controlling TB infections in healthcare facilities. IPT is cost saving, particularly in view of the secondary cases prevented. The third objective is to reduce the burden of HIV in patients with tuberculosis by providing HIV testing and counseling for patients with TB; by introducing HIV prevention interventions for patients with TB, including condoms and behavior change interventions; by introducing cotrimoxazole preventive therapy (CPT) for TB patients who are HIV positive, which has consistently reduced the risk of death and improved survival for co-infected patients during routine tuberculosis care; and by linking to and enrolling those TB patients who are HIV-positive in HIV care and treatment services, including initiation of ART irrespective of CD4 count (WHO, 2012e).

PEPFAR-Supported TB/HIV Activities

The first PEPFAR Five-Year Strategy acknowledged the importance of linkages between HIV and TB and emphasized screening and treatment for TB and HIV co-infection as an area for rapid scale up and programmatic synergies (OGAC, 2004). The second Five-Year Strategy further committed PEPFAR to scale up efforts to screen, diagnose, and when necessary treat all HIV patients for TB, while ensuring that all TB patients are tested for HIV and, if positive, referred to HIV treatment (OGAC, 2009a, 2009f). In some years, PEPFAR appropriations have included a global budgetary earmark for TB/HIV; when not the case COP guidance has nonetheless emphasized the importance of this aspect of the response to HIV and noted that COP budgets that do not reflect resource commitments that are commensurate to the TB burden must justify their allocation decisions and may expect to receive "additional scrutiny in the review process" (OGAC, 2010b).

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PEPFAR-supported activities for TB/HIV include exams, clinical monitoring, related laboratory services, treatment and prevention of tuberculosis, HIV testing and clinical care of patients in TB service locations, TB screening, and diagnosis, treatment and prevention of TB in PLHIV (OGAC, 2010b). PEPFAR has also recently instituted technical assistance and support for the planning, policy development, and implementation and rollout of Xpert diagnostic testing for TB (OGAC, 2011c, 2012).

A major approach for making progress toward these goals and implementing the activities supported by PEPFAR is through integration and coordinated provision of TB and HIV services with the aim of achieving effective and efficient concurrent screening and entry into prevention and treatment services for both infections.

PEPFAR-Supported TB/HIV Activities: Indicator Data Targets and Results

There are a number of centrally reported indicators that reflect PEPFAR's activities in the area of TB/HIV. Due to indicator changes and the introduction of new indicators over time, not all indicators are available for all years, but the available indicators do serve as one way to assess PEPFAR's progress. With regard to the first major objective identified by the WHO, to reduce the burden of tuberculosis in people with HIV, PEPFAR has contributed to increased TB treatment for HIV-positive patients in terms of both the number of patients (Table 6-4) and the number of service outlets with available TB treatment services (Table 6-5), but has struggled to meet the targets set compared to the results for overall care (presented earlier in this section) and for other areas, such as antiretroviral therapy (discussed later in this chapter).

TABLE 6-4 Number of HIV-Positive Patients in HIV Care Who Started TB Treatment (in Thousands)

	FY04	*FY05*	*FY06*	*FY07*	*FY08*	*FY09*	*FY10*
Actual	101.5	179.6	147.5	215.2	277.6	308.7	256.2
Target	--	158.9	188.9	264.2	341.9	368.2	369.4
% of Target	--	**113**	**78**	**81**	**81**	**84**	**69**

NOTES: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). TB = tuberculosis. Data corresponds to OGAC indicators 7.2 (direct) and C2.5.D (NGI). OGAC indicator 7.2=Number of HIV-infected clients attending HIV care/treatment services that are receiving treatment for TB; OGAC indicator C2.5.D=Number of HIV-positive patients in HIV care who started TB treatment. These data corresponds to clients who receive TB treatment in HIV facilities but NOT clients who receive HIV treatment in TB facilities. HIV-infected clients who receive TB treatment in TB sites can also be counted in this indicator (OGAC, 2009c).
SOURCE: Program monitoring indicators provided by OGAC.

TABLE 6-5 Number of Current USG-Supported Service Outlets Providing Treatment for TB to HIV-Infected Individuals (in Thousands)

	FY04	*FY05*	*FY06*	*FY07*	*FY08*	*FY09*
Overall	2.6	2.8	4.9	6.6	8.3	9.8

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Data corresponds to OGAC indicator 7.1: "This indicator measures the subset of service outlets providing TB/HIV care. A service outlet refers to the lowest level of service. For example, with regard to clinical activities, the lowest level for which data exists should be a service outlet such as a hospital, clinic, or mobile unit. A service outlet that will count in this indicator will provide treatment for tuberculosis to HIV-infected individuals (diagnosed or presumed)" (OGAC, 2007a). USG = U.S. government; TB = tuberculosis.
SOURCE: Program monitoring indicators provided by OGAC.

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As an assessment of the coverage of TB screening in HIV-positive patients served by PEPFAR in FY 2010, the percentage screened is calculated using as the denominator the number of HIV-positive adults and children receiving a minimum of one clinical service. As shown in Table 6-6, the coverage of TB screening was 49 percent of the number of HIV-positive adults and children in care; the target set for the number screened represented 69 percent of the target set for number of clients reached with clinical care services. The number in clinical care exceeded the target set, while the number screened for TB fell short.

TABLE 6-6 Percent of HIV-Positive Patients Who Were Screened for TB in HIV Care or Treatment Settings (in Millions)

	Number screened[a]		**Number in clinical care[b]**		**% Screened for TB[c]**	
FY 2010	Result	Target	Result	Target	Result	Target
Total	2.9	3.8	5.9	5.5	49	68

NOTES: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). TB = tuberculosis.
[a] Number of HIV-positive adults and children screened for TB in HIV care and treatment settings.
[b] Indicator C2.1.D: number of HIV-positive adults and children receiving a minimum of one clinical service.
[c] Indicator C2.4.D: percent of HIV-positive patients who were screened for TB in HIV care and treatment settings.
SOURCE: Program monitoring indicators provided by OGAC.

With regard to the objective to reduce the burden of HIV in patients with tuberculosis, from FY 2007 to FY 2009 PEPFAR also tracked an indicator for the number of registered TB patients tested for HIV in TB service outlets supported with U.S. government assistance, which increased over time (Table 6-7).

TABLE 6-7 Number of Registered TB Patients Who Received HIV Counseling, Testing, and Their Test Results at a USG-Supported TB Service Outlet (in Thousands)

	FY07	*FY08*	*FY09*
Total	181.6	607.1	767.8

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Data correspond to OGAC indicator 7.4. USG = U.S. government; TB = tuberculosis.
SOURCE: Program monitoring indicators provided by OGAC.

PEPFAR-Supported Activities for Integrated TB/HIV Services

Interviewees across PEPFAR partner countries recognized high TB/HIV co-infection rates as a critical aspect of the HIV response (196-11-USNGO; 396-12-USG). As described by one interviewee, '*We also saw the need to do TB/HIV intervention. HIV and TB are bedfellows*' (331-44-USNGO). Interviewees described different models or types of HIV/TB integration that have been supported at the level of service delivery. The range of integration and coordination of services included '*complete*' integration or a '*one-stop shop*' (542-16-PCGOV; 636-09-USACA); co-location of HIV care and treatment with TB services, such as having an HIV clinic for OI management, male circumcision, and counseling and testing adjacent to a district-run TB clinic (934-15-PCGOV); HIV services integrated into a TB clinic and vice versa (166-15-USACA; 636-09-USACA; 934-15-PCGOV; 636-17-PCGOV); and HIV and TB screening and treatment offered at both HIV and TB clinic sites and inpatient settings (587-05-PCGOV; 396-21-USG; 636-17-PCGOV; 934-15-PCGOV). One partner, for example,

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described the successful implementation of standard screening for TB for every patient at every visit in the HIV care and treatment clinic (934-15-PCGOV) and another country program described similar success in one city district in achieving systematic provision of HIV counseling and testing for outpatient TB patients (396-21-USG). Another model is separate HIV and TB clinics with referral systems (636-09-USACA; 272-21-PCNGO), including facilitated referrals by patient escorts and the use of TB/HIV coordinators and lay counselors (934-24-USNGO; 636-9-USACA). The approach may also depend on the clinical presentation, such as referring out of the HIV care and treatment clinic for active TB while latent TB management is done in the HIV clinic (587-18-PCGOV). In at least one example, linkage between the HIV clinic and the TB clinic also occurred through linking lab results (935-19-PCGOV).

Interviewees also highlighted examples where PEPFAR has supported partners to newly initiate integrated TB/HIV activities, to institute quality management in TB/HIV services, to pilot implementation of IPT, to train providers on TB/HIV, and to incorporate education about TB into services for PLHIV (196-11-USNGO; 396-21-USG; 331-44-USNGO; 331-16-USG).

Interviewees across countries described progress as a result of PEPFAR's efforts in the area of TB/HIV, especially in more recent years. However, there are still a number of critical challenges and unmet needs in this important area of the response to HIV. There are still gaps in screening of both HIV patients for TB and TB patients for HIV, hindered in part by lack of clinical diagnostic capabilities and laboratory capacity (935-24-USNGO). A major challenge that persists is ensuring the delivery of treatment services needed for those who are identified as co-infected, and loss to follow-up for both TB patients identified as HIV positive and HIV patients diagnosed with TB (935-22-PCGOV). Some contributing factors identified by interviewees included resistance to testing, a desire among some patients to complete TB treatment before starting ART, and a lack of facilities to provide the needed services (935-22-PCGOV; 935-24-USNGO). In some countries, interviewees also described challenges with instituting infection control practices (542-8-USNGO).

PEPFAR's Systems-Level Support for TB/HIV

In addition to supporting service delivery for TB/HIV, PEPFAR has also supported TB/HIV at the systems level, emphasizing an integrated approach. As described by interviewees across countries, PEPFAR and its implementing partners have supported Ministry of Health TB/HIV activities (196-14-PCGOV) and have contributed to efforts to link the national TB program and national AIDS program to work together (196-11-USNGO; 935-22-PCGOV; 636-9-USACA). In one country example, this included supporting ministerial-level staff positions dedicated to this effort (935-22-PCGOV). A range of capacity building for TB/HIV through technical assistance and training have also been provided (196-14-PCGOV; 331-16-USG; 396-21-USG).

From the perspective of an implementing partner in one partner country, there has been "*huge progress*" recently with TB/HIV (636-9-USACA). Signs of this progress include that the Ministry of Health sees the need for TB/HIV integration, and PEPFAR contributed to bringing the separate government programs for TB and HIV and separate implementing partners for TB and HIV into an HIV/TB technical working group, which helped develop guidelines on how to integrate TB and HIV that allowed for implementation of new models of TB/HIV integration (636-9-USACA). PEPFAR has supported other efforts to work with the national program to develop guidelines and tools with national stakeholders, for example an algorithm to improve diagnosis of TB (396-21-USG), guidelines and screening tools for pediatric clients (461-13-USACA), and standard

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operating procedures to improve TB case detection among HIV patients and to improve infection control in facilities to reduce exposure of HIV-positive patients to TB (331-16-USG).

PEPFAR has also contributed to national TB/HIV efforts by supporting policies for the expansion of services, such as contributing to the decentralization of comprehensive HIV services, including integrated TB services, to be provided in lower level health facilities (240-2-USG; 461-13-USACA). In addition, PEPFAR has contributed evidence to support policy efforts. In one country, supporting an IPT pilot resulted in the government adopting this policy for adults and children, although the implementation to date varies by region (396-21-USG). Another example of PEPFAR's contribution to TB/HIV at the systems level is support for the implementation of integrated or coordinated monitoring and evaluation (542-8-USNGO; 196-14-PCGOV). In at least one country, PEPFAR has also contributed to TB more generally than as part of the HIV response, by supporting efforts to increase case detection of TB within the general population and initiatives focusing on MDR-TB (396-12-USG).

Several interviewees also identified challenges at the systems level. Funding is one such challenge. Interviewees described limited additional funding for HIV and TB (396-12-USG) and separate donor or national funding streams for TB and HIV (935-ES; 331-16-USG; 396-12-USG), which posed challenges to integrating services for the two health issues. As one interviewee observed, while integration may be well accepted as a PEPFAR-supported policy initiative, '*Programs have a positive view of integration until they are competing for funding*' (331-16-USG). In addition to the challenges of separate funding, interviewees also described the challenges of integrating pre-existing, well-established but very separate and '*very vertical*' programs and clinical services for the two diseases (396-21-USG; 935-ES; 636-09-USACA). In at least one case, progress in overcoming this varied by the level of the system: '*the collaboration is good at the national and provincial level but variable at the district level*' (396-21-USG). The challenge of separate systems also extends to separate systems for monitoring and evaluation (935-ES; 542-8-USNGO); one interviewee described implementing monitoring and evaluation of TB, HIV, and TB/HIV programs as '*the hardest part of the TB/HIV program*' in part due to overall limitations in the country's systems for monitoring and evaluation (542-8-USNGO).

> **Conclusion:** The importance of TB/HIV efforts is well-recognized within PEPFAR and in partner countries. PEPFAR has increasingly supported integration and coordination of screening, diagnosis, and referrals or other linkages to treatment for both infections. PEPFAR has also made a notable contribution in its support for advancing policies and systems for TB/HIV integration in partner countries. However, progress in this area has come more slowly than in other clinical services for HIV, and challenges persist in achieving adequate coverage of both HIV screening for TB patients and TB screening for HIV patients, as well as in ensuring and monitoring subsequent referral and retention in treatment for both infections. Concerted efforts in this area will be critical for reducing mortality from TB/HIV as part of an effective response to HIV.

Other Supportive Clinical Care Services

In addition to services for TB/HIV, PEPFAR supports a number of clinical care services as part of its care and support portfolio, including prevention and treatment of other opportunistic

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infections and HIV/AIDS-related complications. PEPFAR supports these services through health facilities, discussed here, as well as through home-based and community-based care programs (discussed in more detail in the section that follows) and through linkages with other USG health and development programs.

Prophylactic and Therapeutic Drugs for Opportunistic Infections

One major component of care for HIV-infected individuals is the use of cotrimoxazole (CTX), a broad-spectrum antimicrobial agent, to prevent *Pneumocystis jiroveci* pneumonia (formerly *Pneumocystis carinii* pneumonia), toxoplasmosis, and malaria (WHO, 2006b). WHO recommends that all adults with HIV receive CTX prophylaxis indefinitely as a cost-effective method to significantly reduce morbidity and mortality, but country-level policies vary according to the burden of HIV and other diseases, as well as the capacity and infrastructure of health systems (WHO, 2008). As of the NGI indicators, PEPFAR has a centrally reported indicator available to the committee for the number of HIV-positive persons receiving cotrimoxazole prophylaxis (see Table 6-8). In FY 2010, PEPFAR met its target for this service. WHO also recommends that all infants born to HIV-infected mothers receive CTX until they are shown not to be HIV infected (WHO, 2006b). Age disaggregation is not reported centrally for this indicator, so it was not possible with the data available to the committee to assess this output indicator for reaching infants with the recommended prophylaxis.

TABLE 6-8 Number of HIV-Positive Persons Receiving Cotrimoxazole Prophylaxis (in Millions)

	FY10 Result	*FY10 Target*
Total	2.9	2.9

NOTE: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Data correspond to Indicator C2.2.D: Number of HIV-positive persons receiving cotrimoxazole prophylaxis (subset of C1.1.D).
SOURCE: Program monitoring indicators provided by OGAC.

Cryptococcal disease is also common and often treatable in PLHIV, although many countries lack the infrastructure and human capacity for diagnosis (OGAC, 2009b; WHO, 2008) and without early recognition, mortality from cryptococcal disease is high (OGAC, 2009b). Where cryptococcal disease is common and diagnostic capacity exists, WHO recommends consideration of antifungal prophylaxis (fluconazole or itraconazole) for severely immunocompromised PLHIV (WHO, 2008). PEPFAR has provided limited training and laboratory capacity building for diagnosis. Currently, there is limited availability of antifungal prophylaxis, but PEPFAR is working with its Supply Chain Management System and Pfizer, which runs a fluconazole donation program, to increase access to drugs for treatment and prevention (OGAC, 2009b).

Screening for Cervical Cancer

Women who are HIV positive have high rates of infection with cancer-causing strains of human papilloma virus, and they have increased risk of cervical cancer. WHO recommends that where possible, women with HIV should be screened for cervical cancer annually (WHO, 2008). As part of a comprehensive approach to OIs, PEPFAR is currently supporting cervical cancer

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pilot programs for HIV-positive women (OGAC, 2009a). These pilot programs are using the "see and treat" approach, which includes visual inspection with acetic acid, visual inspection with Lugol's iodine, and direct visual inspection (Kaur and Singh, 2010). Services for cervical cancer is an area where PEPFAR has recently initiated an approach using public–private partnership through the launch of the "Pink Ribbon, Red Ribbon" campaign to support and scale up improved services for cervical cancer as well as breast cancer in HIV-positive women (George W. Bush Institute et al., 2012). This initiative is in its early stages, so it was too early for the committee to make any assessment of its progress or effects.

Several interviewees in partner countries described PEPFAR-supported efforts with regard to integration of cervical cancer screening, including offering cervical cancer screening in care and treatment facilities, launching a nationwide human papilloma virus vaccination campaign, and fully integrating cervical cancer screening program into the Ministry of Health with a PEPFAR partner providing quarterly oversight and health care professional training for cervical cancer screening and treatment (636-17-PCGOV; 272-20-PCNGO; 461-18-USG; 461-13-USACA; 587-10-USG; 587-13-USG; 587-18-PCGOV). One organization described success in this area though an intensified screening program that ensures all their sites have cervical screening programs; however, they noted that they are the only nongovernmental organization (NGO) implementing partner in that country with these intensified screening services (272-20-PCNGO).

Prevention and Treatment of Malaria

Malaria is another area of focus in services for those who are HIV-positive. WHO recommends the integration of malaria and HIV services with a particular focus on prevention (WHO, 2008). As previously mentioned, CTX may reduce malaria-related morbidity and mortality in PLHIV. Insecticide-treated nets (ITNs), when used properly and regularly, are cost-effective and greatly reduce exposure to malaria infection. WHO also recommends intermittent preventive therapy (IPTp) for HIV-positive pregnant women who are not taking CTX, which can reduce the risk of malaria and its consequences (WHO, 2008). The President's Malaria Initiative (PMI) is a USG interagency initiative to reduce malaria in 15 focus countries, 9 of which also have significant PEPFAR programs (CDC and USAID, 2012). PMI is working to expand coverage of effective malaria prevention and treatment interventions, including ITNs, indoor residual spraying with insecticides, IPTp, and artemisinin-based combination therapy (CDC and USAID, 2012). PEPFAR is intended to routinely link to PMI, and their efforts overlap in ITN distribution and education programs as well as coordination of lab services (OGAC, 2009a).

Increased Access to Safe Drinking Water and the Promotion of Basic Hygiene and Sanitation

Another source of infection in those who are HIV positive is waterborne and enteric pathogens, the risk of which is exacerbated in many developing countries by poor infrastructure and lack of safe management of human waste (WHO, 2008). Diarrhea from these pathogens affects 90 percent of PLHIV, and interventions to improve water, sanitation, and hygiene, such as provision of safe water storage vessels and education regarding hand-washing, can greatly reduce diarrhea-related morbidity (OGAC, 2009b). The latest USG "Framework for Addressing Water Challenges in the Developing World," which guides USAID and DoS efforts, encourages the incorporation of these interventions into all HIV/AIDS programs (USAID and DoS, 2009). PEPFAR's preventive care package also includes water purification systems (OGAC, 2009a).

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Food and Nutrition Support Services

HIV infection may cause or intensify malnutrition by reducing appetites, increasing energy needs, and impairing nutrient absorption in PLHIV (OGAC, 2009b). Proper nutrition also supports the immune system, preventing OIs. Nutritional and micronutrient supplementation may reduce HIV-related morbidity and mortality and improve outcomes for patients on ART (OGAC, 2009e). Through its Food by Prescription programs, PEPFAR targets clinically malnourished children and adults with HIV infection, pregnant and lactating women and their infants in PMTCT programs, and orphans and other vulnerable children (regardless of HIV status) for food and nutrition care and support, including nutrition assessment and counseling services, specialized food products, and micronutrient supplementation (OGAC, 2009b). Although PEPFAR does not support direct food distribution to families, the new Five-Year Strategy emphasizes linkages and referrals of those in need to the new USG Global Hunger and Food Security Initiative, Title II programs, and other initiatives such as the World Food Program (OGAC, 2009a, 2009b). This linkage was described in several interviews in partner countries (240-15-USG; 636-9-USACA). Interviewees also described the provision of nutrition services through various organizations and partners, including nutritional counseling at community health care centers and food support (934-7-PCGOV; 272-18-PCNGO; 240-25-PCGOV; 272-32/35-PCNGO; 587-06-CCM; 331-23-USNGO).

As of the NGI indicators, PEPFAR has a centrally reported indicator for the number of clinically malnourished HIV-positive persons receiving therapeutic or supplementary food (see Table 6-9). For FY 2010, PEPFAR fell short of its target for this service.

TABLE 6-9 Number of HIV-Positive Clinically Malnourished Clients Who Received Therapeutic or Supplementary Food (in Thousands)

	FY10 Result	*FY10 Target*
Total	256.7	457.3

NOTES: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Data correspond to Indicator C2.3.D: Number of HIV-positive clinically malnourished clients (based on anthropometric assessment) who received therapeutic or supplementary food. "Therapeutic foods are defined as foods for the management of severe malnutrition and include products such as ready-to-use therapeutic foods (RUTFs), supplementary foods for continued treatment of severe malnutrition after an initial stabilization and weight recovery period and for patients who are mild-to-moderately malnourished at entry. Food provided for household use or as a safety net does not meet the definition of therapeutic and supplementary food for this indicator" (OGAC, 2009c).
SOURCE: Program monitoring indicators provided by OGAC.

Palliative Care, Including Management of Pain and Other Symptoms

PEPFAR defines palliative care as a "holistic approach to providing services that includes a focus on pain and symptom management and on improving quality of life," which is consistent with the WHO definition (OGAC, 2009b). Palliative care, including pain management and end-of-life care, enables PLHIV to lead happier, more productive lives and reduces the burden of care on families. Up to 80 percent of those with advanced HIV infection experience pain, and pain management programs can greatly improve quality of life for PLHIV (OGAC, 2009b). In many countries, restrictive policy environments prohibit effective pain management programs, and access to strong pain medications such as opioids is limited (OGAC, 2009e). PEPFAR's second Five-Year Strategy calls for continued efforts to "support policy changes that ensure pain management is included both in guidelines and actual clinical services for PLHIVs," as well as increased efforts to "strengthen commodity systems, train providers, and expand access to

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opioids for pain management" (OGAC, 2009e). Many of the home-based and community-based care programs described in the next section include pain management among the services they provide. In addition, PEPFAR partners participate in advocacy for palliative care and pain management. In one example, a local association's role as a pain control advocate was described as follows:

> *'They have been successful through advocacy, so that [the country] is now procuring morphine. Through PEPFAR funding, [the country] now has morphine. Talking about morphine is a taboo, but the association has managed to convince the government. Using the PEPFAR funding, they sent the director for the 'medicine and poison fund' to go to [another country] to learn about how they are doing with morphine. After that exposure, the government was convinced.'* (116-13-PCNGO)

Home-Based and Community-Based Care and Support Services

PEPFAR supports care and support service provision through home-based and community-based mechanisms across the spectrum of both the clinical services described earlier (when a health facility is not required) and nonclinical services, which are also critical for the health of people who are HIV positive and for their adherence to treatment once initiated. One interviewee highlighted the need for these services, describing the successful initiation of HIV treatment as *'a cascade of effects that includes a lack of social support, loss of income, [and] hard to maintain adequate nutrition'* (331-8-PCNGO).

Across countries visited for this evaluation, a review of Country Operational Plans and information gathered from interviewees reflected a wide range of clinical and nonclinical services and activities provided through home-based and community-based care, which some interviewees pointed out was first introduced or funded by PEPFAR (396-18-USG; 272-32/35-PCNGO). From just a few examples (not a comprehensive listing), interviewees described management and prevention of opportunistic infections, pain assessment, palliative care, nutrition, treatment of sexually transmitted infections, adherence monitoring, home-based care kits, psychosocial and social support, and home visits for persons who are bedridden (461-3-USG; 396-21-USG; 272-32/35-PCNGO; 395-56-USNGO; 240-29-USNGO; 331-32-PCNGO; 587-13-USG).

This section first describes overall findings from interview data collected for this evaluation that apply generally to home- and community-based care, followed by some findings for specific subsets of PEPFAR-supported nonclinical services for adults. Nonclinical services for children are discussed in full in the section on OVC programs in Chapter 7.

Evolution of Care and Support Services: From Caring for the Dying to Supporting the Living

One theme that emerged across many countries and types of interviewees was that a shift has occurred over time in the nature of care services. Initially, home-based care focused on the critically ill in most countries and on providing end-of-life care and hospice. Although there is still a need for services for the critically ill, now with increased availability of care and treatment services, a move from inpatient to outpatient care, and the generally improved health status of PLHIV, patient populations requiring end-of-life care have declined and the needs are changing

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to different kinds of care and support services (272-32/35-PCNGO; 272-07-USG; 240-2-USG; 935-ES). As described by one interviewee,

> *'For the first 5 years, the beginning of PEPFAR, the care and support activities were very much focused on the late stages of illness through palliative and hospice care. As the lay of the land has changed, so have the care activities. They are focusing on a wider range of care aspects.'* (272-07-USG)

One implementing partner described home-based care as divided into three categories, one in which the patient can perform all activities without any assistance, one in which the patient needs minimal assistance, and one in which the patient is bedridden. Currently the majority of patients fall into the middle category, although at the beginning of PEPFAR they were mostly providing home-based care and hospice, mostly for terminal patients discharged from the hospital (272-32/35-PCNGO). Home-based and community-based care has shifted to the goal of keeping those infected with HIV healthy and to case management and more integrated services, such as chronic disease management (461-3-USG; 240-2-USG; 587-18-PCGOV). One interviewee noted in addition to the introduction of ART, the need for home-based care may also be reduced due to effective care for PLHIV who are pre-ART, consistent with the concept that *'care starts at diagnosis'* (272-07-USG).

Implementation with a Focus on the Community and Using Local NGOs

Another overall characteristic of PEPFAR-supported home-based and community-based care programs that was highlighted across countries is their implementation with a strong focus on the community and on the use of local community and nongovernmental organizations (166-14-PCNGO; 934-10-PCGOV; 272-32/35-PCNGO; 935-19-PCGOV; 240-15-USG). In addition, many programs are implemented using community volunteers or community health workers, many of whom are also PLHIV. These workers provide services such as case management, adherence monitoring and counseling, personal care, palliative care, pain assessment, nutritional assessment, assistance in navigating health services; and referrals to helplines, health facilities, and other program linkages including to facilities known to be '*friendly*' to high-risk targeted populations (272-7-USG; 272-32/35-PCNGO; 166-23-USG; 396-31-PCGOV; 461-13-USACA; 240-15-USG; 240-2-USG; 272-18-PCNGO; 331-14-USG; 331-16-USG). In one example in one partner country, a restructuring was taking place to shift to community care provided by a higher cadre of workers that can do ART and counseling (272-7-USG). In another example, an NGO partner trained traditional healers and community authorities in HIV and associated diseases since these individuals played an integral role in community health care, described as an important approach because a large proportion of the population in a partner country used traditional healers for care (331-19-USNGO).

Linkages between Home/Community-Based Care and Facility-Based Care

As one of the aims across care and support activities, PEPFAR has supported the implementation of different approaches to link facility-based and community-based/home-based care services. Several interviewees described home-based care programs that included an emphasis on promoting linkages with HIV care and treatment clinics and health facilities and providers who can make appropriate referrals (272-32/35-PCNGO; 331-10-PCGOV; 396-25-PCGOV; 166-23-USG). In other cases, the home-based care program or home visits for adherence support and reducing loss

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to follow-up is based out of outpatient facilities or other care and treatment programs, and is therefore directly linked to patients enrolled in clinical care and treatment (935-15-ONGO; 935-25-PCGOV; 396-29-PCGOV; 396-21-USG; 240-19-USACA; 240-25-PCGOV). There were also a few examples for children and adolescents of linking community and nonclinical services with clinical services in health facilities, such as age-specific clubs for children in HIV care and treatment clinics, youth friendly services for HIV positive youth that include support groups, education and programs for youth in school and those not in school, and community workers who focus on helping children stay in treatment (636-17-PCGOV; 935-13-PCGOV; 272-14-PCNGO) (see Chapter 7 for further discussion of services for children and adolescents).

Overall Challenges with Home-Based and Community-Based Care

Although many achievements in home-based and community-based care were described across countries, interviewees also identified challenges with the implementation and scale of these services. These challenges included a lack of knowledge, training, policies, and funding support for home-based care, which was described as '*capital intensive*' (587-10-USG; 272-32/35; 331-27-PCGOV). Interviewees in one partner country described home-based care as not very strong (331-8-PCNGO) or lacking (331-11-PCNGO). In another country, clients in remote areas not reached by home-based counseling and testing were coming to facilities for testing late in their disease (461-17-PCNGO). The limitation of the scope of interventions that could be done in the community was also described as a challenge, as was the lack of clinical services available for referral which was linked to the need for health systems improvements to increase the availability of '*adequate services at public health facilities'* (461-7-PCNGO).

Another specific challenge described by implementing partners is the interpretation of indicators and the quality and timeliness of reporting, primarily due to challenges with the capacity of local providers and with barriers to reporting such as transportation (272-32/35-PCNGO; 331-32-PCNGO; 272-15-PCNGO).

Specific Areas of PEPFAR-Supported Nonclinical Services

Psychological and spiritual support Psychological and spiritual support supported by PEPFAR may include group and individual counseling and culturally appropriate end-of-life care and bereavement services (OGAC, 2010a). Although *'a lot has happened since 2004,'* (166-15-USACA), interviewees generally echoed the perspective that, *'programs with psychosocial and spiritual support is an area of greatest need but no strong undertaking'* (240-15-USG). Another interviewee's observation that, *'psychosocial support is weak nationwide'* (166-29-PCGOV) was affirmed by another interviewee's recognition that such support is an area *'that needs more attention'* (396-21-USG), particularly since, in this country, the need is not being met for the general population (396-45-USNGO).

Several interviewees reported the provision of psychosocial care or, more rarely, spiritual care, including services such as peer education and peer support, self-help groups for PLHIV and their families, and provision of psychosocial counseling for PLHIV or "psychosocial support," although this concept as a service was often not clearly defined or articulated (331-10-PCGOV; 396-21-USG; 461-18-USG; 587-13-USG; 331-32-PCNGO; 196-07-PCNGO; 396-44-PCGOV). Reflections on the providers for such care included that few trained professionals are available for service provision (272-15-PCNGO; 461-10-PCNGO). In one country, qualified social workers were described as difficult to recruit and retain, particularly in rural areas (272-15-PCNGO). An interviewee in another country observed that '*counselors and clinical psychologists are cadres that don't really exist in the public service*

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payroll' (461-10-PCNGO). PLHIV have played an increasingly important and direct role in offering individual, family, community-, or hospital-based psychosocial or spiritual support. As volunteers or recipients of stipends, they offer such support primarily by means of: organizing and facilitating HIV support groups, peer education that involves psychosocial support, and role modeling (331-09-PCNGO; 240-15-USG; 240-25-PCGOV; 331-32-PCNGO).

Social support Social support services supported by PEPFAR may include social and legal protection as well as training and support of caregivers (OGAC, 2010a, 2011a). As with "psychosocial support," interviewees mentioned programs or activities that offered "social support" or described an unmet need for this support, but a clear understanding of what that entailed as a service or set of services was difficult to determine across the scope of PEPFAR-supported programs (196-20-PCNGO; 240-14-USPS; 396-21-USG; 396-32- PCGOV; 396-50-PCGOV; 461-10-PCNGO; 331-08-PCNGO). Some linked "social support" with the nature of assistance provided by faith-based organizations (196-20-PCNGO). Others asserted that "social support" was needed in order to prevent defaults from treatment. One partner described "social support" as *"overwhelming"* and a *"big need to tackle"* (272-22-USG).

As one subset of social support, several interviewees identified efforts to provide training and support for caregivers of PLHIV. One partner described caregivers as "*wounded healers*" for whom care is provided in some programs (272-11-PCNGO). Another described some limited economic empowerment projects to help families that provide care. Yet another highlighted the role of women as caregivers:

> *'In terms of care, women are the primary caregivers. This role has been acknowledged and there have been efforts to lighten the burden. "Women have borne the brunt of HIV/AIDS."'* (934-07-PCGOV)

Home- and community-based support for legal protection is primarily implemented in the context of OVC programs or gender-focused programs; these are discussed in Chapters 7 and 8 respectively.

Economic strengthening activities Recognizing that a lack of economic assets increases vulnerability, PEPFAR supports activities that "supply, protect, or grow physical, natural, financial, human, and social assets" (OGAC, 2009f). These activities may include vocational training, microfinance and microcredit programs to expand access to financial services, and income-generating activities, including communal gardens (that may also provide food) (OGAC, 2009f, 2010a). Interviewees in partner countries affirmed the importance of this area of intervention. One interviewee described a need for more *'social interventions'* for people with HIV in order to assist them to become more employable and productive, *"like any other person"* (331-08-PCNGO). Another described the ideal as supporting PLHIV to be able to return to the jobs they held or businesses they had prior to becoming ill (331-32-PCNGO). Yet another described positive outcomes of PLHIV participation in income generating activities, including a source of productive work, opportunity for skills building, means of contributing to the community, improved self-esteem and morale, and assumed improved treatment adherence. According to this organization, *'They don't just let patients sit and say I'm sick… It is not only about giving them ARVs'* (272-32,35-PCNGO). The link between income generating activities and reducing risk was also

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highlighted by one partner organization, as exemplified by sex workers who could find no other means of employment (331-08-PCNGO).

A number of partner organizations across countries, including many local community-based organizations, described providing or linking PLHIV with support for income-generating activities (IGAs) such as farming or raising animals, making products to sell like beads, candles, and soap, and providing small grants to start businesses (240-14-USPS; 240-26-PCNGO; 240-29uUSNGO; 331-20-USNGO; 272-32,35-PCNGO; 240-25-PCGOV; 331-08-PCNGO). As described in one partner country:

> *'One of the most important successes for our PEPFAR-funded [faith-based organization partners] project is that all our beneficiaries have been linked to local support and some have been successful in their income generating activity. The challenge is to scale up with other projects, other partners.'* (240-26-PCGOV)

Although IGAs were generally endorsed, some interviewees did report doubts about the value and viability of IGAs for PLHIV (272-32/35-PCNGO; 240-24-USG).

There were also a number of interviewees across countries who described programs and issues related to vocational training. Resources associated with vocational training posed challenges, and despite isolated program successes, vocational training remained a largely unmet need for PLHIV. Challenges are compounded for PLHIV in marginalized populations:

> *"Livelihood options, vocational trainings, that type of thing, it's not that people are not trying to meet it, but it's just very difficult because you have these double stigmatized populations. Many of them are really uneducated, and the very urban environment, relatively high cost and no land. So it's a huge, huge gap. But not for want of trying."* (396-45-USNGO)

In addition to specific income generating and vocational training activities, PEPFAR has also contributed to the availability and stability of employment for people living with HIV through activities to reduce workplace discrimination, including policy and legislative efforts as well as support for workplace programs for HIV awareness and HIV counseling and testing in the workplace (587-ES).

Conclusion: PEPFAR has made a tremendous contribution to a wide variety of clinical and nonclinical care and support services, beyond provision of antiretroviral therapy, through scale-up of services and programs in facilities and communities and through support for partner country policies, guidelines, and protocols. However, for the area of nonclinical care and support in particular, services span a diffuse range of activities across countries and it is difficult to assess their effects. Information is lacking on the distribution of services, the intended outcomes, how well the services are matched to population and subpopulation needs, and the effectiveness of these services.

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Recommendation 6-1: To improve the implementation and assessment of non-clinical care and support programs for adults and children, including programs for orphans and vulnerable children,[6] the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.

Further considerations for implementing this recommendation:

- Outcomes for consideration should reflect the aims of care and support programs, which are to optimize quality of life, promote health, slow the progression of AIDS, and reduce HIV-related complications and mortality. Other outcomes of importance for the performance and effectiveness of care and support programs include measures of quality of services and equitable access to services.
- PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to assess country-specific needs and select a subset of the core key outcomes to focus on when planning, selecting, and developing evidence-informed activities and programs for implementation.
- OGAC should provide general guidance for country programs on continuous program evaluation and quality improvement to measure and monitor achievement of the key outcomes. This may include, for example, template evaluation plans and methodological guidance. To allow for comparability across countries and programs, evaluation plans should include (but not be limited to) the defined indicators or other measures of the core key outcomes. Evaluations should emphasize the use of in-country local expertise (e.g., local implementing partners/subpartners and local academic institutions) to enhance capacity building and contribute to country ownership. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)
- PEPFAR should develop a system for active dissemination and sharing of evaluation outcomes and best practices both within and across countries that is driven as much by country-identified needs for information as by opportunities for exchange of information identified by headquarters-level leadership and Technical Working Groups. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)

[6] The discussion of programs for orphans and vulnerable children leading to this aspect of this recommendation can be found in Chapter 7.

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ANTIRETROVIRAL THERAPY

Global Context for the Scale-Up of Antiretroviral Therapy

The rapid scale-up of ART in the past decade resulted from intense advocacy efforts, unprecedented political commitments at the highest levels, dramatic reductions in the cost of antiretroviral drugs, and record increases in donor country foreign assistance dedicated to HIV/AIDS. It represents one of the most significant achievements in the more than 30-plus-year global fight against AIDS (Kapstein and Busby, 2009; UNAIDS, 2011).

When combination ART became available in 1996, it cost more than $10,000 per patient annually, placing the life-saving treatment largely out of reach for those in low- and middle-income countries. A lack of political will to address the pandemic from leaders in both donor and many developing countries—largely due to the high cost of treatment, but also due to ongoing stigma and the pervasive opinion that HIV/AIDS treatment was too complicated to implement in low-resource settings—meant that an HIV diagnosis continued to be a death sentence for the majority of the world's population (Kapstein and Busby, 2009; UNAIDS, 2011).

By the turn of the 21st century, however, the tide had begun to change. By then, the ability of ART to bring patients from the brink of death to relative good health had transformed HIV/AIDS in high income countries to a largely manageable chronic disease. This was a stark difference from the ongoing and rapidly increasing mortality rates that remained in low and middle income countries (UNAIDS, 2011). There was increasing recognition among a wide range of stakeholders of the profound and growing toll of HIV/AIDS on the health, economies, and future development in the most affected developing countries and increasing evidence that it was possible to treat HIV/AIDS in low-income settings. Under increasing pressure to take concerted action to expand access to life-saving ART and prevention tools in developing countries, the world's political leaders stood poised to finally recognize the significance of the HIV/AIDS pandemic and make meaningful commitments to address the global crisis. A major worldwide political commitment to address the pandemic at the highest levels and established global targets and goals for the response came at the 2001 United Nations General Assembly Special Session (UNGASS) on HIV/AIDS (UNAIDS, 2011).

Momentum from the UNGASS on HIV/AIDS led to the ambitious World Health Organization 3 by 5 Initiative in 2003, which set the goal of placing 3 million patients in need on life-saving ART by 2005. This represented an ambitious goal in the international response to HIV/AIDS given that when the initiative began in 2003, only an estimated 400,000 people living with HIV were receiving ART. As a part of the 3 by 5 Plan, WHO also established global guidelines for the eligibility and treatment of HIV in developing countries (WHO, 2004).

The global political commitment that emerged from the 2001 UNGASS on HIV/AIDS also led to an unprecedented increase in financial commitments to combat the pandemic, including the establishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) in 2002, with financial pledges totaling more than $15 billion from most of the world's leading donor nations, who also support bilateral HIV programs (Kapstein and Busby, 2009; UNAIDS, 2011; WHO et al., 2009) and the initiation of PEPFAR, with its commitment to scaling up HIV/AIDS treatment and prevention programs in the countries most affected by the

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epidemic.[7] The financial support of PEPFAR and the Global Fund, reductions over time in the cost of ART, robust political commitments, and efforts to strengthen health systems that support service delivery have combined to allow for the rapid scale up of HIV treatment and prevention programs in low- and middle-income countries.

By the end of 2011 more than 8 million people living with HIV in low- and middle-income countries were receiving ART and of these, about 562,000 were children. This was a 20-fold increase in the number of people receiving ART in developing countries from the 400,000 receiving ART in 2003. The costs of providing ART have also come down dramatically, with the current per patient-year cost estimated to be under $1000 (Menzies et al., 2011; PEPFAR, 2012; UNAIDS, 2012). The benefits of using antiretroviral therapy to reduce the mortality and morbidity of persons living with HIV/AIDS and reduce HIV transmission cannot be overemphasized (Mat Shah et al., 2012), and there is increasing evidence of the effectiveness of ART in resource-constrained settings (Bussmann et al., 2008; Herbst et al., 2009; Jahn et al., 2008; Mermin et al., 2008). Global efforts to expand the availability of ARV drugs have resulted in a greater proportion of people in need of treatment receiving ART, which is contributing to lower HIV-related mortality in multiple countries and regions (UNAIDS and WHO, 2009). WHO estimates that as of December 2009, ART had saved 14.4 million life-years since 1996, of which 3.7 million life-years have been saved in sub-Saharan Africa (UNAIDS, 2011; WHO et al., 2009).

However, although progress is being made in increasing coverage, a large proportion of PLHIV in need of treatment are currently not receiving such services, especially in sub-Saharan Africa, where there is the greatest need (WHO et al., 2009). UNAIDS estimated that in 2010 coverage for adults was 51 percent (WHO et al., 2011). Furthermore, 57 percent of the estimated 1.5 million pregnant women living with HIV in low- and middle-income countries received effective antiretroviral drugs to avoid transmission to their children in 2011, up from 48 percent in 2010 but not yet approaching the 80 percent global target (WHO et al., 2010). In addition, UNAIDS reported that children constituted about 14 percent of new cases of HIV infection reported in 2011, and that estimated coverage of children receiving ART was 23 percent (WHO et al., 2011).

PEPFAR's Contribution to Antiretroviral Therapy: Overview

Recognizing the need for delivering life-saving treatment to the millions of people living with HIV as a global health emergency, when it was initiated PEPFAR strategically focused on the rapid scale-up of HIV treatment services and an increase in ART coverage (IOM, 2007). PEPFAR's support for adult and pediatric ART, termed its treatment programs, includes procurement of ARV drugs as well as infrastructure, training clinicians and other providers, exams, clinical monitoring, related laboratory services, and community-adherence activities (OGAC, 2010a). As an ongoing critical component of the continuum of care, patients enrolled in ART also continue to be eligible for the care and support services for PLHIV described in the previous section of this chapter. In addition, PEPFAR supports both care and treatment services through its health systems strengthening activities, which are described in detail in Chapter 9, where most discussion of the treatment program components of workforce training, laboratory

[7] United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L.108-25, 108th Cong., 1st Sess. (May 27, 2003).

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services, and supply chain management can be found. Although not discussed in detail in this chapter, these systems-level activities are nonetheless an integral part of supporting the continuum of care for HIV-positive patients.

The assessment of PEPFAR's treatment programs described in this section followed the program impact pathway framework. The committee assessed how PEPFAR's investments (inputs) for the delivery of ART services affected the availability of ARVs and access to treatment interventions through enrollment in ART (outputs). Within the limitations of the available data, the committee attempted to assess the effects of PEPFAR on the coverage of those in need of and eligible for treatment and the retention in treatment of those enrolled (outcomes) as well as the ultimate effect on mortality in patients enrolled in ART (impact).

Overall, the scale-up of ART was seen across countries and across stakeholders as a major success of PEPFAR that had a tremendous impact saving lives of HIV-positive patients. The progress made after the introduction of PEPFAR-supported care and treatment programs is exemplified by one interviewee:

> *'There was a dramatic increase in uptake of testing and ART, increased awareness and willingness to be tested, increased number of clinicians trained to provide ART, and the number of sites providing ART increased.'* (240-15-UG)

The sections that will follow will address in more detail the achievements and challenges in the component areas of the committee's assessment of PEPFAR's ART programs.

Guidelines for Antiretroviral Therapy

PEPFAR does not issue programmatic guidance of its own for treatment, but instead defers to the normative guidance of the World Health Organization (NCV-10-USG; NCV-13-USG). In its 2010 HIV treatment guidelines the WHO updated its recommendation for ART initiation, and is now recommending that all HIV-positive adults and adolescents, including pregnant women, start antiretroviral drug treatment at CD4 counts of less than 350 cells/mm^3 (compared to previous recommended level of less than 200 cells/mm^3) as a means to curb HIV related mortality and to prevent opportunistic infections such as tuberculosis. This treatment should be commenced irrespective of the presence or absence of clinical symptoms (WHO, 2010b).

WHO also has guidelines for the use of antiretrovirals to reduce the risk of mother-to-child transmission during pregnancy, delivery or breastfeeding. WHO recommends antiretroviral prophylaxis for all HIV-positive pregnant women during pregnancy, regardless of CD4 count. The guidelines also recommend antiretrovirals for the mother/infant pair in order to reduce the risk of HIV transmission during breastfeeding, in countries where breast feeding is deemed the safest feeding option (WHO, 2010a). In terms of ongoing ART for women initially identified as HIV positive during pregnancy, in prior WHO guidelines, pregnant women with CD4 counts less than 250 were eligible. In the updated WHO guidelines not only does the CD4 threshold increase to 350, as for all adults, but with what is called PMTCT option B+, all pregnant women regardless of CD4 and clinical stage can be started on ART, making pregnant women a priority for treatment if a country elects to implement this as its standard. See Chapter 5 for further discussion of prevention of mother-to-child transmission.

With respect to HIV treatment for children, current WHO guidelines indicate that all HIV-infected infants and children less than 2 years of age should be started on ART immediately

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upon diagnosis, irrespective of CD4 count or WHO clinical stage. WHO suggests specific regimens for infants born to mothers receiving nevirapine as a single drug assuming that these infants, if infected, will have nevirapine resistant virus. Presumptively HIV-positive sick infants should also be treated promptly and not await definitive diagnosis (Grundmann et al., 2011; WHO, 2010c). Those children older than 24 months should commence treatment based on their age-specific CD4 cell count levels (WHO, 2010c).

More recently, the WHO released new treatment guidelines for serodiscordant couples where only one partner is HIV positive, recommending offering ART to the HIV positive partner, regardless of immune status (CD4 count), to reduce the likelihood of HIV transmission to the HIV negative partner (WHO, 2010c). These guidelines were released after most data collection for this evaluation of PEPFAR was completed, and therefore consideration of them in this report is limited.

The changes in the updated WHO HIV treatment guidelines increased the number of persons estimated to be eligible for and in need of ART (De Lay, 2010). This issue will be discussed in more detail in the subsequent section of this chapter on ongoing challenges with coverage for ART.

At the time of the country visits for this evaluation (late 2010 through early 2012), interviewees in many countries stated that they have started the implementation of the 2010 WHO treatment guidelines for adults, while in some countries there was a lag in adopting the guidelines for children (116-5-PCGOV; 116-7-USG; 116- 9-PCNGO; 116-18-PCNGO; 396-30-PCGOV; 935-5-USG; 542-9-USPS; 272-22-USG; 934-5-USG).

Interviewees described several challenges with adoption and implementation of the 2010 WHO guidelines, many of which were related to the resulting anticipated increase in the demand for treatment services (934-2-USG; 934-10-PCGOV; 934-12-CCM; 542-9-PCGOV), including the costs and availability of drugs to meet the need (272-3235-PCNGO; 934-5-USG; 934-10-PCGOV). Lack of funding to accomplish the transition to the new guidelines was reported (934-17-PCGOV), with great concern about the failure to receive or the cancellation of Global Fund rounds and other potential decreases in funding from international donors (396-30-PCGOV; 934-5-USG; 934-12-CCM). Interviewees also noted operational challenges due to the little time between receiving the final version of the guidelines and the implementation phase (116-9-PCNGO). According to interviewees, PEPFAR has supported ministries of health in the development of national care and treatment guidelines, taking into account the WHO guidelines, as well as their implementation through training and support for increased service delivery, for adults (240-12-USG; 587-13-USG; 196-10-PCGOV; 116-18-PCNGO; 587-5-PCGOV) and for pediatric HIV (240-19-USACA; 240-25-PCGOV; 240-24-USG; 396-21-USG), which has emphasized integration and increased services for children (240-24-USG; 461-13-USACA; 116-9-PCNGO).

Table 6-10 is a summary, at the time this report was finalized in late 2012, of the adoption of WHO and national treatment guidelines in the 31 PEPFAR partner countries that were the main focus for this evaluation.

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TABLE 6-10 Adult and Pediatric Treatment Guidelines Adoption by Country

ID	Country	ART Available as Early as	Start ART Program	Adult ART Guidelines Publication Year	No. Revisions Adult ART Guidelines	Adopted** WHO 2010 Adult ART Guidelines (1)	Peds ART Guidelines*** Publication Year	No. Revisions Peds ART Guidelines	Adopted** WHO 2010 Peds ART Guidelines
1	Angola		2002	2003	-	Yes	2003	-	Yes
2	Botswana		2002	2005; 2008; 2012	2	Yes	2005; 2008; 2012	2	Yes
3	Cambodia		2001	2003; 2007	1	Yes	2004; 2007; 2011	1	Yes
4	China		2002; 2005 (Peds)	2005	-	Yes	2005	-	Yes
5	Côte d'Ivoire	1998	2001	xxxx; 2005	1	Yes	xxxx; 2005	1	Yes
6	DRC		2005	2002; 2005	1	Yes	2002; 2005	1	Yes
7	Dominican Republic		2003	2004	-	No	2004	-	No
8	Ethiopia		2003	2003; 2005; 2008	2	Yes	2000; 2003; 2005; 2007	3	Yes
9	Ghana		2003	2002; 2005; 2008	2	Yes	2002; 2005; 2008	2	Yes
10	Guyana		2002; 2004 (Peds)	2004; 2006; 2008; 2009	3	No	2004; 2006; 2009	2	No
11	Haiti	1999	2002	2003; 2008	1	No	2006	-	No
12	India		2004	2004; 2007	1	Yes	2006	-	Yes
13	Indonesia		2004	2003; 2007; 2010	2	Yes	2003; 2007; 2010	2	Yes
14	Kenya		2003	2005; 2011	3	Yes	2005; 2011	3	Yes
15	Lesotho*	2002	2004	2007 (draft)	-	Yes	2007 (draft)	-	Yes
16	Malawi		2004	2003; 2006; 2008; 2011	3	Yes	2006; 2008; 2011	2	Yes
17	Mozambique*	2002/2003 (Peds)	2003	2006; 2009/2010	1	Yes	2009/2010	-	Yes
18	Namibia		2003	2003; 2007; 2010	2	Yes	2003; 2010	1	Yes
19	Nigeria		2002	2001; 2005; 2007; 2010	3	Yes	2005; 2010	1	Yes
20	Russia		2002	2002; 2007	1	No	2002; 2007	1	No
21	Rwanda		2002	2007	-	Yes	2007	-	Yes
22	South Africa		2001	2004; 2010	1	Yes	2004; 2010	1	Yes
23	Sudan		2005	2004	-	Yes	2004	-	Yes
24	Swaziland		2003	2003; 2006; 2010	2	Yes	2002; 2006	1	Yes
25	Tanzania		2004	2005; 2009	2	Yes	2005; 2009	2	Yes
26	Thailand		2000	2008; 2010	1	Yes	2010	-	Yes
27	Uganda*	1998	2004	2003; 2008; 2009	2	Yes	2003; 2008; 2009	2	Yes
28	Ukraine		2004	2004; 2006	1	Yes	2004; 2007	1	Yes
29	Vietnam		2005	2005; 2009	1	Yes	2005; 2009	1	Yes
30	Zambia		2004	2007	-	Yes	2007; 2010	1	Yes
31	Zimbabwe		2004	2010	-	Yes	2010	-	Yes

NOTES: *If a country makes a distinction between start of ART program at a site(s) and scale-up efforts, the year ART was established at a site(s) is included under "ART Available as Early as"; **Adopted either the new eligibility criteria for all patients or pregnant women and/or already (or planning) phasing out from d4T; ***Either as a component of adult guidelines or separate document.

Key: **Blue** - Inferred after Review of Guideline(s) but Guideline Document(s) NOT Available to Confirm; **Orange** - Found after Review of Guideline(s) But Guideline Document(s) NOT Available to Confirm; **Red** - Found through Supporting Document(s) but Guideline Document (s) NOT Available to Confirm

SOURCES: Updates on adult and pediatric guidelines for treatment of HIV/AIDS available through AIDSTAR-One and WHO; (Srikantiah et al., 2010).

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Funding History for PEPFAR-Supported Treatment Programs

PEPFAR's activities for treatment are captured within the budget codes for ARV drugs, Adult Treatment, and Pediatric Treatment. Figure 6-5 shows the funding over time in these budget codes in both the dollar amount and as a proportion of all PEPFAR funding. The total across these budget codes increased since the beginning of PEPFAR, peaking in FY 2008 at just over $1.3 billion a year, followed by a decline and leveling off by FY 2011 at about $1.1 billion.

From FY 2005 through FY 2011, pediatric treatment received on average 9 percent of the total adult and pediatric treatment budget codes (including the years in which pediatric treatment was not reported). This percentage fluctuated in the early years of PEPFAR, when the budget code definition was also fluctuating. It has been steady at 13-14 percent from FY 2009 to FY 2011.

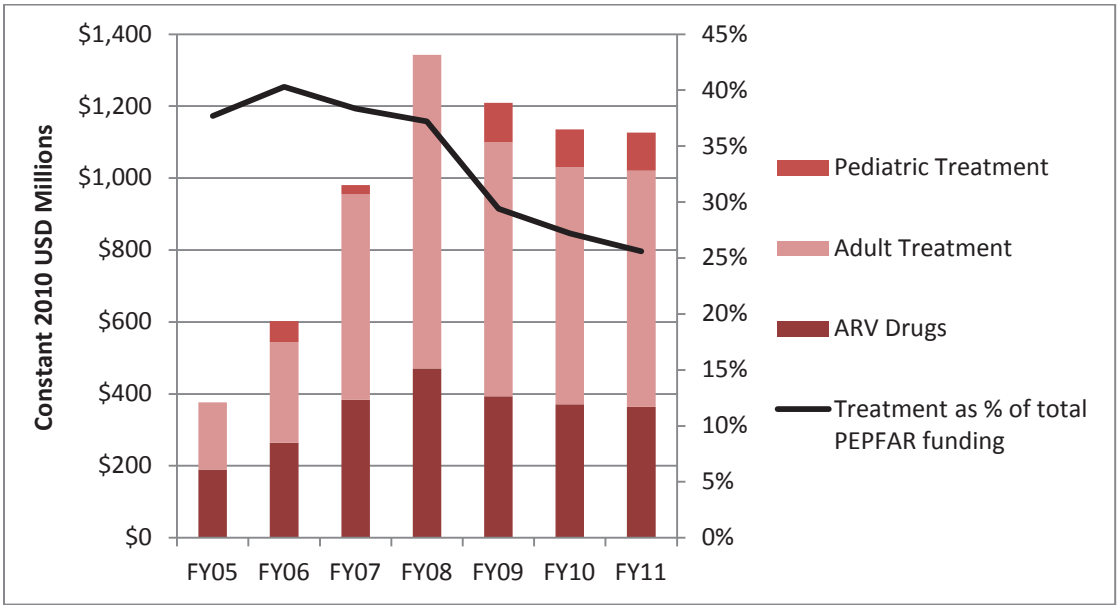

FIGURE 6-5 Planned/approved funding over time for treatment.
NOTE: This figure represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes. Funding for pediatric treatment was not reported in FY 2005 and FY 2008. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by programmatic area. Data are presented in constant 2010 USD for comparison over time. See Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding.
SOURCE: (OGAC, 2005, 2006c, 2007b, 2008, 2010c, 2011d, 2011e).

Legislative Budgetary Allocation Requirement for Care and Treatment Funding

The original legislation authorizing PEPFAR mandated that not less than 55 percent of the budget be used for therapeutic medical care for those with HIV.[8] In the Lantos-Hyde Act of 2008 reauthorizing PEPFAR, this was changed to a requirement that more than 50 percent of funds be used for care and treatment of people living with HIV.[9] PEPFAR's policy for implementing this budgetary requirement is provided in the instructions to country programs

[8]*Supra*., note 7 at §403(a).
[9]*Supra*., note 1 at §403, 22 U.S.C. 7673(d)(1-4).

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through Country Operational Plan (COP) guidance, where it is interpreted as a percentage of the total funds for prevention, care, and treatment. As shown in Table 6-11, based on planned/approved funds aggregated across all PEPFAR countries, PEPFAR has met this budgetary requirement consistently, with the percentage fluctuating across years between 60 percent and 70 percent.

TABLE 6-11 Care and Treatment Budgetary Allocation Requirement: Documented Planned/Approved Funding Over Time (in USD Millions)

	2005	2006	2007	2008	2009	2010	2011	Total
Prevention	$382.1	$383.7	$634.2	$904.7	$1,086.9	$1,142.5	$1,259.1	$5,793.2
Care	$187.9	$252.9	$505.3	$714.9	$870.1	$841.3	$883.3	$4,255.5
Treatment	$376.3	$602.3	$980.7	$1,342.6	$1,209.0	$1,135.5	$1,126.7	$6,773.1
Prevention/ Care/ Treatment Total	**$946.2**	**$1,238.9**	**$2,120.2**	**$2,962.2**	**$3,165.9**	**$3,119.3**	**$3,269.1**	**$16,821.8**
Care and Treatment % of Total	60%	69%	70%	69%	66%	63%	61%	66%

SOURCE: (OGAC, 2005, 2006c, 2007b, 2008, 2010c, 2011d, 2011e).

Some service delivery sites with HIV care and treatment programs may receive financial and other support from more than one source. For treatment programs supported by PEPFAR, the partner country may use Global Fund, other donor, or country resources at the national or subnational level to support specific components of services in sites where PEPFAR also supports treatment (PEPFAR and USAID, 2007). Indeed, several interviewees noted that part of PEPFAR's work in scaling up treatment was in helping the country government also scale up its own response in partnership with PEPFAR, building on the government's strong commitment to treatment (272-22-USG; 461-18-USG). Despite this scale up in government support, the proportion of government contribution to ARV procurement and to treatment varies among countries, and one major theme that emerged about funding from interviewees in many PEPFAR partner countries was that external donor resources, especially PEPFAR and the Global Fund, provide a significant proportion of treatment costs. This issue will be discussed briefly later in this chapter and in much more depth in Chapter 9 in the section on financing and in Chapter 10 on sustaining the response.

PEPFAR-Supported Enrollment in ART

PEPFAR Treatment Indicator Data: Targets and Results

PEPFAR has only very limited central reporting of indicators to reflect the performance of PEPFAR's treatment programs. The primary indicator is an overall output indicator capturing the number of adults and children with advanced HIV infection who are receiving ART. This indicator serves to track the overall legislative target for treatment. Table 6-12 shows that the number of people on treatment supported by PEPFAR has increased over time, and that after the initial year of implementation the annual target has been consistently met or exceeded. PEPFAR reached the initial legislative 5-year target of providing treatment to more than 2 million people

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(PEPFAR, 2009). In the second Five-Year Strategy PEPFAR set the target of providing direct support for more than 4 million people on treatment by 2014, more than doubling the number of people directly supported on treatment during the first five years of PEPFAR. This target was recently increased and the timeline was shortened, to reaching 6 million people by the end of 2013 (Obama, 2011). In FY 2010, PEPFAR provided ART to over 3 million individuals.

TABLE 6-12 Number of Adults and Children with Advanced HIV Infection Receiving ART (in Millions)

	FY04	*FY05*	*FY06*	*FY07*	*FY08*	*FY09*	*FY10*
Actual	0.1	0.2	0.5	1.1	1.7	2.5	3.2
Target	--	0.3	0.5	0.9	1.4	2.2	2.9
% of Target	--	86	102	117	124	113	109

NOTES: This table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2). Data correspond to Indicator 11.4 (FY04-FY09): Number of individuals receiving ART at the end of the reporting period and Indicator T1.2.D (FY10): Number of adults and children with advanced HIV infection receiving ART
SOURCE: Program monitoring indicators provided by OGAC.

Because so many treatment programs in PEPFAR partner countries are jointly funded to varying degrees by the Global Fund, it is important to note that the total number of individuals directly supported on ART includes an estimated overlap of individuals receiving ART with support by both PEPFAR and the Global Fund. This overlap estimate also is included in the treatment results reported by the Global Fund. To estimate this overlap, PEPFAR conducts a review of the treatment and funding data with the Global Fund and WHO, on a country-by-country basis. In its review, PEPFAR and the Global Fund take into account the percentage or level of contribution to the national HIV/AIDS program in order to determine where there is likely to be overlap (GFATM, 2009; OGAC, 2010a; PEPFAR, 2010).

The program monitoring data available to the committee had limited utility for fully understanding the effects of PEPFAR's treatment programs. One key limitation is that indicator data provided to the committee by OGAC had limited disaggregation over time. Age disaggregation is important to assess PEPFAR's pediatric HIV programs and the legislative commitment to providing care and treatment to children in proportion to their relative burden. The Next Generation Indicator revision includes central reporting of age disaggregated data to include infants under 1 year old (OGAC, 2009c). Disaggregation by sex and by specific populations is important to assess how services are distributed across these identified populations and to assess the success of PEPFAR's efforts to implement women- and girl-centered approaches to delivering services, including reaching women through entry points other than PMTCT, and to work towards gender equity in service delivery as well as equitable access for marginalized populations, including men who have sex with men, people who inject drugs, and people who engage in sex work. Finally, measures that reflect outcomes for the clients who received services are critical to assess the effectiveness or quality of PEPFAR-supported care and support programs.

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Results from PEPFAR's Track 1.0 Partners[10]

Although the centrally reported treatment indicator is limited, many country programs and partners collect additional indicators for treatment programs that are not routinely reported centrally. To pursue additional data that were systematically collected longitudinally across as many countries as possible, the committee requested data from the CDC that were collected through the Track 1.0 partner care and treatment programs. These are four partners who have been major implementers of ART and other HIV services since PEPFAR was initiated through a program centrally managed by CDC and the U.S. Health Resources and Services Administration (HRSA). They are each active in multiple countries, implement programs through a wide range of facilities and sub-partners, and provide services to a large number of clients. Taken together, they support programs in a subset of 13 PEPFAR partner countries that receive a large proportion of PEPFAR treatment investment; total funding to these 13 countries represents 94 percent of the total planned/approved treatment funding from FY 2005 to FY 2011. The Track 1.0 partners were not the only implementers of that funding, but they represent a large proportion of the clients served in each of the countries.

The following section presents data on enrollment from these partners, who are also a data source in the subsequent sections on retention and mortality. These data are presented in the aggregate, without identification or disaggregation by partners and countries.

Track 1.0 Enrollment in ART

Since the beginning of PEPFAR in 2005, Track 1.0 partners have supported a steadily increasing total number of people enrolled in ART (Figure 6-6). Table 6-13 shows the annual number of individuals currently enrolled for the Track 1.0 partners, and by comparison the annual numbers across all PEPFAR ART programs. The proportion of PEPFAR ART enrollment represented by the Track 1.0 partners decreased over time as the number of partners implementing ART programs expanded. Beginning in 2011, as the Track 1.0 partners begin to transition patients to other programs the numbers enrolled for Track 1.0 partners began to decrease (see Figure 6-6); the Track 1.0 transition process is described in more detail in Chapter 10 on the sustainability of the response.

TABLE 6-13 Currently Enrolled Adults in ART, in Thousands (Annual, 2005-2010)

	FY2005	*FY2006*	*FY2007*	*FY2008*	*FY2009*	*FY2010*
Total currently enrolled in ART, n						
Track 1.0 partners	92.8	203.2	339.7	513.6	694.2	856.5
Entire PEPFAR program	249.2	541.5	1,091.7	1,743.7	2,485.3	3,209.7
Track 1.0 contribution to PEPFAR (%)	**37**	**38**	**31**	**29**	**28**	**27**

SOURCE: Programmatic data from Track 1.0 partners provided by CDC.

[10] Track 1.0 Partners in this report refers to four partners that were the primary large-scale implementers of ART in PEPFAR's centrally funded Track 1.0 program (for more information, see Appendix C, Methods). These partners also implemented other HIV services and programs, and there were also other centrally funded Track 1.0 partners in other program areas.

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Figure 6-6 shows the increase over time in the total number, by quarter, of people enrolled in ART. An increase quarterly in total enrollment is complemented by a steady increase quarterly in newly enrolled ART patients through 2009 when new enrollment began to level off and increase at a much lower rate. The decrease in new enrollment even as total enrollment continued to increase could be explained by a decrease in the population need for ART; however this is not the case in most PEPFAR partner countries. Therefore, the relative slowing of new enrollment in the programs supported by these partners may be because as the number surviving who need to be maintained in care and treatment accumulates and represents a greater proportion of total capacity, the number of newly enrolled patients may be limited by the available funding, the availability of facilities providing care and treatment, and the availability of providers.

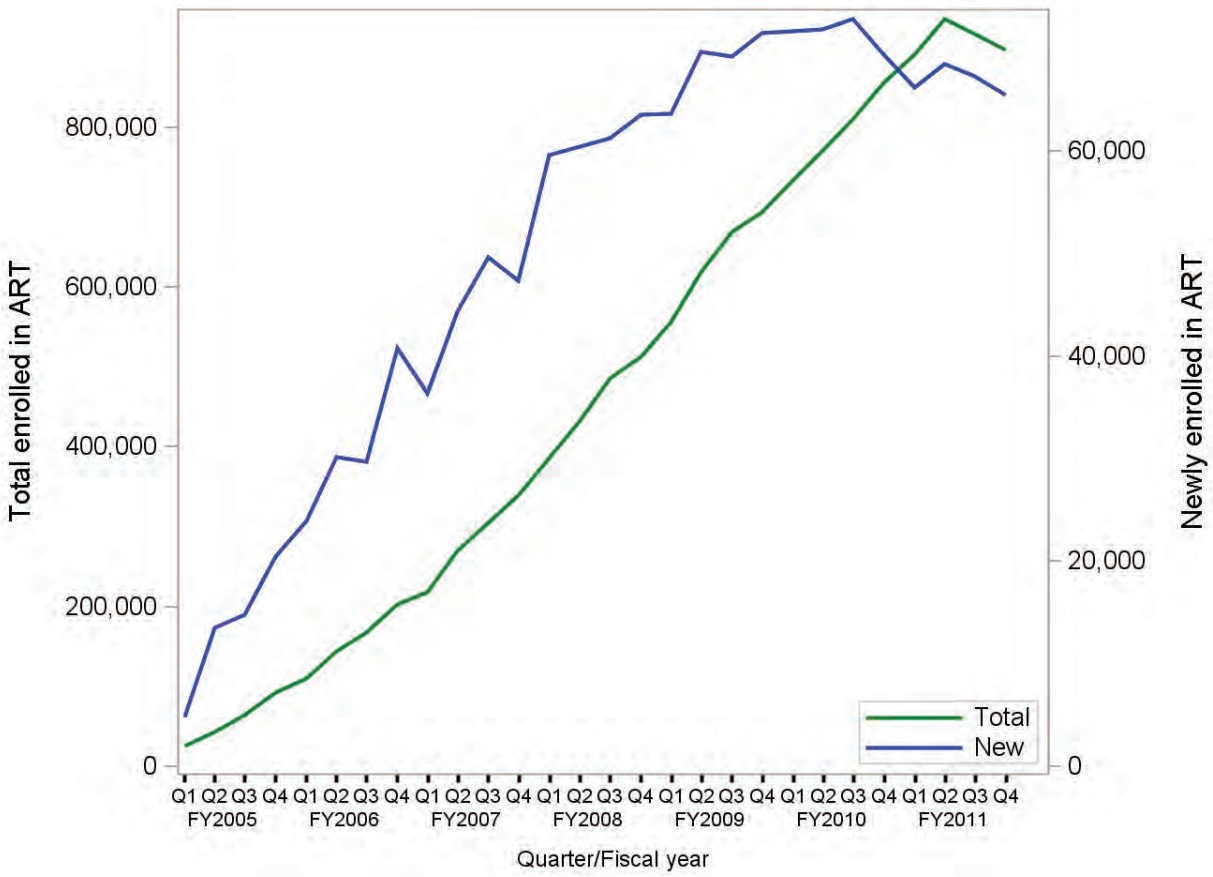

FIGURE 6-6 Total enrolled and newly enrolled individuals (adults and children) in ART (quarterly, 2005-2011).
SOURCE: Programmatic data from Track 1.0 partners provided by CDC.

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Figure 6-7 and Table 6-14 show annual new enrollment of adults in these care and treatment programs, disaggregated by sex.

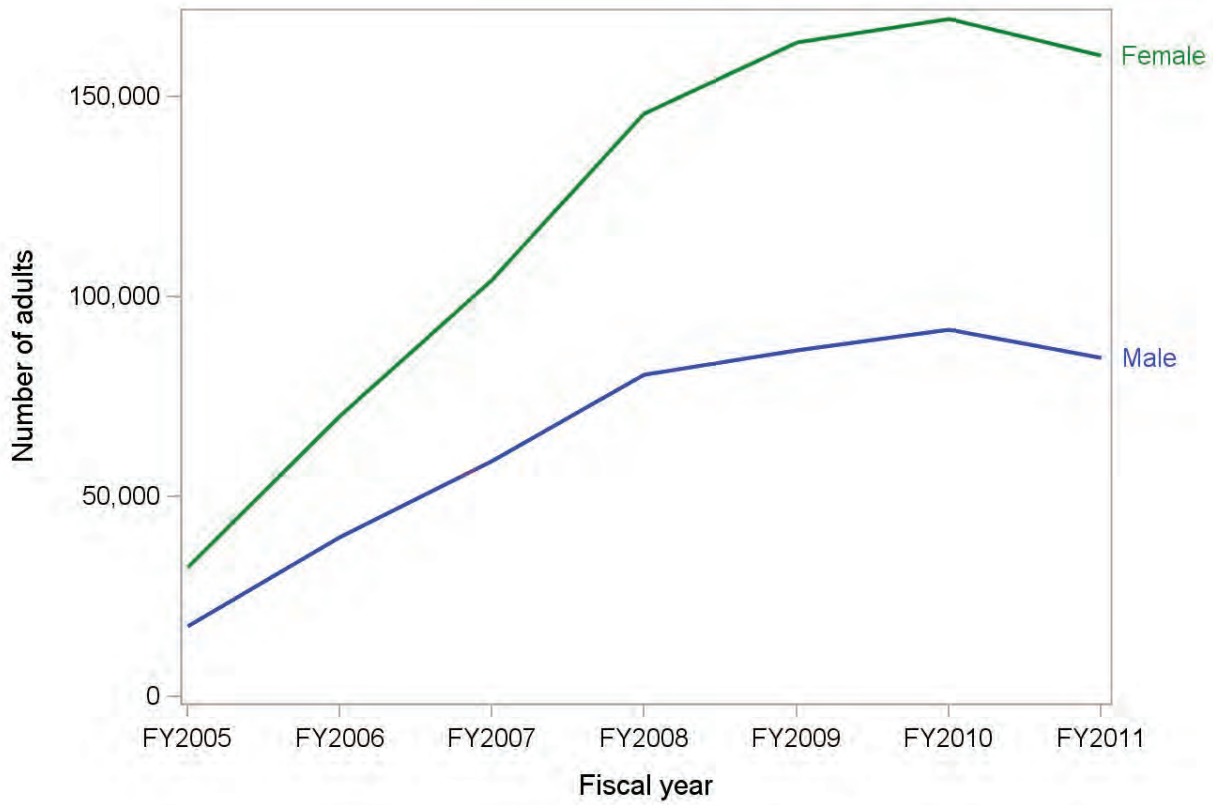

FIGURE 6-7 Number of newly enrolled adults in ART by sex (2005-2011).
SOURCE: Programmatic data from Track 1.0 partners provided by CDC.

TABLE 6-14 Newly Enrolled Adults in ART by Sex (Annual, 2005-2011) (in Thousands)

	2005	*2006*	*2007*	*2008*	*2009*	*2010*	*2011*	*Total*
Newly enrolled adults in ART, n	**50.0**	**110.2**	**163.2**	**226.2**	**250.0**	**261.2**	**244.8**	**1,305.6**
Male, n (%)	17.6(35)	39.9(36)	58.9(36)	80.5(36)	86.6(35)	91.8(35)	84.6(35)	459.9(35)
Female, n (%)	32.4(65)	70.2(64)	104.2(64)	145.7(64)	163.4(65)	169.4(65)	160.2(65)	845.7(65)

SOURCE: Programmatic data from Track 1.0 partners provided by CDC.

There are more women newly enrolled annually in ART than men; the proportion has remained steady over time at about 65 percent women and 35 percent men (see Table 6-14). A difference between men and women, with a greater proportion of women, would be expected given international estimates of the disparity of HIV infection rates and HIV prevalence between men and women in the largest generalized epidemics and the key PEPFAR-supported regions where these implementing partners are operating; women account for a disproportionate share of prevalence in sub-Saharan Africa, making up an estimated 59 percent of people living with HIV (UNAIDS, 2011). However, the data for this subset of countries and partners reflect a larger imbalance than in the prevalence estimates, with men proportionately under-enrolled compared

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to women. It is important to note that it is very difficult to draw conclusions about these sex differences without having better data on men and women who are in need but not receiving care and treatment across countries to be able to compare coverage rather than numbers enrolled. The data are aggregated from programs in thirteen countries, and thus are not matched to country-specific information on the relative disease burden between men and women in these settings; they are also not matched to estimates of the need for ART in men and women, which also vary by country.

Within this limitation, it is feasible to observe that the reasons for this imbalance would likely be consistent with prior discussion in this chapter suggesting that men may not be accessing testing and subsequent referrals for enrollment in care and treatment services as readily as women. One reason for this may be differences in provider initiated testing, primarily due to increased access for pregnant women who are enrolled in ART through the entry point of PMTCT services (Chen et al., 2008; Hawkins et al., 2011; Larsson et al., 2012). Another contributing factor may be differences in health seeking behavior, which may be influenced by culturally-determined gender roles for men and women (Chen et al., 2008). As an interviewee in one country observed:

> *'Most [of the] people that go to health centers and access counseling and testing programs are pregnant women getting prenatal care. Men essentially do not go to health centers unless they are dying.'* (166-05-USG)

Differences in access between men and women may also be affected by how services are planned by policymakers or how outreach is targeted by providers. Gaps in access to services for men, and the resulting coverage gaps, have negative implications for the health and wellbeing of men and for controlling the epidemic and sustaining the HIV response. For example, for serodiscordant heterosexual couples with an HIV positive male partner who is not in treatment there will be increased risk of transmission to female partners.

Although the relative under-enrollment of men is a major challenge, there are also barriers in accessing services for women, and the contribution from PMTCT as an entry point is only facilitating access for pregnant women, and primarily those who attend antenatal care at least once in clinics or deliver in health facilities. Even when PMTCT does contribute to access to testing, and may contribute to the proportionally higher enrollment of women in ART, the reality is that results are mixed for efforts to link PMTCT and ART. Interviewees described widely variable experiences across countries with coverage of ongoing ART in women initially identified as eligible during pregnancy, from around 90 to 93 percent at the very high end to only 10 percent (272-24-USG; 636-17-PCGOV; 177-13-PCGOV; 116-5-PCGOV; 116-18-PCNGO; 934-5-USG). Several examples of efforts to provide ongoing provision of ART to women identified during pregnancy were mentioned by interviewees (396-25-PCGOV; 587-5-PCGOV; 636-6-USG; 166-13-PCGOV; 542-9-PCGOV; 116-18-PCNGO). For example, in one country all maternity hospitals registered HIV-positive women at the government's AIDS centers and referred them for sero-staging for ongoing treatment (542-9-PCGOV). Some of the challenges in identifying, enrolling, and retaining pregnant women identified as HIV positive on subsequent ongoing ART included limited access to CD4 testing, including point-of-care testing; limited staff to provide follow-up and linkages to ART; and a lack of systems for data sharing between PMTCT programs and care and treatment programs (116-18-PCNGO; 587-5-PCGOV; 636-6-USG; 166-13-PCGOV; 935-ES).

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Gender-related aspects of access to services for both men and women are discussed in more depth in Chapter 8, Gender.

Pediatric Enrollment in ART

In its OVC guidance, PEPFAR has recommended disaggregation of health requirements and interventions by the following age groupings: infants (<2 years), early childhood/toddler (2-4 years), middle childhood (5-11 years), and late childhood/adolescence (12-17 years) (OGAC, 2006b). However, data are not routinely collected utilizing these subgroups for age disaggregation at any level of treatment programs.

The data requested from the CDC for the Track 1.0 partners included age disaggregation of newly enrolled children in ART for the years 2008-2011 (Table 6-15). The total absolute number of children newly enrolled on ART decreased from 2009 to 2011, illustrating the difficulties of implementing treatment for children. The largest number and proportion (Table 6-15 and Figure 6-8) of children enrolled in care are 5 years of age or older. Many of these may be children with HIV infection from maternal transmission who survived even without early therapy in the early period that is critical for identifying HIV infection and initiating treatment. The numbers of those who are 0-1 years of age increased the most from 2008-2009, but the increase slowed from 2009-2011. This likely represents the net result of successes in preventing infections with PMTCT and challenges in identifying infected infants in the first 12 months of life. The proportion of newly enrolled children who are 0-1 years of age has increased to about 30 percent of all children who are treated, the 2-4 year old age group has diminished to about 25 percent and the 5- to 14-year-old age group has also diminished over time.

TABLE 6-15 Newly Enrolled Children in ART (2005-2011) (in Thousands)

	2005	*2006*	*2007*	*2008*	*2009*	*2010*	*2011*	*Total*
Newly enrolled children in ART, n	**3.8**	**9.9**	**14.6**	**18.8**	**28.1**	**24.9**	**22.7**	**122.6**
0-1 years, n (%)				3.9(21)	6.4(23)	6.9(28)	7.0(31)	24.1(20)
2-4 years, n (%)				5.3(28)	6.5(23)	6.3(25)	5.5(24)	23.7(19)
5-14 years, n (%)				8.7(46)	10.4(37)	11.7(47)	9.6(42)	40.4(33)
Unclassified, n (%)	3.8(100)	9.9(100)	14.6(100)	0.8(4)	4.8(17)	0.1(<1)	0.6 (2)	34.5(28)

NOTE: Dissagregated pediatric ages were not reported prior to 2008. When the total number of children enrolled exceeds the sum of those classified within specific age ranges, the difference is displayed in the 'Unclassified' row.
SOURCE: Programmatic data from Track 1.0 partners provided by CDC.

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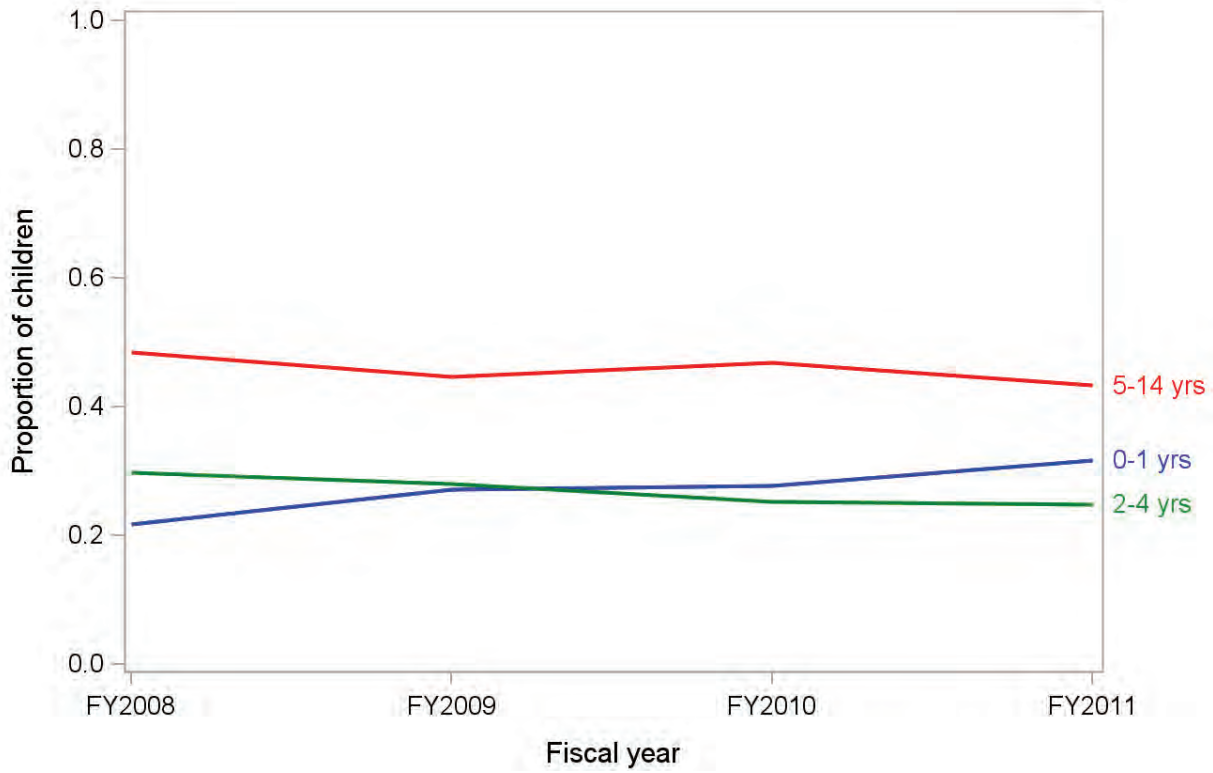

FIGURE 6-8 Proportion of newly enrolled children in ART by age groups (2008-2011).
SOURCE: Programmatic data from Track 1.0 partners provided by CDC.

These data are consistent with the experience of interviewees, who also described low enrollment of pediatric ART and lack of early enough initiation of ART in children (240-24-USG; 461-19-USG; 166-18-USNGO; 636-17-PCGOV; 934-25-USPS; 396-7-PCGOV; 461-18-USG; 166-18-USNGO). However, they also noted that the numbers of children being enrolled in treatment had increased with PEPFAR's support, noting that PEPFAR had provided pediatric treatment for the first time in facilities and had sustained life for children (240-8-USG; 461-24-PCNGO; 166-18-USNGO; 166-29-PCGOV). PEPFAR procured first- and second-line treatment for children in several countries visited (240-5-PCGOV; 587-6-PCML; 587-13-USG; 587-22-USG; 166-15-USACA; 396-56-USNGO) and supported partners that were leaders on pediatric care and treatment in the country (240-19-USACA; 272-22-USG; 396-25-PCGOV; 396-42-PCGOV; 636-17-PCGOV; 396-56-USNGO; 461-13-USACA). In one example, PEPFAR was described as supporting scale-up by having all of their treatment partners implement pediatric units in the facilities in which they work (272-22-USG). In others, PEPFAR was described as working closely with the partner country government (240-19-USACA) and with other external donors such as the Clinton Foundation (396-21-USG). PEPFAR has also covered gap periods for pediatric ART when it was needed (934-5-USG; 934-12-CCM).

Another contribution highlighted by interviewees across countries has been PEPFAR's support for training of providers in pediatric treatment, from working with the Ministry of Health and local universities to provide pediatric HIV training and develop technical materials and curricula as well as standard operating procedures (240-19-USACA; 240-24-USG; 272-22-USG; 461-13-USACA) to direct training and mentoring of staff on treatment of HIV-exposed infants and HIV-positive children (636-17-PCGOV; 166-18-USNGO; 166-29-PCGOV; 396-21-USG; 396-42-PCGOV; 461-24-PCNGO). These training examples included training for generalist doctors and medical officers and approaches using experienced physicians as the trainers with follow-up for remote provinces. Task shifting from medical doctors to nurses and lower-level health care providers has also been attempted (240-24-

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USG; 272-22-USG), but this has met varying levels of success for pediatric treatment as the physicians, pharmacists, and newly trained providers were least comfortable with taking on initiation and management for pediatric patients (272-22-USG).

Integration with other health services was another PEPFAR-supported strategy for improving access to and enrollment in pediatric treatment. Interviewees described integration with maternal and child health, especially for children less than 5 years old (240-24-USG; 116-2-USG; 461-13-USACA), integrated care in '*family clinics*' (116-7-USG); efforts to better identify children in need of HIV services through maternal and child health programs (461-13-USACA; 240-24-USG; 166-10-USNGO; 396-21-USG), and identification of HIV-infected sick children in HIV/TB nutrition wards (461-13-USACA).

PEPFAR has also supported community involvement, working with home-based care programs, social workers, lay counselors and others in the community to reduce stigma, provide ART adherence counseling, identify children for referrals for HIV testing, and mentor parents as a way to increase access to pediatric ART (396-21-USG; 934-29-USNGO; 636-15-PCNGO; 461-13-USACA; 396-42-PCGOV; 461-19-USG; 272-15-PCNGO). This linkage between the community and treatment facilities was identified by one interviewee as an area where more attention would be warranted (934-29-USNGO) and by another as something that has been piloted successfully but is too expensive to continue (461-19-USG). In addition, another PEPFAR contribution to this population has been on advocacy to bring pediatrics to the forefront of the agenda in ministries of health through the organization of national workshops with high level Ministry of Health officials (240-19-USACA) and the support of an advocacy focal person at the Ministry of Health who was specialized in pediatrics (461-13-USACA).

Retention and Adherence

Retention in care and treatment and adherence of patients to ART is critical to increase survival of patients, improve the quality of their lives, and avoid emergence of drug resistance. Retention in ART has been articulated for four stages in the continuum of care, starting from the diagnosis of HIV to the enrollment of a patient in care, from the enrollment in care to ART eligibility, from ART eligibility to ART initiation, and from ART initiation to lifelong in ART. Adherence to ART once initiated has been shown to reduce rates of resistance, increase HIV viral suppression and increase the survival of HIV patients. All four of these stages are challenging for retention in care and treatment.

Studies to understand retention in ART do not share the same methodology, making it difficult to compare the results, and there is a lack of studies to assess long-term retention (WHO, 2011b). Rosen and Fox, following patients in sub-Saharan Africa, have estimated 60-70 percent retention in ART at 2 years (Fox and Rosen, 2010; Rosen et al., 2007). A study conducted in Tanzania, Zambia, and Uganda through medical chart review in 2010 and questionnaires to health care center managers in 2011 assessed retention of patients in ART. This study concluded that men, the very sick, and younger people had more chance to be lost to follow-up, and that dispensing ART at the community facility level proved to be an important strategy for retention (Koole et al., 2012). A systematic review has shown that physical tracing increases retention of patients at their original site with a decrease of loss to follow-up and an increase in registration of mortality (McMahon, 2012). Several studies have concluded that adults receiving community based adherence support had reduced mortality and loss to follow-up and improved virological suppression after starting ART (Fatti et al., 2012).

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Track 1.0 Data on Retention and Loss to Follow-Up

Although retention of patients in care, as well as patient adherence to ART, is considered essential to successful treatment, the centrally reported indicators made available to the committee did not include any data that could serve to assess it over time across PEPFAR country programs. Although these data were not available for this evaluation, in the provision of treatment at the facility, district, and sub-partner levels, adherence and retention has been monitored by implementing partners for whom it is necessary for the delivery of ART and is a reflection of the quality of care. Monitoring is usually done via return visits, pill counts, clinical assessment, and self-report.

One of the four Track 1.0 partners was able to share with the committee an analysis of retention and loss to follow up that represents more than 200,000 patients at over 200 care and treatment sites across nine PEPFAR partner countries. Treatment retention at 12 months, defined as the number of patients whose care terminated for any reason subtracted from the number of patients who ever began treatment, is shown in Figure 6-9 disaggregated by year of ART start and by population. There has been a downward trend for recent years of ART start, with significantly lower retention for those who started in 2010 compared to other years. The populations with the highest retention were the pediatric population and adult females, with the lowest retention found in adult males.

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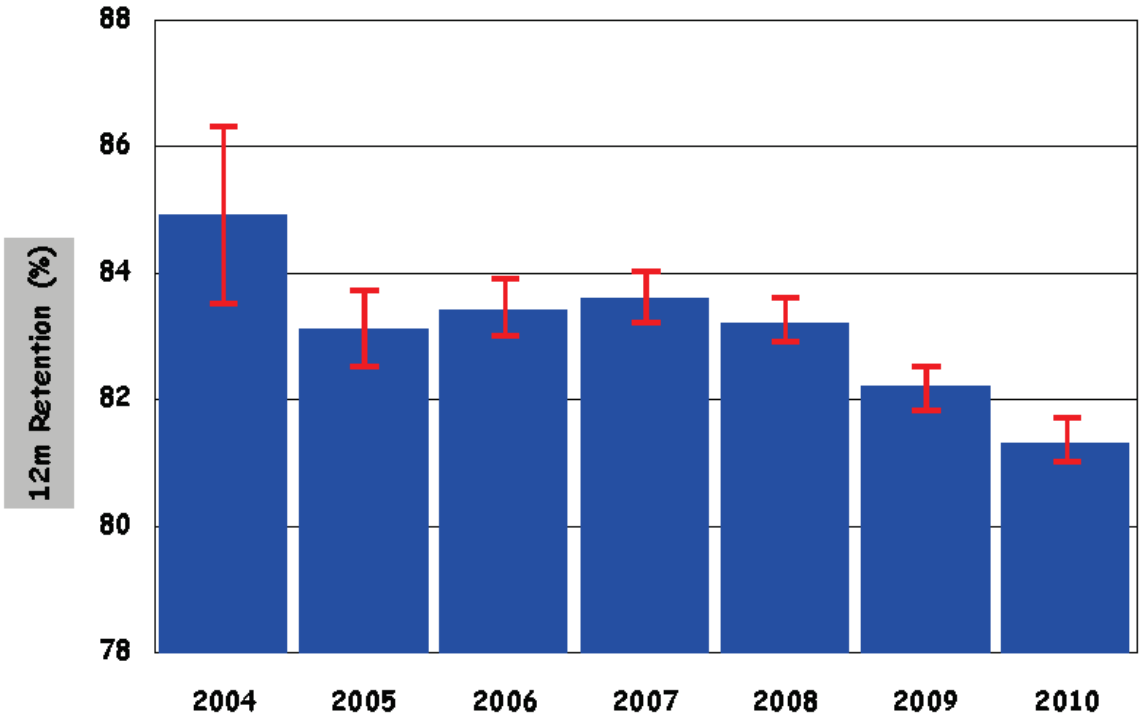

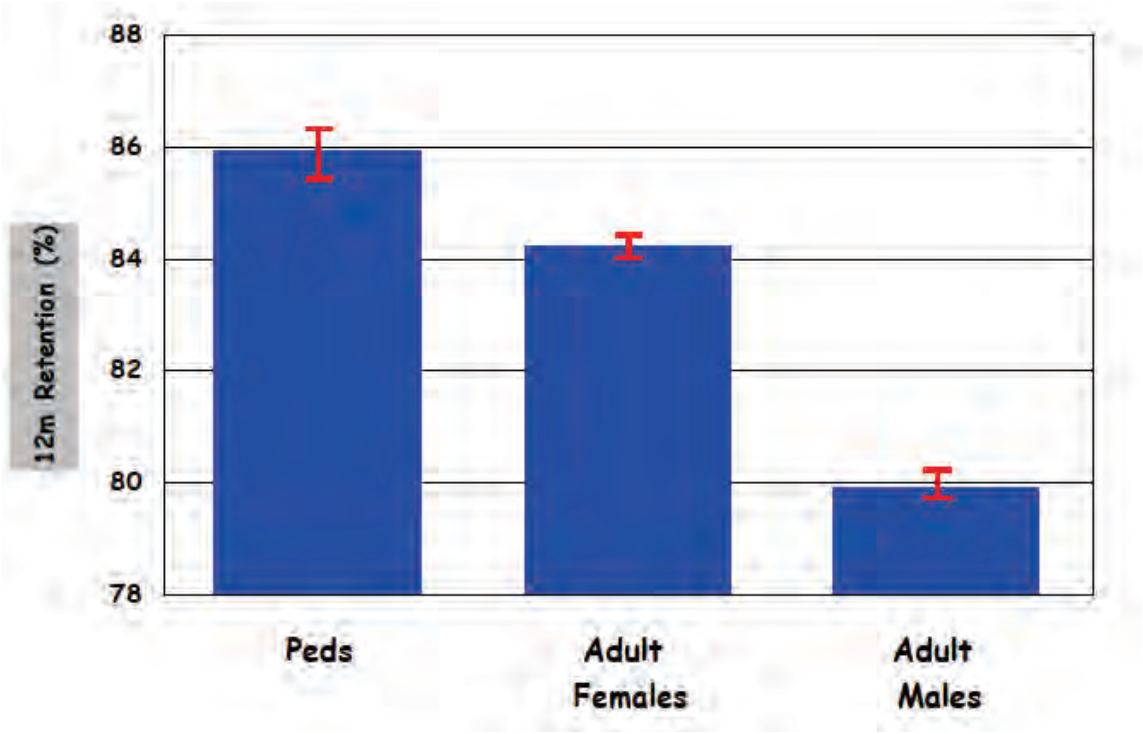

FIGURE 6-9 12 month retention (alive and in care) by ART start and by population in a subset of patients in 9 PEPFAR partner countries.
SOURCE: Programmatic data provided by Track 1.0 partner.

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There were also similar differences in loss to follow-up (LTFu), defined as having missed a clinic appointment for 90 days or more, by both population (Figure 6-10) and year of ART initiation (Figure 6-11). LTFu was higher among adult males compared to adult females and pediatric patients. LTFu also increased by year of ART start. After 12 months on ART, patients who started in 2004 had the lowest LTFu while those who started in 2010 had the highest. Similar trends were observed at 24, 36, 48, 60, and 72 months. It is important to note that one limitation to these analyses is that some deaths may have been reported as losses to follow-up because the patients' treatment records were not linked to mortality records.

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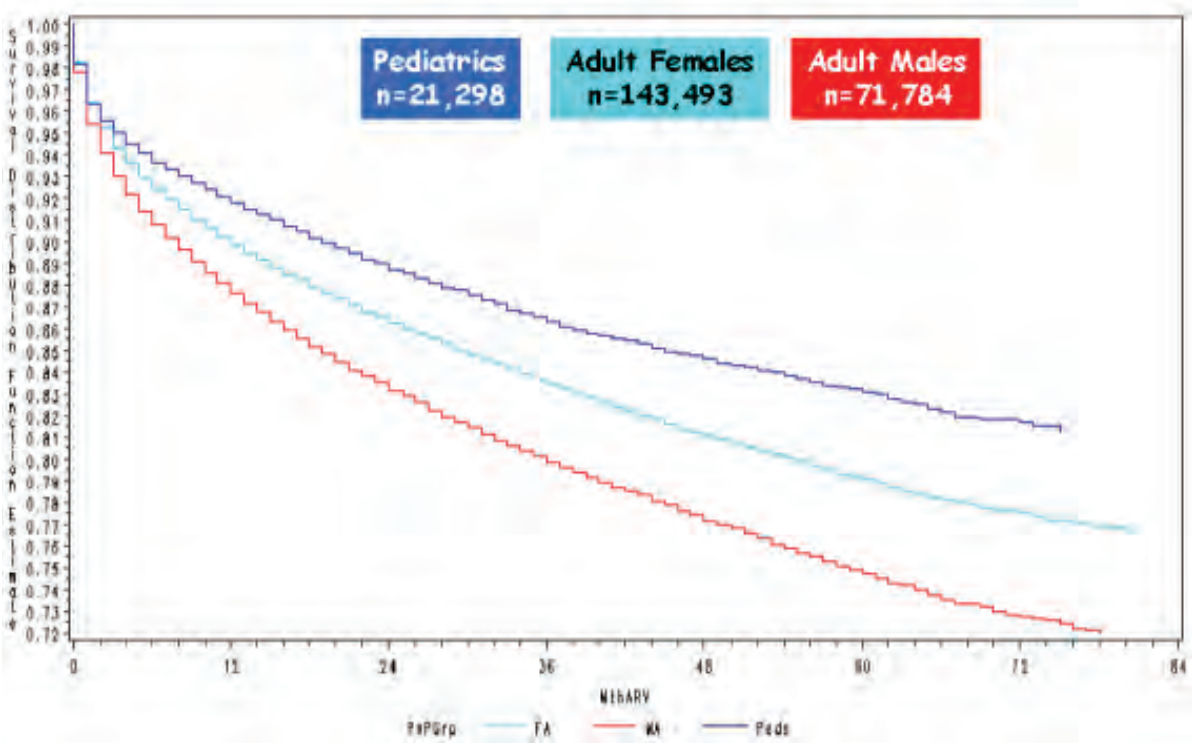

FIGURE 6-10 Loss to follow-up by population.
NOTE: The curves indicate the proportion of patients at different time points that are successfully in follow-up.
SOURCE: Programmatic data provided by Track 1.0 partner.

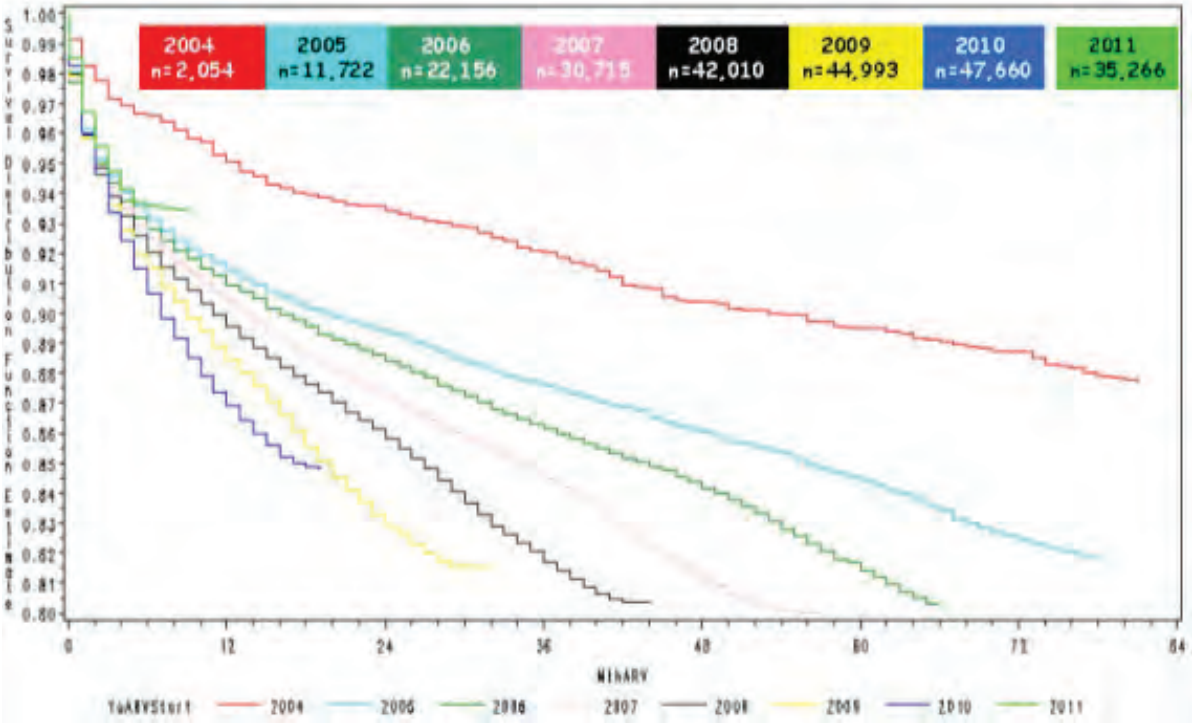

FIGURE 6-11 Loss to follow-up by year of ART initiation.
NOTE: The curves indicate the proportion of patients at different time points that are successfully in follow-up.
SOURCE: Programmatic data provided by Track 1.0 partner.

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One explanation for the trend toward increasing loss to follow-up at later years of ART start may be that financial resources and staff became more and more constrained over time, in the face of increasing numbers of patients in care and treatment, and therefore efforts focused on retention such as racking activities became more difficult to sustain. In addition, compared to those enrolled in the early years of PEPFAR when the focus was rapid scale-up in areas with high population density and facility capacity, those enrolled in recent years are being reached as ART expands to more geographically remote areas with lower-level health facilities, and these newly enrolled patients may face disproportionately greater challenges to retention, such as transportation barriers and economic limitations, and facilities with lower overall capacity. The section that follows presents perspectives from interviewees in partner countries that further inform the issues of retention and adherence in the context of implementing PEPFAR-supported programs.

Perspectives on Challenges with Retention, Loss to Follow-Up, and Adherence

During the country visits conducted, retention of PLHIV in care and treatment services and adherence of patients to treatment was voiced as a great concern with respect to both HIV-positive individuals who had been diagnosed but had not yet initiated treatment and attrition for individuals who had been linked to services (240-15-USG; 240-19-USACA; 331-14-USG; 166-15-USACA; 272-22-USG; 240-19-USNGO). The challenges with linkages from testing to care and treatment were described earlier in this chapter. The follow-up of those who had initiated treatment was similarly reportedly as a *"huge challenge for treatment"* (240-19-USACA). Interviewees recognized that *'HIV patients need to have strong adherence but loss to follow-up is very high'* (166-15-USACA) and that adherence *'is a big problem'* (240-15-USG). One reason for concern about patients' adherence to prescribed ARV regimens centered on the following perspective voiced by one interviewee: *'if [we] don't push adherence then resistance will become outrageous'* (272-22-USG).

Interviewees did not all share the same specific criteria for designating an individual as lost to follow-up, but they generally referred to missed appointments as signaling an initial loss of contact with the patient and potential loss to follow-up. Interviewees cited death as a major contributor to loss of follow-up (166-15-USACA; 240-19-USACA), due in part to late identification with advanced HIV. The type of facility was also described as affecting loss to follow-up, with hospitals serving more critically ill patients whose loss to follow-up is more likely to reflect mortality (240-15-USG).

Among the other reasons for loss to follow-up or lack of adherence that interviewees described were patient-initiated treatment cessation or '*drop out*,' transfer to another treatment site, distance from treatment site and lack of access to transportation, stigma, and cultural beliefs (240-25-PCGOV; 166-18-USNGO; 272-3235-PCNGO; 240-19-USNGO; 272-3235-PCNGO; 587-18-PCGOV). The issue of stigma affected some individuals' willingness to continue treatment or their willingness to use health facilities in their home communities; this exacerbated the barrier of transportation when PLHIV sought health facilities more distant from their places of residence that offered a greater degree of privacy. Transportation was also a barrier when there was a need to travel greater distances for specialized care such as a hospital-based pediatric center (166-18-USNGO; 587-18-PCGOV). In general, distance and a lack of resources for transportation to treatment sites was commonly noted as a major contributor to loss to follow-up (272-3235-PCNGO; 240-19-USNGO). Interviewees also recognized malnutrition as an important issue for PLHIV who are taking ARVs. In addition to a need for food security among some partner country populations in general and nutritional support among

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PLHIV in particular, one interviewee observed, *'people on ARVs' bodies change and they have an appetite. Appropriate nutrition improves adherence'* (461-10-PCNGO).

Although pediatric patients had relatively better retention in the Track 1.0 data presented here, achieving retention and adherence of the pediatric population was considered to be particularly challenging (935-19-PCGOV; 166-18-USNGO). Adolescents were of particular concern due to the lack of support structure and to their adjustment as they mature as a person living with HIV, which is sometimes accompanied by anger or fear about their status and rebelling against ARVs (272-22-USG; 636-6-USG).

Individuals' cultural beliefs and experiences were also described as having a role in adherence. A treatment-related program in one country, for example, faced the ongoing challenge of getting people to understand how ART works and the need to continue treatment, *'People would do well in the beginning and then stop taking medication'* (331-12-USG). In some cases, patients perceived ARVs to aggravate their ill health based upon their experience of side effects upon initiating drug treatment (240-25-PCGOV; 587-18-PCGOV). In some countries interviewees reported that some PLHIV believed ARVs were unnecessary due to other traditional methods they believed could were used to heal them (240-25-PCGOV; 935-ES).

PEPFAR Efforts to Improve Adherence and Retention

Interviewees identified personnel and strategies they used to follow-up and increase retention and adherence among PLHIV on ARVs, most of which were based on the premise of personal contact with patients. In general, they believed that *'some kind of individual contact is important for adherence'* (272-22-USG). Personnel involved in following up with patients were: peer educators, counselors, or case managers (240-15-USG; 240-19-USACA; 331-12-USG); urban or rural health extension workers (240-19-USACA); home-care workers (272-22-USG); health care providers (166-18-PCNGO); and trained volunteers (240-15-USG). Follow-up and adherence-promotion strategies were described as pre-treatment patient preparation (272-22-USG); monitoring (331-12-USG); tracking (272-22-USG); empowerment (240-19-USACA); home visits (240-19-USACA); phone calls (including cell phone calling systems) (272-22-USG); and hospital–health center networks with outreach workers (240-19-USACA). In many cases, PLHIV served as peer educators, counselors, case managers and trained volunteers in providing adherence support (240-ES; 331-ES; 935-ES).

Other strategies to improve retention and adherence have included improving laboratory services to reduce wait times for CD4 testing and increasing access to care and treatment by expanding the availability of clinics in more geographically widespread areas, efforts made feasible in part by task shifting of ART provision and removing restrictions on the services that can be provided at lower level facilities.

Conclusion: Retention and adherence are critical and persistent challenges in PEPFAR-supported HIV care and treatment programs. Understanding the factors that contribute to the lack of retention and the most effective strategies to improve it are needed to fully maximize the role of care and treatment in a sustainable HIV/AIDS response.

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ARV Drug Resistance and Treatment Failure

Data regarding the emergence of HIV drug resistance in resource-limited countries have not been collected in a systematic, standardized or representative manner; nevertheless, two recent analyses across the available published literature provide sufficient information to generate a reasonable sense of the impact of treatment rollout on HIV drug resistance. Broad access to antiretroviral therapy in resource-limited settings, in addition to conferring substantial benefits on survival and quality of life, has not surprisingly engendered the emergence of both acquired and transmitted drug resistance (Gupta et al., 2012; Stadeli and Richman, 2012).

The magnitude of drug resistance increases with duration of treatment in the individual and the duration of access to treatment in the population. The prevalence of transmitted drug resistance (TDR) varies with geographic region, which is likely attributable to different timelines for access to ART. Within Africa, significantly higher rates of TDR exist in Middle and East Africa than in West or Southern Africa, which in general reflect the timing of the roll-out of ART. In addition to the duration that ART was available, differences in rates of TDR could be attributable to interruption in medication availability (such as medication stock out), suboptimal adherence, the regimens prescribed (cheaper but less effective and less well-tolerated regimens are associated with more rapid failure and rates of drug resistance), disease stage at time of treatment initiation, and limited use of viral load monitoring for regimen failure, as these are known risk factors for HIV drug resistance (El-Khatib et al., 2011; Fox et al., 2010; Obiako et al., 2010; Severe et al., 2010; Walensky et al., 2009).

The available data largely reflect studies of convenience samples rather than results from sampling designed to be representative of the total populations at risk for drug resistance. Furthermore, available studies vary widely in their designs, patient populations, inclusion criteria, drug resistance mutation lists, viral load thresholds for genotype sequencing, sequencing protocols, and methodologies of data analysis, in the absence of selection pressure of drug treatment. Even with the limitations in the available data, these data have several potential implications for the future of HIV/AIDS treatment programs in resource-limited settings. High rates of acquired drug resistance suggest poor adherence (which can be improved with better counseling and minimizing supply stock-outs), suboptimal regimens (for example, those containing thymidine analogues (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2012; Thompson et al., 2012), and a lack of monitoring for failure to reduce the continuing use of a failing regimen (Gill et al., 2010; Murphy et al., 2010; Tuboi et al., 2010). Drug-resistance monitoring programs in resource-limited settings are limited by cost and laboratory availability (Kimmel et al., 2010). In the absence of laboratory monitoring, strategies to monitor and improve treatment delivery and patient adherence may help minimize sustained virologic failure more than clinical monitoring alone (El-Khatib et al., 2011; Hong et al., 2010).

In countries visited for this evaluation, interviewees expressed concerns about treatment failure that included a need to understand it not only because were they unaware of the proportion of people taking ARVs who were failing treatment (240-15-USG); but also because they were concerned about consequences of interrupted drug treatment regimens that in some countries were due to stock-outs (934-05-USG); changes in drug regimens that occurred for nonclinical reasons (i.e., seeking stock-out-related drug treatment from neighboring countries that used different regimens) (934-05-USG); and general concerns regarding strategies and a lack of tools to diagnose treatment failure (461-18-USG) and low treatment failure detection rate for both adults and children (240-24-USG). An interviewee in one country also identified a lack of guidance from OGAC on how to switch from second- to third-line drugs (461-18-USG). Although in the case

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of two countries, 88 percent to 95 percent of those on ARVs were taking first-line drugs (587-18-PCGOV; 461-18-USG), the expectation was that, from the perspective of one interviewee, *'as we move down the road we will need drug resistance testing and support for second-line drugs'* (461-18-USG). An interviewee in another country emphasized the challenge that patients are not compliant; noting that there is resistance to second line regimens and a need for third line regimens (396-44-PCGOV).

Countries reported varying degrees of access to ARV drug resistance testing resources. Although no interviewee specified particular testing strategies, an interviewee from one country indicated access to drug resistance testing at four of its laboratory sites (461-10-PCNGO). Interviewees from another country reported that the expense of specific testing for drug resistance made it unaffordable (272-3235-PCNGO), thus necessitating the use of alternative tests that were consistent with government protocols.

Interviewees called for research into the issue of treatment failure. One individual cited, for example, a need to evaluate, *'the number of patients on second line therapy [since it] is very low and, based on knowledge from other countries, it should be higher'* (240-15-USG). Interviewees identified PEPFAR as responsible for funding not only ART but also the monitoring of the emergence of drug resistance using advanced molecular techniques and conventional techniques. (240-21-PCGOV; 587-18-PCGOV) Several countries mentioned efforts being done to monitor drug resistance. Some countries were awaiting their drug resistance threshold survey results (934-15-PCGOV; 240-21-PCGOV). Drug resistance surveillance monitoring recently started for a partner country (272-13-USG), with the government implementing pharmacovigilance work and many partners tracking genome changes (272-22-USG). The World Health Organization was implementing an HIV-Drug Resistance protocol survey through a National Care and Treatment Center, with plans to distribute the survey to sentinel sites in order to facilitate routine data collection on drug resistance (587-13-USG; 587-18-PCGOV). PEPFAR supported drug resistance surveillance activities using the WHO early warning indicators in several countries (240-21-PCGOV; 116-01-USG; 587-18-PCGOV) including pediatric drug resistance surveillance activities (116-01-USG). The Global Fund was also mentioned to support drug resistance studies in drug-naïve patients in one partner country (331-24-PCGOV; 331-28-PCGOV).

Conclusion: The expansion of treatment has an ancillary effect of increasing drug resistance. The earlier ART programs were implemented in a region, the more drug resistance is present. With the limited availability of second line antiretroviral drugs in resource-limited settings, as drug resistance increases, the need for an expanded pharmaceutical arsenal for effective treatment intensifies. The emergence of HIV drug resistance is cause for greater efforts to improve the effectiveness and expand the implementation of adherence support, treatment failure and drug resistance monitoring strategies, and treatment options in resource-limited settings.

Impact of PEPFAR-Supported Care and Treatment Programs on Mortality

Across countries, many interviewees of all stakeholder types identified the lives saved through HIV care and treatment programs as the greatest successes of PEPFAR. As one interviewee simply put it: *'People are not dying because they are on [ARVs]'* (934-05-UG; 272-22-USG; 272-32,35-PCNGO; 240-15-UG).

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The congressional mandate for this evaluation requested an evaluation of the impact of care and treatment programs on 5-year survival rates. As described earlier in this chapter, the benefits of ART in reducing mortality have been well established ((Mat Shah et al., 2012); Bussmann et al., 2008; Herbst et al., 2009; Jahn et al., 2008; Mermin et al., 2008). However, in general for ART programs, data on 5-year survival rates is very limited in any setting and for any population, and it is not available across PEPFAR countries and programs. Therefore, it was not possible to assess this outcome comprehensively for PEPFAR beneficiaries. One of the four Track 1.0 partners was able to share with the committee an analysis of survival from a subset of patients enrolled in ART representing facilities in nine PEPFAR countries. Figure 6-12 shows survival by year of ART start, and Figure 6-13 shows survival by population.

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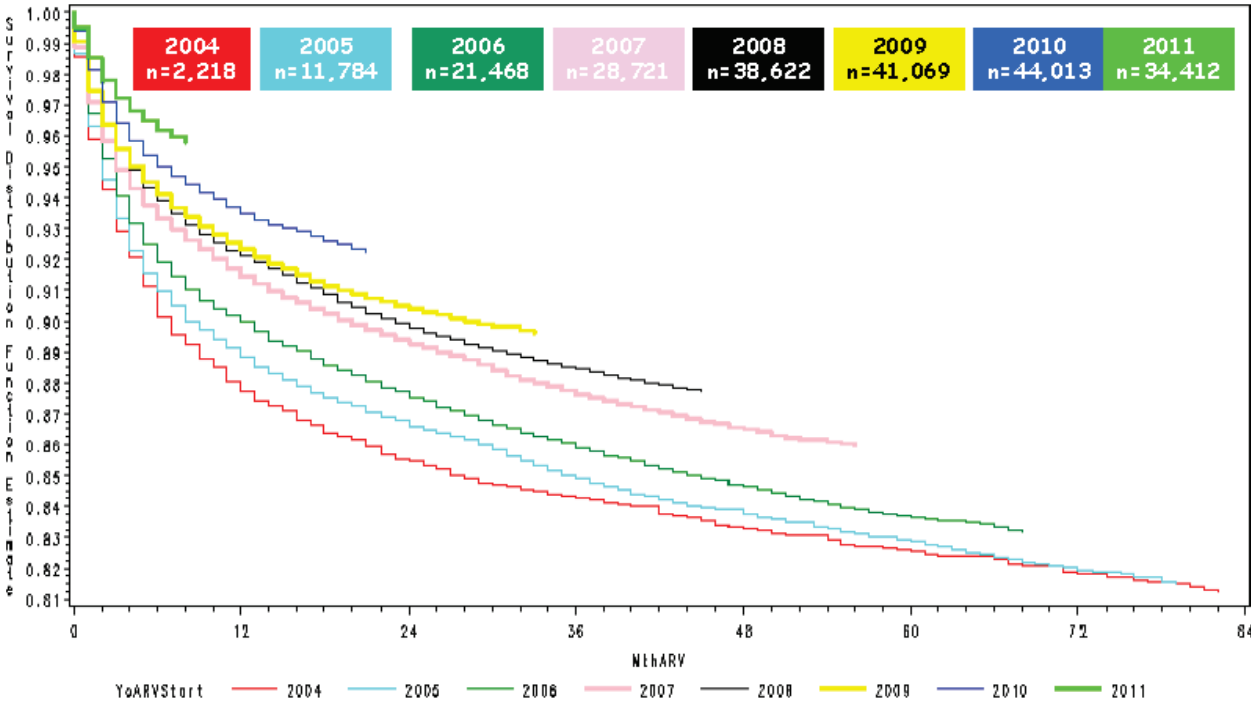

FIGURE 6-12 Survival by year of ART initiation (2004-2011).
SOURCE: Programmatic data provided by Track 1.0 partner.

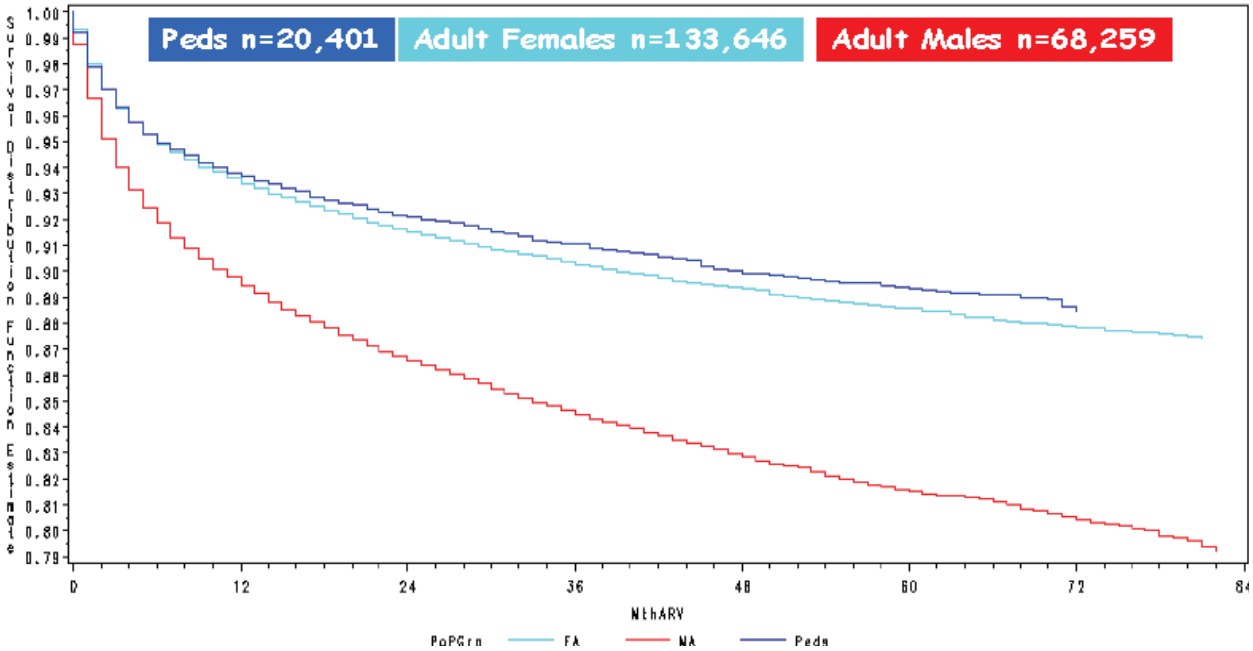

FIGURE 6-13 Survival by population (2004-2011).
SOURCE: Programmatic data provided by Track 1.0 partner.

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These data suggest that survival after initiation of ART improved each year. This trend may reflect that over time patients were starting treatment earlier and had better outcomes. This is consistent with the perspectives of interviewees described earlier in the section on care and support, where a theme emerged that the increasing availability and success of ART has led to improved health outcomes for PLHIV.

These data also reflect sex differences in survival, with women faring better than men; this is a similar result to the data on retention presented earlier. An additional analysis from a subset of these data representing seven PEPFAR countries provides a little more information on the sex differences in survival on ART, including a breakdown of characteristics at baseline (Figure 6-14).

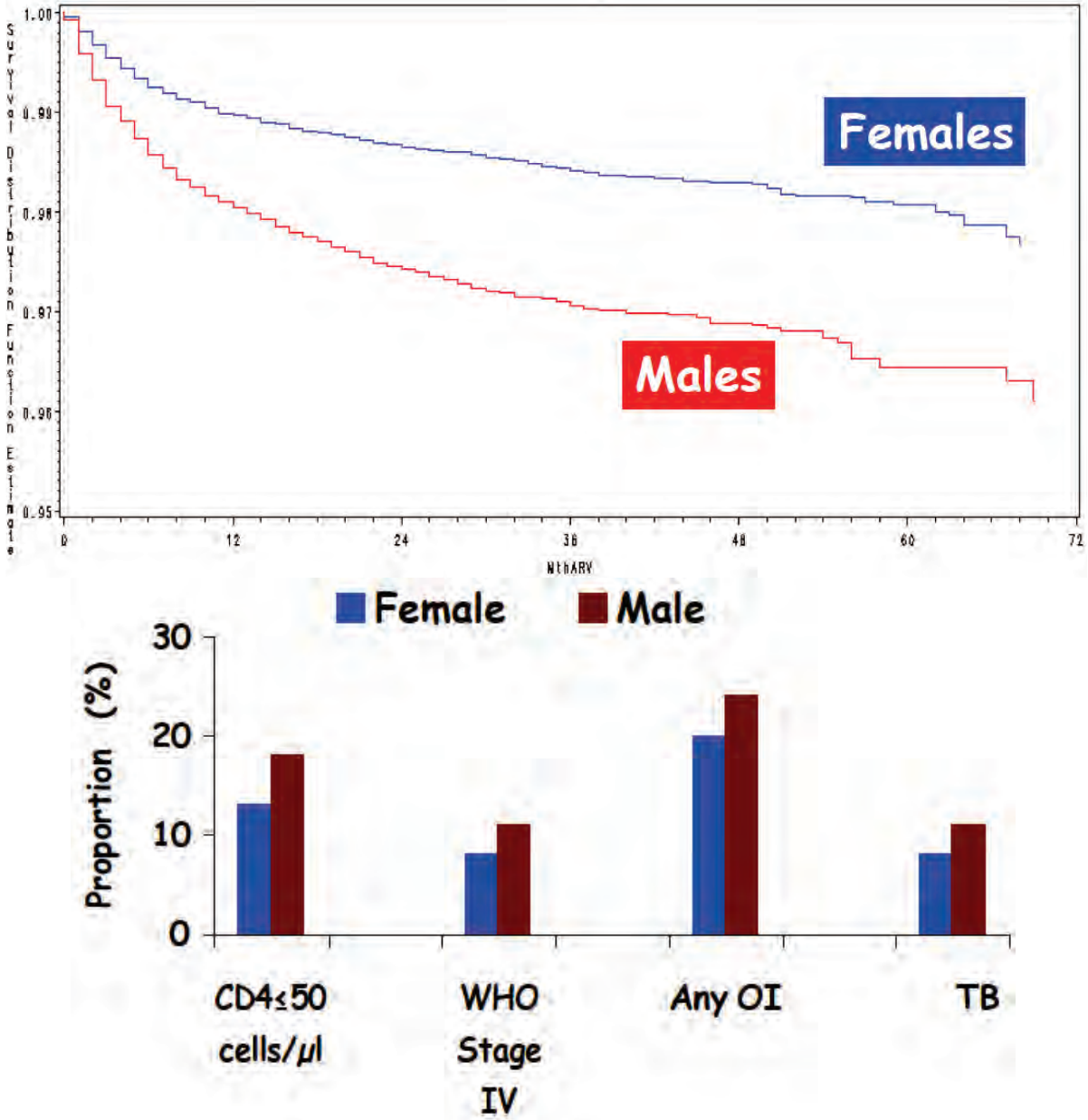

FIGURE 6-14 Differences between men and women on ART in survival and in baseline characteristics (7 countries, 165 clinics), 2004-2011.
SOURCE: Programmatic data provided by Track 1.0 partner.

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These data indicate that men present later in the disease course and with more complications. Reasons for this may include that, as described earlier, many women enrolled in ART are identified through screening for PMTCT, an entry point that is not dependent on symptomatic presentation for HIV and is likely to catch more women in earlier stages (Chen et al., 2008; Hawkins et al., 2011; Larsson et al., 2012).

The enrollment, retention, and mortality outcomes presented in this chapter for patients enrolled in these PEPFAR-supported treatment programs is consistent with the published literature, where men have also been shown to have a higher mortality rate than women when receiving antiretroviral therapy (Chen et al., 2008; Taylor-Smith et al., 2010). Possible reasons that have been identified for poorer outcomes on ART for men than women include poor adherence to therapy (Chen et al., 2008; Taylor-Smith et al., 2010); starting therapy at a more advanced stage of the disease (Chen et al., 2008; Taylor-Smith et al., 2010); cultural norms with respect to stigma, fear and pride (culture of masculinity) (Chen et al., 2008); biological sex differences related to doses of the specified drugs in therapy (Taylor-Smith et al., 2010); and other outside factors such as smoking, alcohol consumption and life expectancy (Taylor-Smith et al., 2010).

Issues related to differences between men and women in HIV-related services are also discussed in Chapter 8.

Impact of PEPFAR on Population Health Outcomes

In addition to survival and mortality outcomes for patients enrolled in PEPFAR-supported care and treatment programs, an important question for an impact evaluation of PEPFAR is whether the PEPFAR program has had a population impact on mortality. PEPFAR-supported HIV programs have the potential to reduce mortality through a number of pathways encompassing the full range of activities and efforts, but the most direct plausible pathway to an impact on mortality is through PEPFAR's support of HIV care and treatment programs.

Several papers using modeling methods to address this question have recently been published comparing PEPFAR focus countries to non-focus countries (Bendavid and Bhattacharya, 2009; Bendavid et al., 2012; Duber et al., 2010). The committee reviewed these analyses as one source of information to assess the impact of PEPFAR on HIV/AIDS. One of these analyses did not find an effect on health outcomes (Duber et al., 2010), perhaps due to timeframe and data limitations, but the other analyses indicated a measurable population health impact of PEPFAR on adult mortality in a subset of partner countries (Bendavid and Bhattacharya, 2009; Bendavid et al., 2012). However, none of these studies covered the full scope of countries included in the scope of this evaluation, and using non-focus countries as a control is problematic since, although they were not focus countries, they nonetheless also received some level of PEPFAR funding. These studies also had other limitations reflective of the difficulty of evaluating a large, complex program retrospectively, such as limited data availability and quality and the difficulty of controlling for non-PEPFAR factors in the analyses.

During its deliberations, the committee explored the possibility of conducting its own modeling to evaluate the impact of PEPFAR. After careful consideration, the evaluation committee determined that within the scope, time, and resources of this evaluation it was not feasible to conduct statistical analyses to correlate changes in key outcome or impact indicators with explanatory variables comparing among countries with variable levels of PEPFAR funding over time. Several key factors contributed to this decision.

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One such factor was that there are critical differences among PEPFAR countries with respect to demographics, social and economic factors, the epidemiology of the epidemic, and availability of appropriate data. Similarly, in order to compare PEPFAR countries, which were not chosen randomly, to non-PEPFAR countries, an analysis would need to account for important differences related to economic, political, and health factors; population sizes; the stage of the epidemic; and available infrastructure and capacity prior to the introduction of PEPFAR. In addition, many countries receive some level of PEPFAR investment (see Chapter 1), and where PEPFAR has not been implemented or has been implemented with less intensity, programs with support from other external or national funding sources may have implemented similar interventions to achieve similar objectives. This poses a critical challenge for identifying control countries that can be suitably compared to PEPFAR countries.

Another important factor was the lack of reliable data across all of the countries of interest for key benchmark indicators including HIV-related deaths and all-cause mortality despite intense efforts reviewing multiple sources for these data. Potential sources of mortality data that were considered are described in more detail in Appendix C. In addition, for a number of measures of interest for this evaluation, data are not collected across PEPFAR and non-PEPFAR countries.

Finally, as described in more depth in Chapter 4, complete and reliable data on annual PEPFAR expenditures by country were not readily available. Ideally the committee would have liked to design a model to determine if a bigger annual investment of PEPFAR funding over time, across all PEPFAR-funded partner countries, had led to a greater impact on health. This would introduce a larger scope and the use of a continuous variable for the funding as the input to the model, rather than the dichotomous use of focus versus nonfocus countries, which would address some of the limitations of the existing analyses.

Ultimately, the limitations were determined to be too great to design and carry out analyses in the time available that would meaningfully add to the existing analyses in the published literature. Although these limitations described prevented the committee from quantitatively modeling the impact of PEPFAR, across the many data sources reviewed by the committee and presented in this chapter it was feasible to conclude that PEPFAR's support for care and treatment services have had a major positive effect in partner countries.

SUMMATION FOR PEPFAR'S SUPPORT FOR CARE AND TREATMENT SERVICES

Conclusion: PEPFAR has made a major contribution to increasing the number of people living with HIV who are in care and on ART through the expansion of the number and geographic distribution of care and treatment sites, the training of providers, the procurement and delivery of drugs, improvements in laboratory services, and support for the adoption and implementation of national policies and guidelines in partner countries. Support for care and treatment programs is a success that has contributed to saving lives and improving the quality of life for people living with HIV in PEPFAR partner countries.

Conclusion: The ability to assess the impact of PEPFAR-supported care and treatment programs across countries and partners is restricted by limitations in the available data. The available program-wide output measures provide a sense of the growth of PEPFAR-supported treatment programs over time but do not provide an

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understanding of the distribution of those services in populations of interest and do not provide a measure of effectiveness and outcomes. It was a missed opportunity not to invest more resources earlier in standardized, realistic, and useful monitoring of outcomes.

Recommendation 6-2: To contribute to sustainable care and treatment programs in partner countries, PEPFAR should build on its experience and support efforts to develop, implement, and scale up more effective and efficient facility- and community-based service delivery models for the continuum of adult and pediatric testing, care, and treatment. These efforts should aim to enhance equitable access, improve retention, increase clinical and laboratory monitoring, ensure quality, and implement cost efficiencies.

Further considerations for implementation of this recommendation:

- This recommendation should be implemented in coordination with recommendations and considerations discussed in Chapter 9, Health Systems Strengthening.
- PEPFAR should develop a system for active dissemination and sharing of best practices in service delivery both within and across countries. (See also recommendation for PEPFAR's Knowledge Management in Chapter 11.)

Recommendation 6-3: To assess PEPFAR-supported HIV care and treatment programs and to evaluate new service delivery models, the Office of the U.S. Global AIDS Coordinator should support an enhanced, nested program monitoring effort in which additional longitudinal data on core outcomes for HIV-positive adults and children enrolled in care and treatment are collected and centrally reported from a coordinated representative sample across multiple countries and implementing partners.

Further considerations for implementation of this recommendation:

- This activity would serve as a targeted, nested evaluation within routine program monitoring systems to allow for long-term operational assessment of performance and outcomes for care and treatment across a representative sample of PEPFAR-supported programs. The aim would be to focus on key areas for evaluation and improvement of programs going forward, including as PEPFAR supports innovations in service delivery and as PEPFAR-supported programs transition to new models of implementation.
- Data collected and reported for this sample should be harmonized with existing data collection whenever possible, including data already collected by implementing partners but not centrally reported (for example, see the discussion of Tier 3 data in the implementation considerations for Recommendation 11-1A). Collaborative opportunities may be feasible with existing or new large-scale national and multicountry samples.
- This data collection effort should be designed by first identifying and prioritizing the key questions that require longitudinal data and then focusing on relevant key outcomes with measures that are standardized across the sample. Priorities should

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include core outcomes related to clinical care and treatment, including adherence and retention; outcomes related to the reduction of HIV transmission through biomedical and behavioral prevention interventions for people living with HIV; quality measures; and program measures, such as the costs of services, that can help inform strategies for efficiencies, sustainable management, and resource planning for the trajectory of need.

- There may also be opportunities for an established data-collection effort of this kind to serve as a synergistic platform for targeted implementation research studies in subset samples to assess innovations and advance best practices with maximal readiness for translation for scale-up.
- In addition to implementing this approach prospectively, OGAC should explore working with and coordinating Track 1.0 partners to pool data for retrospective outcome analyses.

ONGOING CHALLENGES WITH ART COVERAGE

ART Coverage in PEPFAR Partner Countries

Although PEPFAR has had a major effect on increased access to ART, interviewees indicated widely varying proportions of people eligible for treatment who were actually receiving treatment, and across countries there remains a large unmet need for care and treatment, including ART. As an interviewee described in one partner country, thousands of PLHIV are dying due to lack of drug treatment (331-08-PCNGO). One issue raised related to assessing treatment coverage is a lack of current, consistent data related to the total number of people in need of treatment (587-13-USG; 240-15-USG). In addition, the current understanding of who is eligible depends on where the partner country is in the transition to implementing the revised WHO HIV treatment guidelines, which expand eligibility and thus the number in need.

To get a reasonable sense of the status of coverage in PEPFAR partner countries and how this has changed over time, the committee used the best available, consistent data to look at two time points since PEPFAR was initiated, 2006 (Figure 6-15) and 2009 (Figure 6-16). The need and the coverage varies widely bv country; nonetheless, these figures provide an overall, sense that coverage has increased in PEPFAR partner countries, as has the proportion of the national coverage supported by PEPFAR. However, the underlying need has also increased, and gaps in coverage remain.

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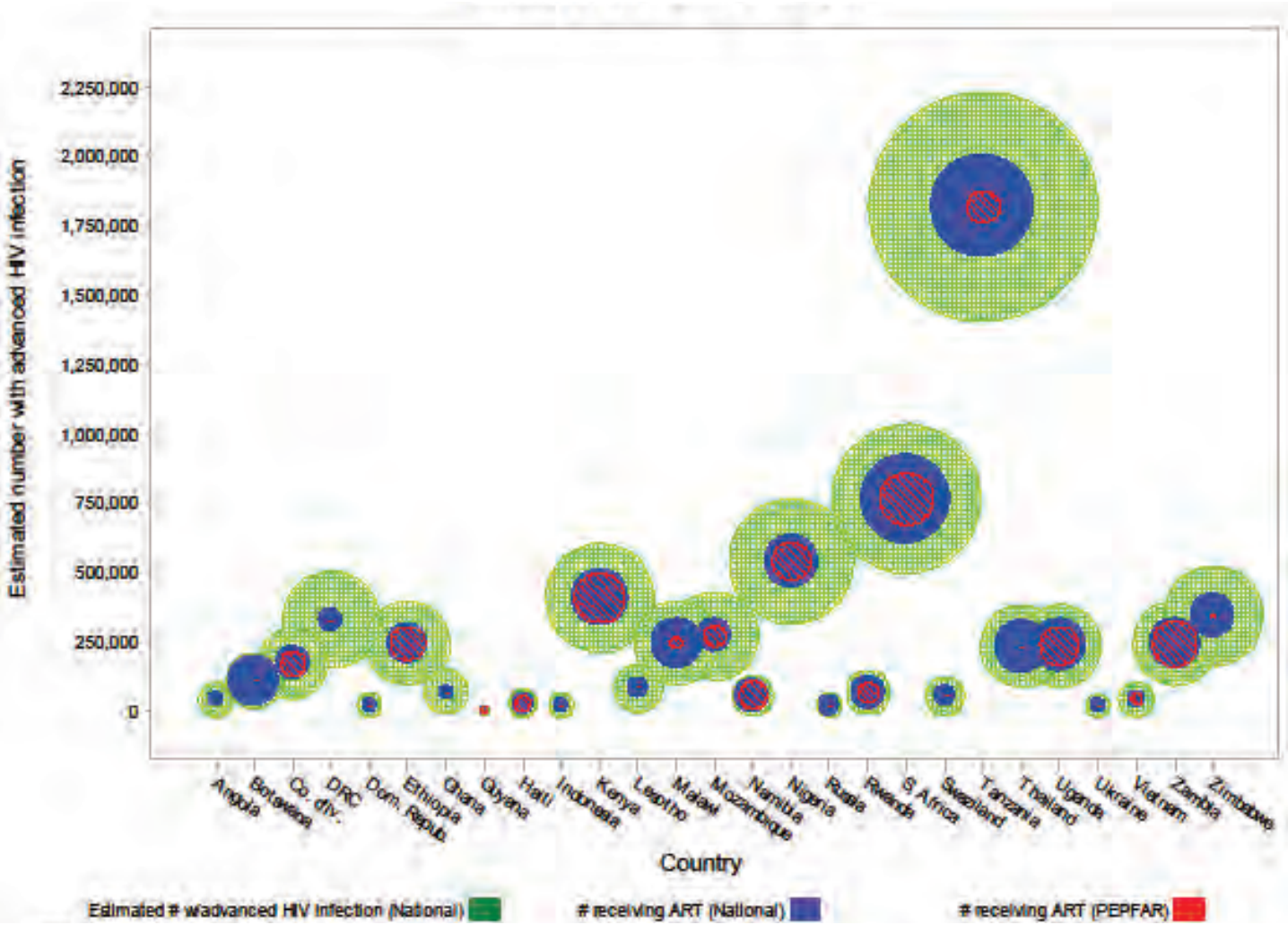

FIGURE 6-15 2006 estimated HIV prevalence and ART coverage.
NOTE: The area of the green circles, as well as the height of the center of these circles, represents the estimated magnitude of advanced HIV infection within each country (UNGASS Indicator 4, denominator). The area of the blue circle within a green circle represents the national ART coverage (UNGASS Indicator 4, numerator). The area of the red circle within a blue circle corresponds to the amount of ART coverage contributed by PEPFAR programs (OGAC Indicator 11.4). This figure represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2), except Cambodia, China, India, and Sudan which were excluded because national estimates were not available for 2006 and 2009.
SOURCES: National numbers correspond to UNGASS indicator 4. PEPFAR numbers correspond to OGAC indicator 11.4.

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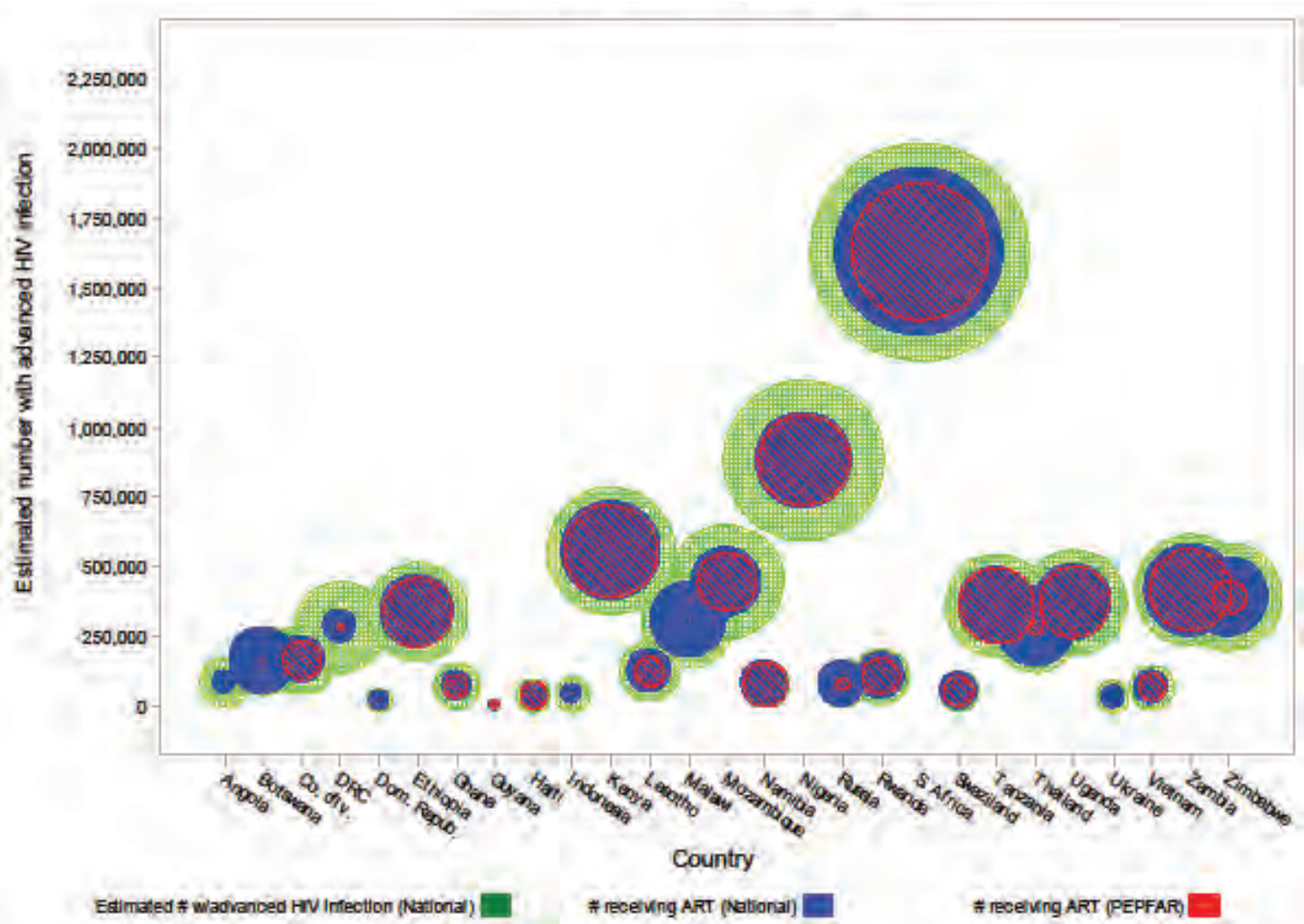

FIGURE 6-16 2009 estimated HIV prevalence and ART coverage.
NOTE: The area of the green circles, as well as the height of the center of these circles, represents the estimated magnitude of advanced HIV infection within each country (UNGASS Indicator 4, denominator). The area of the blue circle within a green circle represents the national ART coverage (UNGASS Indicator 4, numerator). The area of the red circle within a blue circle corresponds to the amount of ART coverage contributed by PEPFAR programs (OGAC Indicator 11.4). This figure represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2), except Cambodia, China, India, and Sudan which were excluded because national estimates were not available for 2006 and 2009.
SOURCES: National numbers correspond to UNGASS indicator 4. PEPFAR numbers correspond to OGAC indicator 11.4.

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Factors that Contribute to Coverage Challenges

The major factors affecting the ability of a partner country to achieve greater coverage of ART are financial resources, discussed in the next section on sustainability; capacity in the health system; and access to care and treatment services.

Health Systems Capacity

In many low-resource countries, HIV continues to overwhelm the health system (166-10-USNGO). Sustaining a large number of PLHIV on treatment requires the support of a particularly strong health system. Interrelated health systems factors affect the availability, accessibility, and quality of treatment, including health facilities, information systems, laboratory services, counseling and testing, trained health care providers, and ARVs and other drugs to treat TB other opportunistic infections. Health systems factors that contribute to coverage challenges are introduced briefly here, while a full assessment of PEPFAR's health systems strengthening efforts can be found in Chapter 9.

Facilities in poor condition and a lack of infrastructure posed serious impediments to treatment access and care (240-15-USG; 461-13-USACA). Donor-funded renovations of facilities in some countries were undertaken to address quality improvement in care and treatment (240-24-USG). In addition to the poor physical condition of some health facilities, compartmentalization of function by designating facilities ART-initiating sites, ARV/drug dispensing sites, and follow-up care sites in some countries (934-15-PCGOV) had implications for patient access, continuity of care, and retention. Although targeted patient needs could be addressed, when comprehensive care was unavailable at a single site, this raised patient access issues of distance and transportation. In addition, in several countries interviewees described challenges with establishing care and treatment in facilities in rural areas, where either few health facilities existed or it was difficult to staff existing local health centers. As a result, the time and expense of travelling to access services, a challenge noted in both urban and rural settings, poses a difficulty that is magnified for residents in rural and remote areas where distances to services are largest. Transportation for individuals who are distant from sites of care or cannot access care despite proximity continues to be one of the primary issues in accessing care across countries (166-29-PCGOV; 240-19-USACA; 272-3235-PCNGO). Innovations such as mobile units and internet communication increase the possibility of care in some remote areas (587-05-PCGOV).

As care and treatment services were expanded, a need existed for an adequate health care workforce to oversee ART. Many countries had shortages of physicians or trained knowledgeable health care providers. In addition to training efforts, task shifting from physicians to trained nurses and other health professionals was commonly implemented in countries as a workforce capacity building strategy (396-21-USG) that facilitated the provision of routine patient care and clinical management (934-15,16-PG). In many cases, task shifting addressed the clinician shortage problem and brought health care services to those in need (240-15-USG; 240-24-USG; 934-15,16-PG), particularly those living in remote rural areas. However, such shifting in responsibilities was also met with varying levels of implementation and degrees of success (272-22-USG), particularly since some people believed that HIV care and treatment was '*too complex*' to be delivered by providers other than physicians (587-13-USG). A significant policy and implementation-related task shifting challenge in some countries was establishing '*nurses to prescribe ART*' (934-05-USG), particularly for pediatric populations and, less commonly, training nurses in the diagnosis and treatment of tuberculosis, a major cause of death in PLHIV (331-12-USG).

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Countries also experience drug shortages, including lack of ARVs and unavailable OI drugs (331-08-PCNGO; 240-25-PCGGOV; 461-18-USG), for various reasons that include drug procurement and supply chain management issues. Ineffective supply chain management systems episodically impaired patient's access to treatment to a significant degree. Interviewees reported periodic stock-outs of drugs, (587-18-PCGOV; 166-18-PCNGO; 272-22-USG), a situation that some viewed as '*a critical area to wrestle with*' (331-43-USG). Countries that had effectively organized functioning supply chain management systems rarely experienced stock-out occurrences (240-25-PCGOV; 272-32,35-PCNGO) that were linked to systems management. Different countries and health facilities had varying ways of coping with stock-outs, one of which was to pool resources from regional clinics. In these circumstances, patients sometimes received medication substitutions (166-18-USNGO) but were able to continue ART. In emergency circumstances, PEPFAR occasionally came to the aid of the country by serving in a gap-filling role and by providing buffer stocks to cover stock-outs (461-10-PCNGO; 934-05-USG; 272-22-USG). A particular gap-filling need arose in some countries that experienced a transition from one donor to another.

Laboratory services also clearly underlie some of the unmet need for ART (461-18-USG). An interviewee underscored the importance of laboratory services in HIV/AIDS treatment as, '*one of the major challenges that limits access to ART*' (461-10-PCNGO). Another interviewee's perspective echoed that contention: '*low case detection rates were due to low laboratory capacity*' (240-24-USG). Challenges related to laboratory services that ultimately affected ART access included the long turnaround time required for results from some laboratories and the difficult transport of laboratory samples, particularly in more remote and rural areas where transportation is difficult and there are fewer laboratory facilities. In addition, few personnel were trained in techniques such as obtaining dried blood spot samples and performing early infant diagnosis (396-21-USG), or had limited or no access to equipment or reagents for such services as CD4 testing in the health facility where they worked (240-24-USG). Occasional stock-outs of reagents or HIV rapid tests also posed access challenges in the provision of laboratory services (166-15-USACA).

Overall, interviewees perceived the need for a significant investment in health systems strengthening efforts (272-22-USG; 396-21-USG;587-02-USG). One aspect of this was the need for integration of HIV-related services with other health services (240-24-UG; 598-02). As one interviewee observed, '*HIV is being treated as a separate entity and not integrated with other health services. ART clinics will only provide care to HIV patients. This is a missed opportunity*' (240-24-USG).

Access to Care and Treatment

Each of the preceding sections of this chapter described challenges with access to care and treatment services. In summary, across the continuum of services, interviewees indicated that key elements that affect access include physical distance to facilities resulting in transportation barriers, stigma, and costs of care to clients. Some specific barriers to accessing care were discussed in this chapter for key vulnerable populations, including people who inject drugs, sex workers, and men who have sex with men; these populations are discussed in more depth in Chapters 5 and 8. As noted throughout this chapter, interviewees across countries consistently observed that PEPFAR has contributed to improving both the availability of and access to care and treatment both in general due to its support for scale up of services as well as through efforts to address barriers to access.

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Conclusion: Despite progress in the availability of and access to HIV services, there remains a large unmet need for care and treatment in PEPFAR partner countries. Intrinsic limitations of the health system infrastructure continue to be barriers to delivery of care treatment services including clinical care, clinical and laboratory monitoring, and antiretroviral therapy.

ART Coverage Challenges for Children

Coverage of treatment of children has been a persistent challenge, and a number of factors contribute to this, including a lack of accessible testing for children of all ages, especially the difficulties of early infant diagnosis and the failure to adequately support alternate diagnostic measures to initiate therapy; a lack of providers familiar with treating children, a lack of pediatric ART services at primary care, postnatal, and other maternal-child health care facilities; and shortages of ART regimens for children.

As described earlier in the chapter, the identification of children with HIV-infection is suboptimal. The children of an index patient with HIV-infection are not screened because the system is over-burdened. Diagnosis of children less than 1 year old is particularly challenging. Without treatment, HIV infection in children follows an aggressive course including a faster progression to AIDS and death than in adults (Newell et al., 2004; Violari et al., 2008). Without ART, about one-third of HIV-infected infants will die by age 1 year and 50 percent by age 2 years (Newell et al., 2004). Despite PEPFAR-supported progress in supporting early infant diagnosis, when testing is conducted to identify children, results are often too delayed. This contributes to a chain of events leading to delayed initiation of treatment and poor outcomes, including a need for complex treatment for children in whom the disease has progressed and quite often death.

Improved access to pediatric treatment depends on the ability to identify women and children routinely through maternal-child care service entry points such as services in MCH, including PMTCT, and to refer them to care and treatment facilities or provide integrated care. PEPFAR has put in place several efforts described previously in this chapter to increase pediatric enrollment by improving linkages to care and treatment after identification of children in need, but this continues to often be lacking.

According to interviewees, another contributing factor to the lack of coverage for children is a lack of trained workforce for pediatric care and treatment (272-20-PCNGO; 272-22-USG; 935-13-PCGOV; 240-24-USG), including a shortage of trained pediatricians. Training in pediatric treatment and care is a critical factor because of the sense of insecurity from many providers about their skills to confidently provide these services. For this reason, task shifting for pediatric treatment has resulted in mixed effects, as has the integration of pediatric services into general health facilities.

Stock-outs of drugs for children is also a challenge (934-29-USNGO), in one example forcing the purchase of medicine using local city funds when no other external resources were available (542-16-PCGOV). Facilities in poor conditions (934-29-USNGO; 461-13-USACA) and lack of laboratories with the technology required for testing (166-13-PCGOV) prevented putting more children on ART, with special concern for the quality of laboratory services (240-2-USG).

Stigma was also one of the factors that played a role in identifying children. Parents would take their children to health facilities outside their communities to avoid disclosing their status (240-25-PCGOV). Moreover, there was fear of the negative impact on the development of the

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child if the children were identified as HIV positive in school or through participation in support groups, as this would mean children could not participate in all school activities (116-15-USNGO).

Finally, the lack of data to assess progress represented a great challenge (587-5-PCGOV; 166-18-USNGO). In one country, PEPFAR is planning an interagency pediatric treatment assessment and working to increase indicators to assess more outcomes, loss to follow-up, and age groups (272-22-USG).

The challenges with pediatric treatment are compounded by inadequate funding for pediatric treatment—although PEPFAR purchases pediatric ARVs in some countries, in several countries, UNITAID[11] and the Clinton Foundation are the sole purchasers of ART formulations and second regimes for children, EID commodities, cotrimoxazole, and other drugs for opportunistic infections (OGAC, 2009b; UNITAID and CHAI, 2010). UNICEF and UNAIDS have determined that about $6 billion of the $25 billion, needed by 2010 to enable countries to reach universal access goals[12] is required to attain the universal goals specific to women and children (UNICEF, 2009). UNITAID and the Clinton Foundation are winding down shipment of some of these commodities; therefore, countries will need to make up for the gap (OGAC, 2009b).

Another challenge is meeting the specific needs of HIV-positive adolescents in care and treatment programs and transitioning to adult care and treatment programs. There are some PEPFAR-supported programs in a few countries that have developed strong adolescent components, including for example, adolescent-specific care and support programs, bimonthly provider forums to discuss challenges in the adolescent population, and facilitation of referrals between clinics and community services (Sharer, 2012). However, comprehensive services that focus specifically on the unique needs of adolescents living with HIV are a remaining gap identified by interviewees across countries (396-43-OML; 396-42-PCGOV; 935-ES). Challenges in services for adolescents are discussed further in Chapter 7.

> **Conclusion:** Treatment of infants and children remains a persistent challenge across the continuum of care. The main barriers, especially for infants, come at the stages of testing and diagnosis, linkages to care and treatment, and timely initiation of therapy. Limitations in health systems for support of pediatric HIV services are also a major factor. PEPFAR has contributed to increasing pediatric treatment, but the coverage of pediatric HIV remains proportionally much lower than coverage for adults, despite the goal in the reauthorization legislation to provide care and treatment services in partner countries to children in proportion to their percentage within the HIV-infected population.

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[11] UNITAID is an international facility dedicated to purchasing drugs for HIV/AIDS, malaria, and tuberculosis, primarily for people in low-income countries. UNITAID leverages its funds, received through airline ticket taxes or regular multiyear budget contributions from member countries, to reduce the price of quality diagnostics and medicines as well as to accelerate the development and availability of these products in low- and middle-income countries (UNITAID and CHAI, 2010).

[12] At the United Nations General Assembly High-Level Meeting on AIDS in 2006, countries committed to work toward "universal access to comprehensive [HIV] prevention programmes, treatment, care and support by 2010" (United Nations General Assembly, 2006).

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Expansion of Eligibility Under Evolving WHO Guidelines

The issue of gaps in coverage and unmet need is complicated by the changes in the WHO HIV treatment guidelines recommending that ART treatment initiation begin earlier, at a CD4 count of <350 cells/mm^3. Implementing these guidelines will expand the eligible population for whom treatment is indicated. As of December 2010, there were approximately 9 million people globally who were eligible for ART under the new guidelines but not receiving it (approximately 60 percent unmet need of the total eligible population of 14.6 million) (UNAIDS, 2011). A recent UNAIDS estimate was that in 2011, 12.8 million adults in low- and middle-income countries were eligible for ART under the 2010 guidelines (Stanecki, 2013).

To illustrate the effect of the change in guidelines on the population in need, Figure 6-17 shows an estimate from 2010 of the difference over time in the number of eligible adults in different regions of the world based on the different eligibility criteria.

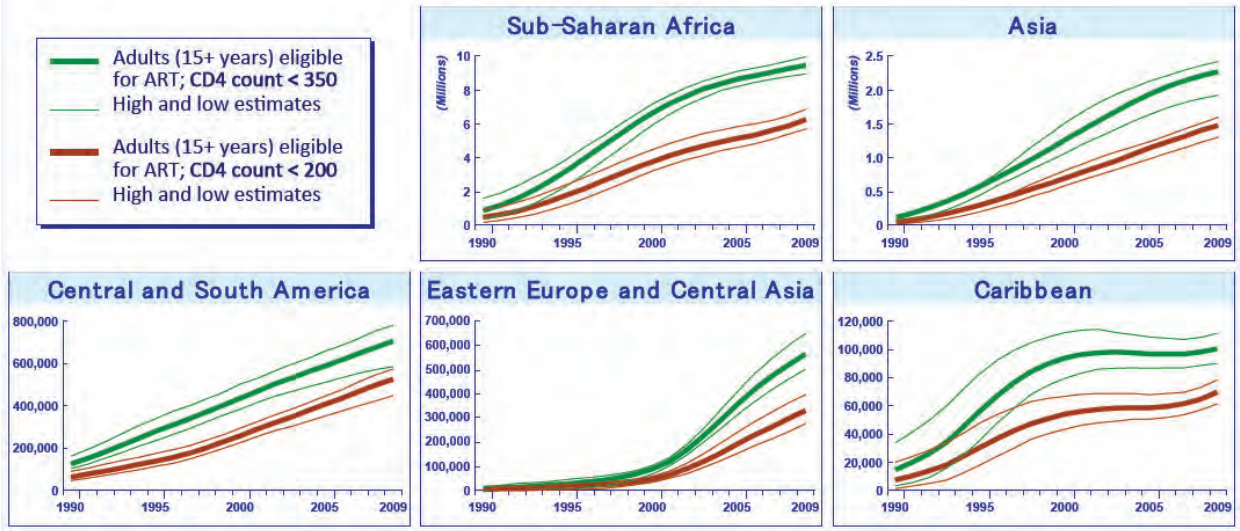

FIGURE 6-17 Number of adults (>15 years old) eligible for ART in low- and middle-income countries, by region, according to WHO 2006 and 2010 guidelines.
SOURCE: (Stanecki et al., 2010).

The expansion of coverage and its associated challenges will be compounded further by implementation of PMTCT Option B+ and the recently released WHO guidelines recommending offering antiretroviral therapy to the HIV positive partner in serodiscordant couples, regardless of CD4 count (WHO, 2012a, 2012b).

SUSTAINABILITY OF CARE AND TREATMENT

While the rapid scale-up of ART has been a success of the global AIDS response, and PEPFAR has made a major contribution to this success, there is still a long way to go before the goal of universal coverage is achieved. As described in the preceding section, there remains a large unmet need overall in low- and middle-income countries, and access and coverage among several populations, most notably children, marginalized populations, and pregnant women, continues to lag behind that of the general population or behind the global targets. An important challenge for the future of the response to HIV, given the realities of limited resources, is how to

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maintain those currently enrolled in care and treatment, address the care and treatment needs for the many currently eligible patients who may remain untreated, and plan for those who will become eligible in the future. There is a critical need for PEPFAR, its partner countries, and other global stakeholders to focus on how to support countries in discussing what resources are needed to respond to the HIV/AIDS epidemic, how to prioritize the large unmet need for treatment of adults, adolescents, and children, and how to identify resources for the gap.

Currently in many partner countries the vast majority of treatment is funded by either PEPFAR or the Global Fund, or commonly by some combination of the two. This can represent a very fragile state for care and treatment programs, especially as there is ongoing uncertainty related to future HIV/AIDS funding levels due to the global economic recession, which has complicated planning efforts for continued ART scale-up (UNAIDS, 2011; WHO et al., 2009). This fragility was exemplified on several country visits when a Global Fund proposal had been rejected or a round had been cancelled. As one interviewee put it, '*Now that the Global Fund is out, there's no other back-up plan.*' (331-12-USG)

While financial resources are a clear challenge to sustainability, a number of other challenges also hamper the effort to maintain current levels of care and treatment and to achieve universal access according to the WHO treatment guidelines. These include distribution and supply chain challenges such as stock outs; infrastructure challenges such as poor laboratory infrastructure; inadequate human resources for health in many low- and middle-income countries; and challenges relating to ensuring patient adherence to treatment. In addition, challenges with retention and adherence and the emergence of drug resistance and co-infection of HIV patients with tuberculosis continue to undermine care and treatment efforts.

Interviewees conveyed their awareness of a desire by the PEPFAR program to foster sustainability and, in that light, reduce or eliminate support for the HIV response in partner countries. Their central concern was the continuing availability of funding for ARVs. As one interviewee stated,

> *'Obviously, absolutely, we should be looking at long-term sustainability. But at the same time, don't let that be the catchall. And right now, PEPFAR, we have the money, and one of the most important things right now is saving lives. We've lost too many lives here in [this country]. It was an absolute horror and a tragedy. And we're stopping that now. And we should continue to stop it. But treatment is one of the most important things that we can do. Obviously, as we all know, it's not the only thing. We've also got to focus on prevention. But this is an inexpensive way to stop the deaths.'* (934-05-USG)

Interviewees highlighted initiatives they had undertaken that would eventually become self-sustaining such as, in the case of one country, implementing fees to subsidize a laboratory quality assurance program (934-05-USG). However, overall across countries they questioned the readiness of their countries for anticipated sustainability-related funding reductions or cessation (240-15-USG; 396-21-USG, 30, 934-05-USG) and made recommendations or raised concerns about the pace or timeframe for such reductions (272-05-PCGOV; 272-22-USG). As one interviewee explained,

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> *'It's not that sensible for PEPFAR to leave tomorrow [. . .] it would be difficult to keep scaling up and adding money and replace PEPFAR funding at the same time. If PEPFAR pulled out, the funding would probably just not be replaced. If done over time, it's far more likely it would be a smooth process to sustainability'*. (272-05-PCGOV)

Barriers to partner country readiness for sustainability included such issues as funding treatment scale-up efforts that are currently underway (272-05-PCGOV); lack of partner government capacity to "*take over the response*" (240-24-USG); meeting salary expectations of those previously employed by PEPFAR (240-15-USG); and absorbing demands for services (272-32,35-PCNGO). One interviewee observed that, '*a weak [ART] program is not sustainable*,' implying the need for program strengthening as a pre-condition for sustainability (396-21-UG). Another interviewee focused on facilitating drug treatment adherence, noting that making treatment "*easier and cheaper is sustainability*" (272-22-USG).

In summary, the all-encompassing challenge for care and treatment, as for other HIV services, is that despite remarkable scale-up in PEPFAR partner countries, there remains substantial unmet need. The large numbers of currently enrolled patients who need to be maintained, those currently eligible but not yet enrolled, and the potential for expansion of eligibility if changing WHO guidelines are adopted and implemented are fundamental challenges for achieving adequate coverage and for the sustainability of care and treatment across PEPFAR partner countries. Intrinsic limitations in the health system and other systems involved in the response continue to be barriers to delivery of services, as do the realities of resource constraints, especially with the possible flattening or decreasing of external resources.

Therefore, for care and treatment, as with other HIV programs, the most critical challenge for the future is for PEPFAR to work with partner countries and global partners to sustain the gains made, to continue to make progress, and to ensure the ongoing quality of services provided and programs implemented. Given that this challenge must be confronted while facing limited resources, contributing stakeholders will need to allocate resources with a strategic and ethical balance among coverage priorities. Critically important issues related to this overarching challenge for the future, including strengthening systems, building capacity, and considerations and efforts related to achieving a sustainable, country-led response to HIV in PEPFAR partner countries, are discussed in depth in Chapters 9 and 10.

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7

Children and Adolescents

Main Messages

- PEPFAR has positively affected the lives of children and adolescents living with or affected by HIV. PEPFAR has contributed to major scale up of services (OVC, pediatric care and support, pediatric treatment, and PMTCT) across delivery settings (facility-based, home-based, community-based, family support). With its explicit focus on orphans and vulnerable children, PEPFAR has elevated attention to and investment in meeting the needs of this population through programs and services that are informed by evidence. PEPFAR has also been instrumental in facilitating partner country consideration and adoption of policies, laws, and guidelines on behalf of children and adolescents, including OVC policies and frameworks, policies for pediatric testing and treatment, and efforts to strengthen legislation and enforcement for child protection.

- Despite progress, there remain insufficiently met needs for the health and wellbeing of children and adolescents. Although it is not realistic to expect PEPFAR to meet all the need for children and adolescents in partner countries, there are particular areas where PEPFAR could strive to address these needs more fully. In particular, there remain gaps in coverage for PMTCT relative to PEPFAR's 85 percent goal; coverage of pediatric HIV care and treatment remains proportionally much lower than coverage for adults, despite the goal in the reauthorization legislation to provide care and treatment services in partner countries to children in proportion to their percentage within the HIV-positive population; and OVC programs struggle to adequately meet the needs of adolescents in particular. Across program areas, there is also a need to plan for long term sustainability of services and to build the capability of partner countries to continue the successes they have realized in addressing the needs of children and adolescents living with or affected by HIV.

- The ability to assess the impact of PEPFAR-supported programs for children and adolescents is restricted by limitations in the available data. There are data insufficiencies in three key areas directly related to PEPFAR programs: disaggregation by both sex and age, with age subgroupings (for example, less than 1 year, 1-5 years, 6-17 years), to better understand what populations are receiving what services; baseline and longitudinal data to follow children and families and the effects of the services they receive over time; and data on effectiveness and outcomes to help identify the most effective PEPFAR OVC programs and models. In addition, there is a lack of data about the total population of children "in need," in part due to a lack of clarity and consistency both across countries and across programs within countries in how the population eligible for PEPFAR-supported services is defined (i.e. which children are defined as "vulnerable" or "affected by HIV").

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Recommendation Presented in this Chapter

Recommendation 7-1: To improve the implementation and assessment of nonclinical care and support programs for adults[1] and children, including programs for orphans and vulnerable children, the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.

Further considerations for implementing this recommendation:

- For orphans and vulnerable children, the new OVC guidance and the ongoing developments for program evaluation already represent advances in addressing some of the challenges identified in this evaluation; this recommendation and considerations are intended to reinforce and further inform and support progress in achieving PEPFAR's goals for children and adolescents.
- Outcomes for consideration should be linked to the aims of OVC programs, and therefore could include, for example, increased rates of staying in school, decreased excessive labor, reduced rates of exposure to further traumas, increased immunization completion, and increased coverage of HIV testing and treatment. In continuing to focus on supporting developmentally-informed programs, consideration should be given to identifying appropriate core outcomes for different age groups and for achieving developmental milestones. The program evaluation indicator development process currently being carried out in PEPFAR already offers a reasonable opportunity to link measures to core target outcomes for OVC programs.
- The core key outcomes should also include quality of services and measures to reflect the potential sustainability of programs.
- To enable a shift to a more outcomes-oriented implementation model, partner countries will need support to define their prioritized outcomes and their target population and then conduct baseline assessments so that progress toward outcomes can be measured.
- PEPFAR U.S. Mission Teams should work with partner country stakeholders and implementers to assess country-specific needs and select a subset of the core key outcomes to focus on when planning, selecting, and developing evidence-informed activities and programs for implementation
- Prioritization is critical in the context of large need and finite resources. Planning with partner countries, PEPFAR should improve targeted coverage and quality of supported services for affected children and adolescents by not only prioritizing outcomes and activities but also by more explicitly, clearly, and narrowly defining the eligibility for PEPFAR-supported services. This prioritization should be based on an assessment of country-specific needs with a process that consistently applies considerations and criteria across countries and programs. This prioritization should be done in coordination across program areas that address the needs and vulnerabilities of children and adolescents. These areas, which may target and serve a broader eligible population of children and adolescents than is determined for specific OVC programs, include care and treatment, PMTCT, other prevention

[1] The discussion of nonclinical care and support for adults leading to this aspect of this recommendation can be found in Chapter 6.

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services, and gender programs.

- To improve the targeted coverage and sustainability for children and adolescents, PEPFAR and its implementing partners should continue to enhance services through existing systems and infrastructure and support national governments to expand social support services and the workforce to meet the health, education, and psychosocial needs of affected children and adolescents.
- OGAC should provide general guidance for country programs on continuous program evaluation and quality improvement to measure and monitor achievement of the key outcomes. This may include, for example, template evaluation plans and methodological guidance. To allow for comparability across countries and programs, evaluation plans should include (but not be limited to) the defined indicators or other measures of the core key outcomes. Evaluations should emphasize the use of in-country local expertise (e.g., local implementing partners/subpartners and local academic institutions) to enhance capacity building and contribute to country ownership. (See also recommendations for PEPFAR's Knowledge Management in chapter 11).
- PEPFAR should develop a system for active dissemination and sharing of evaluation outcomes and best practices both within and across countries that is driven as much by country-identified needs for information as by opportunities for exchange of information identified by headquarters-level leadership and Technical Working Groups. (See also recommendations for PEPFAR's Knowledge Management in chapter 11).

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Children and Adolescents

The congressional charge for this study, as laid out in the Lantos–Hyde Act of 2008,[1] requested an "evaluation of the impact on child health and welfare of interventions authorized under the Act on behalf of orphans and vulnerable children" and "an evaluation of the impact of programs and activities authorized in the Act on child mortality."[2] In addition, the request for an assessment in other areas, especially prevention, treatment, and care programs and gender-specific aspects of HIV/AIDS, implicitly includes considerations for children and adolescents as well as for adult populations.

After a brief background on the effects of the HIV pandemic on children and adolescents and on the needs of this population, this chapter presents the committee's assessment, in response to this congressional charge, of PEPFAR's efforts aimed at the needs of children and adolescents[3] living with and affected by HIV/AIDS. This chapter includes the primary presentation of the committee's assessment of PEPFAR's activities that fall under the specific category of programming for orphans and vulnerable children (OVC), following the program impact pathway framework of assessing inputs, activities, and, to the extent possible, outcomes and impact. PEPFAR also supports services for children and adolescents through prevention, treatment, and care programs, and although findings about these programmatic areas are covered in more detail in other chapters, the major conclusions that are specific to children and adolescents are also summarized at the end of this chapter in order to bring together a comprehensive picture of PEPFAR's efforts to improve the health and wellbeing of children and adolescents.

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[1]Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

[2]*Ibid.* at § 101(c), 22 U.S.C. 7611(c)(2)(B)(vi-vii).

[3]The term "children and adolescents" is used throughout this report as a general term without a specific age definition, recognizing that the ages used to categorize children and adolescents vary by data source and organization. The age categories vary in particular for terms like adolescents, youth, and young people. For example, WHO defines adolescents as men and women 10–19 years of age and young people refers to men and women 10–24 years of age (WHO, 1999, 2006c). United Nations defines youth as men and women 15–24 years of age and refers to young people as men and women 10–24 years of age (WHO, 1999, 2006c). Defined age ranges for children and adolescents also vary by programmatic area within PEPFAR, which uses ages 0-17 years for OVC programs and 0-14years for pediatric HIV care and treatment. Throughout this report, the specific age ranges used by PEPFAR or by the cited data source are indicated whenever feasible.

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To meet its charge, the IOM committee assessed PEPFAR's investment in programming for children and adolescents, including its progress in meeting fiscal targets; reviewed PEPFAR's guidance and the activities it has supported for these populations; and examined PEPFAR's progress toward programmatic targets and goals for children and adolescents, specifically its efforts to increase the number of HIV-positive children receiving treatment (discussed in Chapter 6) and to increase the number of orphans and vulnerable children receiving care and support services. To the extent possible, the committee also reviewed the available evidence to assess the effects of services provided to children and adolescents, efforts to support family-centered programs and community-led initiatives, and efforts to support countries to strengthen country policies and systems for supporting this population. The presentation of the committee's assessment in these areas is followed by a discussion of the future directions most recently articulated by PEPFAR in new guidance. Some discussion of child survival in PEPFAR partner countries is also included in this chapter, including the limitations on directly evaluating the effect of PEPFAR on child mortality.

BACKGROUND

The HIV/AIDS pandemic has severely affected the lives of millions of children and adolescents across the globe, endangering their development, life course, and survival. In 2011, approximately 3.3 million children younger than 15 years of age were living with HIV/AIDS, and 13 percent of incident cases of HIV were estimated to be children in this age group. An additional number of adolescents were among the 31 million living with HIV in the adult age group (15 years and older) (UNAIDS, 2012a). By affecting parents and other caregivers who are HIV-positive, the HIV/AIDS pandemic also adversely affects infants, children and adolescents who are not HIV-positive themselves by harming families and depriving children of parental care and protection. As of 2011, an estimated 17.3 million children and adolescents aged 0–17 years old had lost at least one parent to the AIDS epidemic[4] (Luo, 2012). HIV can also indirectly harm children and adolescents by weakening communities and social support networks, welfare systems, and economies. The population of children and adolescents affected by HIV varies widely by geographic, demographic, social, and cultural factors, and their needs and responses to these needs vary according to these factors as well as their developmental stage and gender.

The health and psychosocial well-being of children and adolescents affected by HIV/AIDS are influenced by critical developmental and societal factors. When a parent dies, the grieving process, the deprivation of emotional and material support, and other life changes that occur because of this loss can affect child health and well-being (Cluver and Orkin, 2009; Nyamukapa et al., 2008; Whetten et al., 2011a). Mediators of adverse effects as a result of parental loss include trauma, relocation, residence in poorer households, and residence with more distantly related caregivers, which can lead to inadequate access to nutrition, shelter, and health care, lack of educational support, and other effects. For example, many children and adolescents with sick and dying parents end up becoming the primary caregivers and financial and emotional

[4] In 2001, a consensus was reached among members of the UNAIDS Reference Group on Estimates Modelling and Projection, and international researchers on the definition of orphans due to HIV/AIDS. An "AIDS orphan" was defined as "a child who has at least one parent who has died due to AIDS" and a "double (or dual) AIDS orphan" as "a child whose mother and father have both died, at least one due to AIDS (UNAIDS Reference Group on Estimates Modelling and Projections, 2002)."

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supporters of their households (Cluver et al., 2007), essentially losing the opportunity of being a child. Depending on the economic status of the available caregiver, children often enter into excessive labor and stop attending school (Whetten et al., 2011b). In addition, in settings where stigmatization is high, children and adolescents who lose parents due to HIV/AIDS have to cope with more psychosocial stressors than do non-orphans and children orphaned by other causes (Cluver and Gardner, 2007; Cluver and Orkin, 2009). Children and adolescents living within communities that experience a high HIV burden are also at a greater risk of homelessness, exposure to HIV physical and sexual abuse, and sexual exploitation (UNAIDS, 2002, 2004). Orphans and abandoned children in these communities, both boys and girls, are at high risk of experiencing additional traumatic events of this kind (Whetten et al., 2011a).

In addition to younger children, the vulnerabilities of adolescents between the ages of 15 and 24 years have also been recognized by the international community, along with the opportunities for interventions during this important developmental transition period (UN, 2001; World Bank, 2006) ;). Adolescents are vulnerable due to age-specific changes that are physical, psychological, and social (their relationships and roles, expectations, and economic security) (Call et al., 2002). These changes underlie the ways in which adolescents understand information and are influenced, their abilities to make decisions in the present and plan for the future, and their perceptions of risk and sexual behavior (Dick, 2009).

In 2011, of the incident HIV cases in people aged 15 years and older, an estimated 40 percent were among those aged 15–24 years (UNAIDS, 2012b). About 5 million people aged 15–24 years were living with HIV in 2011, and in sub-Saharan Africa, this age group, and particularly young women, are more vulnerable and at greater risk of HIV infection (Gouws et al., 2008; Napierala Mavedzenge et al., 2011; UNAIDS, 2012b). Beyond greater biological susceptibility to HIV, there are many socio-cultural factors that increase the vulnerability of young women to sexually transmitted HIV infection. These include deep-rooted gender roles, uneven power relations, sexual violence (including rape), intergenerational sex, and a lack of skills and information that would enable them to access services and better protect themselves (UNAIDS, 2009). Issues related to women and girls as well as gender norms are discussed in more depth in Chapter 8.

The United Nations Convention on the Rights of the Child,[5] guides the efforts of the international community to protect the rights of children to survival, healthy development, and access to health services. The Convention's guidelines stress the importance of reversing the HIV epidemic in children and using the MDGs, the UNGASS on HIV/AIDS, and the UNGASS on Children as platforms through which to mitigate the negative effects of HIV on children's health and well-being (UNICEF, 2007). The Committee on the Rights of the Child (CRC) monitors the progress of countries in achieving standards and goals primarily through country reports.

Multilateral and bilateral stakeholders who support efforts and policies for OVC affected by HIV/AIDS have developed the "Framework for the Protection, Care, and Support of Orphans and Vulnerable Children Living in a World with HIV and AIDS." This framework includes five

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[5]The Convention on the Rights of the Child, which the U.S. has not ratified, is the first legally binding international instrument that addresses the complete range of civil, cultural, economic, political, and social rights of children. Through the Convention, UNICEF assumes the responsibility of promoting the rights of children by supporting the Committee on the Rights of the Child (CRC). UNICEF provides governments with technical assistance on implementation of the Convention and the development of implementing reports, which must be submitted every 5 years. (OHCHR, 2007; United Nations, 1990; United Nations Treaty Collection, 2010).

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strategies for improving the well-being of children: "(1) Strengthen the capacity of families to protect and care for orphans and vulnerable children by prolonging the lives of parents and providing economic, psychosocial and other support; (2) Mobilize and support community-based responses; (3) Ensure access for orphans and vulnerable children to essential services, including education, health care, birth registration and others; (4) Ensure that governments protect the most vulnerable children through improved policy and legislation and by channeling resources to families and communities; (5) Raise awareness at all levels through advocacy and social mobilization to create a supportive environment for children and families affected by HIV/AIDS" (UNICEF, 2004).

Given the range and scope of the adverse effects of HIV/AIDS on children and adolescents, addressing their needs is vital to the response to the epidemic. Programs and services for this population, from infancy through adolescence, provide the opportunity to mitigate these effects and promote positive outcomes with a long-term trajectory for accrual of benefits from early intervention. Early intervention of this kind lays the groundwork for supporting healthy and productive lives and promoting HIV-prevention throughout the lifecourse. As part of its contribution to the HIV response in partner countries, PEPFAR supports services for children and adolescents affected by HIV in all of its three main programmatic areas—prevention, care, and treatment. PEPFAR also supports programs specifically for orphans and vulnerable children and adolescents, in keeping with the Framework described above (hereinafter referred to as OVC programs or programming[6]). The Lantos–Hyde Act of 2008 underscored the needs of children and adolescents as part of the USG commitment to prevent 12 million new HIV infections worldwide and increase the number of individuals with HIV/AIDS receiving antiretroviral therapy. It also stated that PEPFAR-supported programs need to "provide care and treatment services to children with HIV in proportion to their percentage within the HIV-infected population of a given partner country."[7] Additionally, PEPFAR II performance targets for the care and support of people living with HIV include the specific target of providing care and support for 5 million children and adolescents orphaned or made otherwise vulnerable by HIV/AIDS.[8]

The committee's assessment of prevention, care, and treatment, including for children and adolescents, were covered in more detail in Chapters 5 and 6. In brief, PEPFAR support has made a major contribution to meet the need in partner countries for PMTCT services that reduce the transmission of HIV to infants. PEPFAR has also contributed to increasing pediatric treatment, but the coverage of pediatric HIV remains proportionally much lower than coverage for adults, despite the goal in the reauthorization legislation to provide care and treatment services in partner countries to children in proportion to their percentage within the HIV-infected population. Treatment of infants and children remains a persistent challenge across the continuum of care. The main barriers, especially for infants, come at the stages of testing and diagnosis, linkages to care and treatment, and timely initiation of therapy.

After a brief summary of PEPFAR's funding over time across all service for children and adolescents, this chapter provides the primary presentation of the committee's assessment of PEPFAR's activities that fall under the specific category of programming for orphans and vulnerable children (OVC).

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[6] For the purpose of brevity, the acronym OVC will be used to describe programs targeting eligible children and adolescents under PEPFAR's programs for orphan and vulnerable children.
[7] *Supra*., note 1 at §101(a), 22 U.S.C. 7611(a)(4)(E).
[8] *Supra*., note 1 at §101(a), 22 U.S.C. 7611(a)(4)(C).

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FUNDING HISTORY FOR PEPFAR SUPPORT FOR CHILDREN AND ADOLESCENTS

There is no single mechanism to capture all of the financial investment that has supported services for children and adolescents through PEPFAR. Activities that support children and adolescents are implemented with funding captured within several budget codes: Pediatric Care and Support, Pediatric Treatment, and OVC. Figure 7-1 shows the funding over time in these budget codes in both the dollar amount and as a proportion of all PEPFAR funding. The total across these budget codes has increased since the beginning of PEPFAR, reaching by FY 2009 a peak of about $500 million dollars per year and over 12 percent of all PEPFAR funding, then with a slight decline in 2010 and 2011. The total planned/approved funding that can be documented from these budget codes as explicit support for services for children and adolescents includes a total from FY 2005 to FY 2011 of $2.3 billion, including $1.7 billion for OVC programs as well as at least $160 million for pediatric HIV care and $405 million for pediatric treatment.

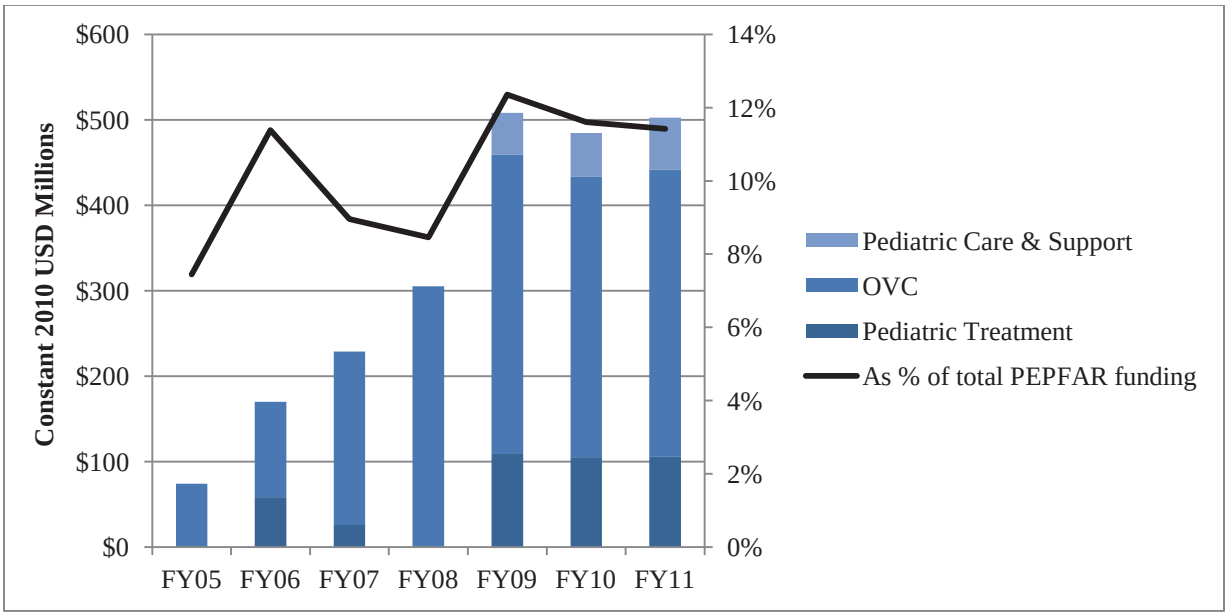

FIGURE 7-1 Planned/approved funding over time for services for children and adolescents.
NOTES: This figure represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by programmatic area. Data are presented in constant 2010 USD for comparison over time. See Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding.
SOURCES: (OGAC, 2005a, 2006d, 2007c, 2008d, 2010b, 2011b, 2011c)

Although these data give a general sense of the funding history and provide an approximation of PEPFAR's overall investment in children and adolescents, it is important to note that it is difficult to compile an entirely accurate accounting over time of the total investment that has gone to serve this population of beneficiaries. There are several reasons for this. First, the services captured by these budget codes have changed over time. In particular, funding for pediatric treatment was not reported in FY2005 and FY 2008 and the separate budget code for pediatric HIV care was not introduced until FY 2009. Second, the age ranges covered

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by these codes vary. The programs captured in the OVC budget code extend until the age of 17 years, while pediatric HIV care and treatment budget codes include services for children less than 15 years of age, and therefore age groups generally considered to be adolescents receiving services are included within the adult budget code and are not reflected in these data. Finally, some services for this population supported by PEPFAR are not included in these codes. Some other services are included in budget codes that are not tracked separately by age, such as other prevention services targeted to children and adolescents but not explicitly and exclusively to OVC. Most notably absent from the totals shown in Figure 7-1 in terms of representing investments in interventions that benefit children is PMTCT, which is a prevention intervention to reduce HIV infection in infants, yet is not tracked in a pediatric budget code but rather in its own prevention budget code (see Chapter 5). In FY 2011, $396 million was planned/approved for PMTCT services, which is more than three-quarters of the total funding for all other documentable pediatric services.

Legislative Budgetary Allocation Requirement for OVC Funding

The original legislation authorizing PEPFAR mandated that starting in FY 2006 "not less than 10 percent of the amounts appropriated…for HIV/AIDS assistance for each such fiscal year shall be expended for assistance for orphans and vulnerable children."[9] This earmark was preserved when the Lantos–Hyde Act of 2008 reauthorized PEPFAR.[10] PEPFAR's policy for implementing this budgetary requirement is provided in the instructions to country programs on planning and budgeting for OVC programming through Country Operational Plan (COP) guidance, and compliance with the requirement is monitored by PEPFAR on a country-by-country basis through the COP review process. As established in the 2006 COP guidance, countries are instructed that in order to comply with the requirement, OVC resources should comprise 10 percent of program resources for prevention, care, and treatment. Countries that are unable to meet the budgetary requirement must provide a justification (OGAC, 2005b). Over time it was clarified in the COP guidance that the expectation for meeting the 10 percent budgetary requirement was for countries with generalized epidemics and less applicable for countries with smaller OVC populations and/or concentrated epidemics (OGAC, 2008c, 2009c). Ultimately it was explicitly stated that all former focus countries, except Vietnam and Guyana, are required to comply with the OVC budgetary requirement and a justification for spending less would not be considered for these countries. For other countries submitting COPs, while OVC programming is still considered essential, those with smaller OVC populations and/or concentrated epidemics can submit justifications for spending less than 10 percent (OGAC, 2010a, 2011a).

Tracking PEPFAR's compliance with the proportional budgetary requirement over time and across countries is complicated because the guidance on what funding and activities were to be counted towards the allocation changed over time and was open to some variation by country. Most significantly, for FY 2006 and FY 2007 countries could select whether to attribute activities for pediatric HIV to either the OVC budgetary requirements or the treatment budgetary requirements that were in place at that time (OGAC, 2005b); (OGAC, 2006c). In both years the COP guidance encouraged countries to prioritize non-treatment OVC activities in a balance with pediatric treatment activities (OGAC, 2005b, 2006c), and the 2007 guidance specifically

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[9]United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L.108-25, 108th Cong.,1st Sess. (May 27, 2003), § 403(b).
[10]*Supra*., note 1 at § 402, 22 U.S.C. 7672(b).

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encouraged countries to "strive to fund OVC programs at, or as close as possible, the 10% level prior to including funding for pediatric treatment" to ensure the provision of a comprehensive OVC program (OGAC, 2006c), p. 5). Since FY2008, the COP guidance has changed to specify that pediatric treatment could no longer be counted towards the 10 percent budgetary requirement. Each year the guidance has emphasized that this change was not intended to lessen the importance of a focus on pediatric treatment as a priority, but rather to establish that the 10 percent requirement should include only OVC programs and that funds for pediatric treatment should be attributed separately as dedicated funds in the pediatric treatment budget code (OGAC, 2007a, 2008b, 2009b, 2010a, 2011a). Another complication in tracking the proportion of OVC funds is that the activities funded that contributed to the denominator of total prevention, care, and treatment resources changed over time when, as of FY 2010, activities in the laboratory infrastructure budget code were no longer included in the total for the denominator.

Given these complications, in order to reasonably and comparably approximate the compliance with the legislative earmark across PEPFAR partner countries and over time, the committee chose to assess the available planned/approved funding data reported through the OVC budget code, compiling the totals for prevention, care and treatment program resources as the denominator using the FY2011 definition retrospectively for all years (excluding the laboratory infrastructure budget code). As shown in Table 7-1, even using the planned/approved funding across all countries, including those with concentrated epidemics and small OVC populations, PEPFAR has maintained or exceeded the budgetary requirement since FY 2007, with total planned/approved funds of $1.7 billion dollars for OVC programs over 7 years.

TABLE 7-1 Tracking the Legislative Budgetary Requirement for OVC Programming (in USD millions)

	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	Total
OVC	$74.3	$111.6	$202.9	$305.1	$350.6	$327.9	$336.0	$1,708.4
Total Program Resources (prevention, care, and treatment)	$946.2	$1,238.9	$2,120.2	$2,962.2	$3,165.9	$3,119.3	$3,269.1	$16,821.8
OVC as % of total program resources	8%	9%	10%	10%	11%	11%	10%	10%

NOTES: This table represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by programmatic area. Data are presented in constant 2010 USD for comparison over time. See Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding.
SOURCES: (OGAC, 2005a, 2006d, 2007c, 2008d, 2010b, 2011b, 2011c)

The original legislation also prescribed that of the 10 percent earmark, "at least 50 percent shall be provided through non-profit, nongovernmental organizations including faith-based organizations that implement programs at the community level,"[11] and this was maintained in the reauthorizing legislation. Country Operational Plans and interview data collected by this committee reflect that PEPFAR's OVC activities are widely implemented by the kinds of organizations described in the legislation. However, because there is no central reporting of funding both by implementing partners and sub-partners and by budget code (see Chapter 4), the

[11] *Supra*., note 9 at §403(b).

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committee was not able to access a comprehensive PEPFAR-wide documentation of funding to assess whether the 50 percent mandate has been met.

In summary, although there are complications in definitively and comprehensively tracking PEPFAR's total investment over time in children and adolescents, the available data on planned/approved funding show that PEPFAR has complied with its policy for implementing the legislative budgetary requirement by spending at least 10 percent of program resources for prevention, care, and treatment on OVC programs. The guidance for complying with this requirement evolved over time to become more clearly focused on support for OVC programs, with separate tracking of investments in pediatric HIV treatment and care. The total planned/approved funding that can be documented as explicit support for services for children and adolescents includes a total from FY 2005 to FY 2011 of $1.7 billion for OVC programs, as well as at least $160 million for pediatric HIV care, $405 million for pediatric treatment, and $1.43 billion for PMTCT.

PEPFAR'S PROGRAMS AND SERVICES FOR ORPHANS AND VULNERABLE CHILDREN

OVC Program Guidance and Supported Activities

PEPFAR provides guidance for programs aimed at improving the needs of children and adolescents living with and affected by HIV through programming guidance documents, "Technical Considerations" provided by headquarter-level Technical Working Groups, and the Country Operational Plan guidance, which is released annually at the beginning of the country planning process. The primary relevant programming guidance for OVC programs is "Orphans and other Vulnerable Children Programming Guidance for United States Government In-Country Staff and Implementing Partners" (OGAC, 2006e). PEPFAR updated its guidance on OVC programming in July 2012; however, because the program operated under the earlier guidance during the timeframe of this evaluation, the committee's assessment is made primarily in the context of the prior guidance, which is reflected in this section. The recently updated guidance is discussed in more detail in the section below on future directions of the program. Guidance related to services for children and adolescents other than specific OVC programming are discussed in Chapter 5 (Prevention) and Chapter 6 (Care and Treatment).

The 2006 guidance document described those who were potentially eligible for PEPFAR supported OVC services as children aged 0-17 years old who are "either orphaned or made more vulnerable because of HIV/AIDS." Further, an orphan was defined as a child who "has lost one or both parents to HIV/AIDS" (OGAC, 2006a), p. 2). Children were described as being more vulnerable "because of any or all of the following factors that result from HIV/AIDS: is HIV-positive; lives without adequate adult support (e.g., in a household with chronically ill parents, a household that has experienced a recent death from chronic illness, a household headed by a grandparent, and/or a household headed by a child); lives outside of family care (e.g., in residential care or on the streets); or is marginalized, stigmatized, or discriminated against" (OGAC, 2006a), p. 2). Among this potentially eligible population, the guidance did not establish priorities of those in most need. Although PEPFAR guidance provides this operational definition for OVC and guiding principles for OVC programming decisions, the guidance directs that "each community will need to prioritize those children most vulnerable and in need of further care" (OGAC, 2006a), p. 2).

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To facilitate age-appropriate development and meet age-specific needs, PEPFAR guidance recommends that OVC programs target different age groups of orphans and vulnerable children and adolescents from age 0 to 17 years (see Table 7-2) (OGAC, 2006a). In addition to these age groups, the Lantos–Hyde Act of 2008 also highlighted a new emphasis on the vulnerabilities and needs of adolescents and young people.[12] In its second Five-Year Strategy, PEPFAR articulated goals for programming for adolescents and young people such as supporting countries in "developing a case management capability to assist the transition of young adults from OVC services into society and careers" and helping to ensure that policies for populations at elevated risk include coverage and referrals for youth subpopulations (OGAC, 2009g), pg 23). The expanded program goals under the new Five-Year Strategy also highlight the importance of coordinating OVC programs with other efforts to address the needs of other age subset populations such as newborns, infants, and toddlers and school-age children. (OGAC, 2009g).

TABLE 7-2 PEPFAR Age Categories for Programs for Orphans and Vulnerable Children

Age	Stage
<2 years	Infancy
2–4	Early Childhood/Toddler
5–11	Middle Childhood
12–17	Late Childhood/Adolescence

SOURCE: (OGAC, 2006a).

PEPFAR's OVC programming guidance identifies important elements of a child and adolescent wellbeing in seven core areas that are based on the principles of the "Framework for the Protection, Care, and Support of Orphans and Vulnerable Children Living in a World with HIV and AIDS" (OGAC, 2006a). These core areas of intervention, described in more detail below, include food and nutritional support, shelter and care, protection, health care, psychosocial support, education and vocational training, and economic opportunity and/or strengthening. PEPFAR also supports linkages of OVC programs and the children and families they serve with PMTCT, palliative care, and treatment (OGAC, 2009c). Further, PEPFAR-supported activities under OVC programs include not only services that directly support orphans and vulnerable children and adolescents but also those that support their caregivers, families, and community members (OGAC, 2009c). In addition, PEPFAR supports activities at the systems level. As emphasized in the second Five-Year Strategy, system-wide OVC program activities aim to build local, regional, and national capacity to strengthen the structures and networks that support healthy development of children. PEPFAR does this in part by helping countries to coordinate among ministries that oversee education, social welfare, and health, thus facilitating the development of policy and program responses that are comprehensive and effective in addressing the needs of orphans and vulnerable children and adolescents (OGAC, 2009g). The strategy identified goals which were "to rapidly scale up compassionate care for OVCs, to build capacity for long term sustainability of care, to advance policy initiatives with outcomes that support care for OVC and to collect strategic information to monitor and evaluate progress" (OGAC, 2009g).

[12]*Supra*., note 1 at § 301(e)(2)(B), 22 U.S.C. 104A(f)(2)(D)(ix)(III).

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Core Areas of OVC Programming

Food and nutritional support OVC programs include nutritional assessments and counseling and the provision of therapeutic or supplementary feeding and micronutrients for children infected with HIV based on national and international guidelines (OGAC, 2006a). PEPFAR's policy guidance on food and nutrition programming, which identifies children with at least one parent who is HIV-positive as one of three priority groups for food and nutrition interventions (OGAC, 2006b). PEPFAR provides food and nutritional support by linking with partners that are not specifically focused on HIV, such as the USAID Food for Peace program[13], the United Nations World Food Program, and programs in partner countries (OGAC, 2006b). To capture information on activities that relate to this cross-cutting issue, PEPFAR's FY 2010 COP Guidance introduced new budget codes for food and nutrition commodities, policy, tools, and service delivery (OGAC, 2009a, 2009c). Currently, however, OGAC requires only one indicator specifically related to OVC programs, which captures the number of eligible individuals under 18 years old who received food and nutrition services (OGAC, 2009e).

Shelter and care As the number of orphans and vulnerable children and adolescents is increasing globally, it is becoming increasingly necessary to enhance the capacity of the families and communities that are caring for these children. PEPFAR funds can be put toward shelter and care activities such as identifying potential caregivers prior to the death of a guardian's, tracing families, fostering, providing transitioning children with access to temporary shelter, helping child- or adolescent-headed households, increasing access to programs that incentivize adoption or the provision of foster care, and strengthening community-based and family-based models of caring for children (OGAC, 2006a).

Protection PEPFAR OVC programs that address protection of orphans and vulnerable children and adolescents may focus on interventions such as health care and social services that facilitate birth registration and identification, community-based assistance to orphans and vulnerable children who need to make inheritance claims, the removal of children from abusive situations and their placement in safe temporary or permanent living situations, and the strengthening of community structures that are responsible for monitoring and protecting orphans and vulnerable children (OGAC, 2006a).

Health care Core health care services for orphans and vulnerable children focus on the general health needs of this population, and also address the health needs of HIV-positive children and promote HIV prevention activities. OVC programs should facilitate access to primary health care for orphans and vulnerable children and are required to use age-specific health requirements and interventions (OGAC, 2006a). Health interventions for OVC include referrals to child health care, the provision of support for abuse survivors, caregiver trainings on monitoring children's health, and building the capacity of public and private health providers (OGAC, 2006a). PEPFAR OVC programs provide health care to HIV-positive children and HIV-exposed children by providing direct access to health providers or referrals to prevention and treatment services.

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[13]The Food for Peace program (Public Law 480, also renamed Food for Peace Act of 2008) is the primary mechanism through which the USG provides international food assistance. Title II of the Food for Peace Act, which authorizes most of the international food assistance given by the U.S., is managed by the USAID Office of Food for Peace. Implementing partners who work with USAID Peace include private voluntary organizations registered with USAID, local and international nongovernmental organizations, and the United Nations World Food Program (USAID, 2009a).

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Psychosocial support Children and adolescents suffer anxiety, fear, grief, and trauma with the illness or death of a parent, and PEPFAR programs include activities that are intended to address their psychosocial and life skills needs. PEPFAR activities to support the psychosocial well-being of orphans and vulnerable children include the provision of gender-sensitive life skills and experiential learning opportunities; the strengthening of connections between children affected by HIV/AIDS and their communities; rehabilitation for children who do not live with their families; and referral to counseling, particularly for HIV-positive children and adolescents (OGAC, 2006a).

Education and vocational training Partnerships with the education sector on national and local levels are important for ensuring that children and adolescents affected by HIV/AIDS have access to education. These partnerships include linkages with other U.S. government development programs (OGAC, 2009a). PEPFAR funding also supports activities that aim to improve access for orphans and vulnerable children to early childhood development programs, strengthen vocational training, integrate orphaned and vulnerable children into the social life of the community, and provide effective anti-stigma education. PEPFAR's efforts in this core area include interagency activities, such as the Interagency Education Steering Committee and other strategic planning activities that work toward the expansion of education programs that target children and adolescents who are living with or made vulnerable by HIV/AIDS (OGAC, 2009a).

Economic opportunity and strengthening PEPFAR programs fund economic strengthening services so that caregivers are able to tend to ill family members or receive orphaned children into the household. These activities include microfinance programs for the caregivers of orphans and vulnerable children, small-business development, and community-based asset building (OGAC, 2008a). Programs also provide orphans and vulnerable children and adolescents with training and other skills that can improve their economic opportunities in the future (OGAC, 2006a).

Effects of PEPFAR's OVC Programs

PEPFAR Indicator Data: Targets and Results

PEPFAR has few centrally reported indicators to reflect the performance of PEPFAR's OVC programs. There is one output indicator, which captures the number of children served by OVC programs; this was reported through 2009 as the number of eligible OVC served by OVC programs (OGAC, 2007b). In the Next Generation Indicators this was revised to be reported as the age disaggregated subset (<18 years old) of the number of eligible individuals provided with a minimum of one care service (OGAC, 2009d, 2009e). This indicator serves to track the overall legislative target of reaching 5 million children who are orphaned or made vulnerable due to HIV.

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TABLE 7-3 OVC Indicator Targets and Results (for Primary Direct Support) (in millions)

	Number of OVC served by OVC programs[a]						*Number of eligible children (age <18 yrs) provided with a minimum of one care service*[b]
	FY04	**FY05**	**FY06**	**FY07**	**FY08**	**FY09**	**FY10**
Actual	0.6	0.8	1.5	2.2	2.9	3.6	3.8
Target	--	0.8	1.3	1.9	2.7	3.3	3.6
% of Target	--	91	117	117	107	111	104

NOTE: [a]Results and targets correspond to OGAC indicator 8.1, direct results only. This indicator counts OVC "who are periodically monitored in all six core areas and who are receiving downstream support in three or more areas, in the relevant reporting period, that are appropriate for that child's needs and context." (OGAC, 2007b)
[b]Results and targets correspond to OGAC indicator C1.1.D.
This figure/table represents data for the 31 countries identified as the focus of this evaluation (see Chapter 2).
SOURCE: Program monitoring indicators provided by OGAC.

In the Next Generation Indicators there is also currently central reporting of the number of eligible clients who received food and/or other nutrition services, with age disaggregation. From the program monitoring data provided by OGAC, in the 31 countries that were the focus of this evaluation, in FY2010 PEPFAR provided these food/nutrition services to just under 800,000 children under 18 years of age, as well as just over 180,000 pregnant or lactating women (OGAC indicator C5.1D).

Many country programs and partners also collect additional indicators on intervention areas within OVC programs that are not routinely reported centrally. However, even with the additional data that may be available at country and program level, there are limitations to the utility of the program monitoring data for fully understanding the effects of PEPFAR's programs. The lack of unique identifiers for each participant in most PEPFAR activities constitutes a major methodological challenge. OVC programs are often offered within different settings in which eligible children and adolescents may receive multiple services. Therefore, there is a risk of a single child being counted several times by different implementing partners, thus potentially over-representing the number of children receiving services (double counting is discussed further in the section in data quality in Chapter 11 on Knowledge Management). This also makes it difficult to track the scope of services received by an individual child and to track that child through programs and services over time. As with the some of the care and treatment indicators described in chapter 6, the lack of age disaggregation by more age range subgroups within children and adolescents also makes it difficult to assess how services are distributed across the identified target age groups and developmental stages. Finally, these indicators do not reflect outcomes for the children who received services and therefore do not inform an assessment of the effectiveness or quality of PEPFAR-supported OVC programs.

PEPFAR has supported the development of tools for more in-depth assessment of children and programming for children, most notably the Child Status Index (MEASURE Evaluation, 2009). In some countries, PEPFAR has contributed to national tools or indices to assess vulnerability or to the development of national directories of available services (461-19-USG;

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272-9-USG).[14] PEPFAR has also supported the Care That Counts initiative to develop, disseminate, and implement tools to assess and improve the quality of OVC services (USAID, 2008). However, these existing tools are not designed for systematic program evaluation or for data collection across countries. To date, there has not been a routine application of tools that would generate readily accessible data to assess PEPFAR'S OVC programs systematically across programs and countries. However, there has been considerable recent progress in this area as OGAC is currently in the process of developing, piloting, and disseminating new outcome measurement tools, including manuals, protocols, templates, and training materials. These are focusing on 10-15 indicators for outcome and impact evaluation and are intended to standardize baseline and endpoints for more comparative assessments of child wellbeing and the effectiveness of PEPFAR-supported programs across programs and countries (OGAC, 2012b).

Achievements of PEPFAR's OVC Programs

Across countries visited for this evaluation, a review of Country Operational Plans and information gathered from interviewees reflected PEPFAR's support for a wide range of OVC programs and activities that spanned the core programming areas described in the OVC guidance. Interviewees noted that with its explicit focus on OVC, PEPFAR has elevated attention to and investment in meeting the needs of OVC. The initiatives that PEPFAR has supported in collaboration with partner countries on behalf of children and adolescents living with and affected by HIV have resulted in substantive improvements in the lives of OVC and even in *'saving children's lives'* (240-12- USG; 461-4-USG; 272-15-PCNGO; 240-05-PCGOV).[15] As described by an interviewee in one country,

> *'Support for orphans and vulnerable children has [positively] impacted the lives of many families and children'* (240-05-PCGOV).

Policy and systems-level effects PEPFAR has supported and guided the implementation of programs in countries that had previously lacked an infrastructure to assist children and adolescents living with or made vulnerable by HIV (461-04-USG). In addition to support of OVC programs through PEPFAR, partner country support of children and adolescents who are living with or affected by HIV is reflected by their inclusion as a population that is targeted in partner country strategic plans and policies and also in the specific duties of the relevant ministries (166-19-PCGOV; 396-21-USNGO; 272-ES). One partner country interviewee described efforts that have been made to align PEPFAR supported child and adolescent-directed HIV efforts with national government-sponsored strategic plans (166-19-PCGOV). In addition, PEPFAR team members actively participated

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[14]Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Non-country Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO

[15] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

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in national technical working groups related to children and adolescents living with or affected by HIV (166-08-USG).

In addition to supporting the overall inclusion of OVC in national strategic planning for the response to HIV, interviewees described PEPFAR's contribution in the area of policies, laws, and legal support, ranging from supporting efforts to put in place legislation for minimum standards for orphanages (587-13-USG; 331-16-USG) to programs to acquire the documentation and provide support to ensure the inheritance rights and access to social security of orphaned children (166-23-USG; 272-11-PCNGO). In another example, PEPFAR is assisting the government to develop policies to facilitate the provision of care and services for orphans in households and the community (240-03-USG).

Child protection is another area frequently mentioned by interviewees. PEPFAR was acknowledged for contributing to enacting legislation to criminalize sexual offenses, establish personnel responsible for child protection, and address issues related to child custody and guardianship, foster parenting, institutional care, and minimum standards for orphanages (587-13-USG). Another approach was to support faith-based organizations to provide support in child protection where the government's child welfare officers were underfunded and cases did not receive follow-up (461-17-PCNGO). In one country a more fundamental approach was taken, with PEPFAR supporting a project to define minimum standards for child protection (166-19-PCGOV). In another, a PEPFAR-supported partner country NGO designed a model to keep children from going into residential care by strategically building capacity and integrating early intervention, prevention, and child protection (272-11-PCNGO). Another partner's program incorporated a strategy for children to enact their own protection (272-18-PCNGO).

At the systems level, PEPFAR has also contributed to the training of providers for child services, including in some cases supporting efforts to develop accreditation systems for child care workers as a cadre and contributing to their adoption by national governments (272-ES; 116-ES; 272-11-PCNGO). Also at the systems level, despite some challenges with PEPFAR's monitoring and evaluation of OVC, several interviewees described PEPFAR as contributing to a stronger approach, more informed by evidence, to OVC programs as well as to greater capacity for measurement of programs. PEPFAR was also acknowledged for enhancing both programmatic and financial accountability and management among partner country organizations and providers for OVC programs, as well as at the level of national systems (272-ES, 272-15-PCNGO; 272-26-PCNGO; NCV-30; NCV-29).

Effects on child and adolescent wellbeing Interviewees in partner countries, including representatives of U.S. Mission Teams as well as local governmental and nongovernmental implementing partners, described achievements of PEPFAR-supported OVC programs and improvements in the lives of children. These included successfully keeping OVC in the community; improving psychosocial wellbeing, especially for HIV-positive children, through clubs and psychosocial support; improving enrollment, attendance, and performance in school; increasing application for social services and foster care grants; assisting with bereavement after the loss of a parent; improving understanding and hope leading to better treatment adherence; children becoming a voice to advocate for and educate other children, and even achieving the training and education to come back and work as OVC; education and referral of children to therapy for substance abuse; education and counseling for extended family caregivers after orphanhoood; and treatment and grant support for HIV-positive parents (272-14-PC-NGO; 240-1-USG; 636-17-PCGOV; 272-18-PC-NGO; 272-15-PC-NGO; 272-32/35-PC-NGO). In one country, local implementing partners

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stated that children now have dreams; before they were hopeless with no reason to live and now children are '*lightening up and their smiles are coming back*' (272-14-PC-NGO; 272-18-PC-NGO).

Challenges for PEPFAR's OVC Programs

Gaps in services Despite PEPFAR's achievements in increasing the attention to, investment in, and implementation of OVC programs, interviewees identified a number of areas where there remain gaps in services needed or insufficiently met needs of children and adolescents.

Food and nutrition HIV-positive children have special nutritional needs, particularly those undergoing pharmacotherapy for HIV. Dietary needs are frequently unmet due to an impaired ability to procure nutritional foods due to the poverty that some children and their family members experience (461-17-PCNGO). Organizations and agencies tend to struggle in addressing the problem of food security (272-11-PCNGO) due to funding issues and the challenges presented by widespread nutritional need. Although PEPFAR does not fund food provision (272-11-PCNGO), other implementing partners that receive Food for Peace support can and sometimes do make an effort to meet this need (331-14, USG; 331-19 & 23-USNGO). In one partner country, PEPFAR added resources to work with OVC by using Title 2 for food commodities to buy food for HIV-positive families (240-03-USG). PEPFAR OVC programs have supported household food generation, but yields have been low (461-19-USG).

Psychological counseling and psychosocial support Psychosocial services were identified as an area where services are provided but are insufficient to meet the need. When psychological support is offered, such care appears to be provided in association with large, full service OVC programs. In one country, for example, a large national program run by a faith-based organization has supported 33 OVC sites and 33,000 children through a program that offered comprehensive OVC care and support that included psychological care provided by professionals. These psychological services included bereavement support, as well as individual and group counseling (272-32,35-PCNGO). In another country a faith-based organization program that similarly served an estimated 10,000 children offered psychological support as one of four primary program areas (461-17, PCNGO). Indeed, faith-based organizations, particularly those that have mobilized the religious community, are sometimes engaged in providing a full complement of OVC services, including psychosocial support. For example, one home-based care project, with the support of religious leaders and volunteers, provided material and psychological support to children who had lost one or both parents. The project addressed personal hygiene needs and provided nutritional support, educational support, life skills training, and psychosocial and spiritual counseling. It also provided economic support for OVC guardians (240-26, PCNGO).

School support and services for out-of-school OVC Discrimination against children and adolescents living with and affected by HIV can be significant. Children who have an HIV-positive parent face the possibility of rejection from school in some settings (196-20-PCNGO) and OVC face other school challenges (331-10-PCGOV), not the least of which is poverty and social support issues, particularly for those living on their own. In order to remain in school, children incur costs related to tuition, uniforms, books, and school fees as well as transportation to and from school. OVC-directed programs may provide all or some funding, but the children are not always identified, deemed eligible, and linked with programs that can help them.

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Out-of-school children and adolescents in particular, face many challenges. One interviewee noted that *'there are lots of dropouts, both females and males, but there are not enough structured interventions to address out-of-school youth'* (272-12-USNGO). Another interviewee reported alarmingly high unemployment that *'leads to increased crime, drug and alcohol use, unintended pregnancy and gender-based violence'* (272-25-USG). According to interviewees, among the challenges were the interrelated issues of reproductive health needs and awareness, gender-based violence, alcohol and other drug use, unemployment, and vocational training.

HIV-positive adolescents in transition HIV-positive adolescents face many challenges as they navigate this developmental stage and as they ultimately face aging out of services directed toward orphans and vulnerable children, despite their continuing need for support and skills building. Interviews in partner countries provided some examples of efforts and programs to support this age group, such as high school and university based prevention programs (272-ES; 240-09-USG; 240-35, PCNGO), facilitating alternate child caregiver arrangements for children born to adolescent parents (240-35, PCNGO), programs for rural at-risk girls and boys (240-35, PCNGO), and special "youth days" at care and treatment centers (935-ES). Nonetheless, despite some positive examples, this population consistently arose from interviewees across countries as an area in need of more concerted attention. In particular, they face a dearth of age-appropriate psychological care services; a need for support for the continuation of schooling, vocational training, and services for those who are out-of-school; and a need for reproductive health information and services. For those who are living with HIV, they also need support in transitioning to adult care and treatment systems as well as knowledge and skills building related to disclosure.

Interviewees reported that many adolescent OVC would benefit from opportunities to participate in training programs for job skills and other skills for economic self-sufficiency. One interviewee commented that even affected adolescents who were able to complete their schooling still needed *'training in simple skills to at least qualify them to obtain a job'* (272-15, PCNGO). After successfully pilot-testing a vocational training program with vulnerable children, a faith-based organization in one country declared that vocational training should be a future priority since program participants had been able to *'transform themselves to be able to generate income'* (461-17, PCNGO). However, countries often lack the resources, personnel, and facilities to offer enough accessible vocational training programs to children and adolescents who might benefit from them.

Adolescents who are HIV-positive have specific needs within care and treatment programs. There are some PEPFAR-supported programs in a few countries that have developed strong adolescent components, including for example, adolescent-specific care and support programs, bi-monthly provider forums to discuss challenges in the adolescent population, and facilitation of referrals between clinics and community services (Sharer, 2012). However, comprehensive services that focus specifically on the unique needs of adolescents living with HIV are a remaining gap identified by interviewees across countries. Another specific issue for these adolescents is the transition to adult services. Adult care and treatment programs often are not geared to meet adolescents' needs. As one interviewee stated, '*the system is not designed for HIV-positive kids growing up'* and '*children will not do well at adult outpatient clinics'* (396-43, OML). This may be particularly true in specialized settings such as those in concentrated epidemics where those living with HIV since infancy or childhood are now surviving into

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adulthood, but adult care has to date focused on specific populations, such as injecting drug users. Preparing adolescents for this transition to adult HIV services is difficult, as is *'trying to decide when to transition...16 is too young, 19 is too late.'* (396-43-ML). Another challenge is that developmentally informed psychosocial support is not generally available or accessible to adolescents, and adolescents who are HIV-positive are in particular need of help to address HIV disclosure issues and developing life skills (396-43-ML; 396-42-PCGOV).

Another need faced in particular by adolescents is reproductive health services. According to interviewees, adolescent OVC face issues such as pregnancy, relationships that involve multiple concurrent partners, intergenerational or transactional sex, safe sex concerns, and a gap in school-based prevention programs (272-17-USG; 240-09-USG; 240-35-PCNGO). Adolescents in general, including those who are living with or affected by HIV, lack the reproductive health information and skills to effectively reduce their risks for sexuality-related issues. Adolescents may not have developed life skills that involve interpersonal communication with sexual partners, including HIV-related disclosure (240-35-PCNGO ;396-42-PCGOV). Adolescent girls in particular need reproductive health services (461-19-USG) and parents may not provide girls with information about reproductive health (240-35-PCNGO). As one interviewee observed, *'Teenage pregnancy rates are high which leads to more vulnerable children'* (272-32/35-PCNGO). Children and adolescents who become adults living with HIV may experience a cycle of effects with their own children. As one interviewee noted,

> *Sometimes achievements can be a challenge for the future. With a successful comprehensive package of services, patients are living longer, may get married and have children and their children may be infected or orphaned so even children of children may be affected.* (396-44, PCGOV)

Finally, aging out of OVC services was raised as a challenge that poses several issues for adolescents. One interviewee indicated that the imposition of an age limit of 18 years to qualify for PEPFAR-funded OVC services poses a barrier to those who may be in need of such support for several years beyond their 18th birthday (331-14-USG). Exiting OVC programs poses issues for the many OVCs who remain in school beyond age 18; according to one interviewee, *'There are no proper plans in place for those who exit at age 18. Most are still at school and there are no resources for them'* (272-32,35-NGO). An interviewee affiliated with a partner country NGO indicated a desire to continue to care for children who were no longer eligible for services due to PEPFAR-imposed age limits (272-18-PCNGO). This was echoed by another interviewee.

> *'[We] assist them [OVCs] officially until [they] turn 18. After that, they are still in the community and we look after them. […] Perhaps they have brothers and sisters in the program and inevitably you still try to assist them as well. Some are still in school as well. We just can't spend PEPFAR money on that. [We] try and obtain other funding and try and help them to get a job, link them to government vocational training, but it is extremely difficult.'* (272-15-PCNGO)

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Other gaps in services Several other insufficiently met needs in services for OVC were identified by interviewees, including support for income generating activities, and adequate access to care for children and adolescents, particularly for those living in poverty and those in rural areas. As described previously, interviewees across several countries emphasized a positive contribution from PEPFAR in the area of child protection. However, a number of interviewees also saw this as an area of major unmet need, seeing child protection is an under-resourced activity in the face of child rape, abuse and neglect (272-15-PCNGO; 272-11-PCNGO). Interviewees also identified concerns related to the early detection of HIV in both infants and children, which was seen as a key component to providing services through OVC programs to meet the needs of HIV-positive children (HIV testing for children is discussed in depth in Chapter 6). Another identified gap is addressing the needs of children with disabilities, who represent a particularly vulnerable population due to issues related to access, transportation, availability of assistive devices, and skills building (272-11). Finally, an area identified as receiving insufficient attention is the chronicity of care for children and adolescents living with HIV. As one interviewee stated,

> *'There are a growing number of HIV-positive children in school who have to take drugs on a daily basis and there are side effects of the drugs and there are nutritional needs. This is a key gap, not doing enough to address dealing with chronic treatment. PEPFAR could take a stronger look at children living with HIV as a core program with special needs that are now not being addressed.'* (461-17- PCNGO)

Linkages among services and settings PEPFAR guidance recommends comprehensive services designed for the individual child, but not necessarily with a single PEPFAR program providing all services. PEPFAR also emphasizes household-centered approaches that link families to other services (PMTCT, clinical care and treatment, etc.) (OGAC, 2006a; OGAC, 2009g). The reliance upon a functioning referral system poses an ongoing logistical and implementation challenge to effectively achieving comprehensive services. Some examples exist of explicit efforts to improve integration and linkages, such as a pilot of integrated care for orphans living with HIV (166-19-PCGOV), efforts to integrate care for orphans and vulnerable children 'family clinics' (116-07-USG), and efforts to better link the OVC and home-based care programs, which were described as having previously been *'separate, requiring lots of effort, especially with staff recruitment, and lots of staff making different visits for different purposes'* (587-13-USG). There is also increasing recognition in the PEPFAR program of the need to establish and support a continuum of services beginning with pregnant women and following mother infant pairs from the cascade of PMTCT and MCH care through to ensure that the child is ready for school (NCV18-USG).

Stigma and discrimination Observing that, according to an interviewee, *'vulnerable children are very poor and stigmatized'*(461-17-PCNGO), HIV-related stigma and discrimination against children and adolescents persists and remains a continuing focus of the HIV response (166-19, PCGOV). Interviewees suggested that over time the problem of stigma and discrimination has improved to some degree compared to the past (196-20-USNGO), but despite improvements, stigma and discrimination remains a problem of such magnitude that disclosure of one's HIV-positive status continues to pose significant issues for children and adolescents as well as for adults. To reduce the problem of stigma, in some cases PEPFAR has changed its service delivery focus

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from child-specific delivery, which could be stigmatizing to individual children, to a service delivery approach that is family focused or community-focused (461-19-USG). In circumstances where services generally targeted children who were living with or affected by HIV, some governments and programs reportedly avoided referencing HIV/AIDS in an effort to avoid stigma and discrimination (166-19, PCGOV).

Defining eligibility for funded services One persistent challenge associated with addressing the needs of children and adolescents living with and affected by HIV has been defining eligibility and criteria for inclusion in service provision. As interviewees in one country observed,

> *Trying to qualify children as OVC is a challenge. When you look at it, every child … counts as a "V" (vulnerable child). It is not a science and OGAC is trying to make it into a science. How do we know that the needs of HIV-positive children or exposed children are being [met]?* (461-03, USG)

> *There are many more vulnerable children than they are able to reach, and so the concern is that the programs might not be reaching the most vulnerable children.* (461-19-USG)

Another challenge is when different implementing partners in a country are using different models to identify children as *"vulnerable,"* thus using different standards to determine eligibility for services (461-19-USG). In response to data in one country indicating that only 11 percent of orphans were being reached, PEPFAR partnered with UNICEF and a partner country ministry to develop systematic criteria to identify children eligible for services (461-19-USG).

In terms of focusing resources and effort, PEPFAR and partner governments do not necessarily agree about the designation or prioritization of certain OVC populations as vulnerable or at elevated risk (240-09, USG). Another part of the challenge to determining eligibility, setting priorities, and monitoring how well the identified need is being met is the lack of population size estimates of children and adolescents living with or affected by HIV, as well as lack of information about geographical locations and the specific programs currently supporting OVC (396-39-USG, 166-19-PCGOV). A related issue raised by an interviewee was the inability of the partner country government to track OVC-directed funding; in this case the government was aware that funds were disbursed to national and international NGOs working with OVC but had received no information to facilitate the monitoring of these activities (166-19-PCGOV).

Meeting PEPFAR targets Interviewees raised several issues related to PEPFAR OVC targets including, as mentioned above regarding eligibility criteria, the need for clear criteria associated with the designation of "OVC," how to resolve the trade-off between target attainment and service quality, and the services provided to OVC that can be "counted" (461-03-USG) toward PEPFAR targets. According to one interviewee:

> *'We are chasing the numbers. We have to find a balance of achieving the target but also rendering a quality service to the OVC. Sometimes it is just the figures that make a difference. If you do not achieve the target you get 'rapped on the knuckles,' but if*

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> *you achieve the target nobody ever asks [if] you can ensure the quality of the services. We try and render quality services and also meet the targets.'* (272-15-PCNGO)

In keeping with this challenge of providing quality and meaningful services, from the perspective of one interviewee, support for children and adolescents living with and affected by HIV had amounted only to lip service and a small one-time disbursement of money (331-11-PCNGO). Another described that community based OVC care efforts have been undertaken but perceived such efforts to be *'not well structured'* (331-10-PCGOV), observing that PEPFAR had not met expectations regarding community-based care.

In addition, interviewees raised questions about the number of services a partner must provide to constitute support for OVC. One interviewee described the following interpretation issue for PEPFAR indicators for OVC Care and Support:

> *There are still areas that people do not understand, for example, OVC indicators under Care and Support. It used to be that in order to be counted as a recipient of care services, someone had to actually receive a service from that menu, but now, people have found a loophole because needs assessment is now counted as 'a service' when it previously was not. In this loophole scenario, an OVC can be assessed for needs three times and counted three times as recipient of care and support services without actually receiving any of the services for which he/she was assessed. Operational guidance for proper assessment with stricter guidance [is needed ….]. Providers really need to provide psychosocial support or nutritional counseling for OVCs or other clients.* (331-34-USNGO)

In one country, for example, interviews described *'a little bit for everyone approach'* in which three services must be provided before the effort can be counted as an OVC contribution (461-03-USG). While this may help ensure more comprehensive services for OVC, there was concern that it also may mean that partners are providing services beyond their scope of capability (272-15-PCNGO).

Capacity to sustain and expand programs to meet the needs of OVC Sustainability as an overarching issue for PEPFAR is discussed in more detail in Chapter 10, but it is worth noting here that interviewees were deeply concerned about sustainability specifically for OVC programs, viewing it as a serious challenge. As one interviewee stated,

> *'OVC-PEPFAR has done a good job of saving lives for children. With the emergency response there was no strategy for sustainability and continuing the successes is a challenge.'* (461-03-USG)

An interviewee from another country stated, *'It is going to be very difficult for OVC sites to continue providing services once PEPFAR pulls out. Some will manage but probably two thirds will not be able to continue'* (272-32,35-PCNGO). The capability of partner countries to continue

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the successes they have realized in addressing the needs of OVC, to sustain existing programs over time, and to meet the remaining gaps in services such as those described in the preceding section remains a continuing challenge and an unanswered question in the face of expected future reduction or cessation of donor support (272-3235-PCNGO; 461-04-USG). Moreover, addressing the needs of *all* children and adolescents living with and affected by HIV in partner countries remains an elusive goal. Despite involvement in a *'very old, mature epidemic,'* for example, one country reportedly had achieved only limited coverage for children and adolescents living with and affected by HIV (934-10-PCGOV). From the perspective of an interviewee from the government, a need exists to ultimately *'increase attention on the younger age group and move towards an AIDS free generation'* (934-07-PCGOV).

Funding for OVC services and training remains a challenge, particularly in terms of the available financial resources to meet the magnitude of need, the timeliness of funding received, and the inability of partner governments to track funded services. Although it is *'difficult to turn a child away that needs OVC support because there is not enough funding'* (331-19-USNGO), PEPFAR funding is limited and the magnitude of need on the part of children and adolescents often outstrips the financial resources that are available (461-19-USG). Limited resources have led some programs to reduce program eligibility by narrowing their inclusion criteria for OVC services (396-39-USG). In addition to insufficient funding, delays in funding can have negative consequences for affected children and adolescents. A consequence of funding delays for educational support, for instance, is that children and adolescents must remain home from school and thus risk getting behind in their schoolwork (331-19- USNGO).

In the face of declining or absent donor funding, interviewees also voiced great concern about the continuing need to support not only children and adolescents living with and affected by HIV but also their caregivers and families. The situation is problematic at the present time, let alone in the face of anticipated resource cuts. One interviewee, for instance, described success with the training of OVC caregivers in income generation that enables them to build skills and knowledge about starting and managing a small business. An absence of startup funds after the training, however, derails any ability to start their own business (467-17-PCNGO).

In addition, the toll that HIV has taken on families in these partner countries is reflected in the outcome associated with the eventual loss of grandparent caregivers:

> *There is going to be a big gap when an older generation dies, because there are places where the middle generation (30-50 year olds) doesn't exist anymore or have HIV and will not be there to care for their children. This will lead to child-headed households. They need to concentrate on children. This needs to be a priority for PEPFAR.* (272-32,35-PCNGO)

Funding presents a fundamental problem and funding sources have yet to be identified if PEPFAR, its implementing partners, and other donors depart. Some programs will continue to be supported by the faith-based organizations with which they are presently affiliated, though they will need *'a sustainable structure to hold them together and good leadership'* (272-32,35-PCNGO). A suggested sustainability strategy to ensure the ongoing care of children and adolescents living with and affected by HIV that an interviewee offered entailed continuing efforts to build the capacity of local organizations, especially *'the best organizations or community-based organizations, so that they can take care of the families, continue providing services to these*

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children.' (934-05-USG). Someone else offered the admonition to try to do *'more economic empowerment'* so that families will be able to sustain their efforts (461-19-USG). Yet another individual suggested the possibility of opportunities for sustaining services to this population by bridging to the welfare system. (396-39-USG). In the end, a need exists for *'creative ways to address this issue'* (934-07-PCGOV).

> *Transitioning to sustainability of the response has just started ('take-off point'). It needs time. The United States needs to talk explicitly with [partner country] government[s] about an exit strategy.* (461-19-USG)

Effectiveness of PEPFAR's OVC Programs: Reviews of Existing Evaluations

Three recent reviews of PEPFAR OVC program evaluations have used available data to determine which activities and services are most effective in improving the well-being of children affected by HIV/AIDS. Scherr and Zoll synthesized the findings of 18 evaluations that surveyed a total of 22 OVC programs in 9 countries (Kenya, Tanzania, Uganda, Mozambique, Rwanda, Namibia, Zambia, South Africa, and Haiti) (Sherr and Zoll, 2011). Bryant et al. reviewed findings from 5 studies, four effectiveness studies of OVC programs in Zambia, Namibia, South Africa, Tanzania, and Kenya and one baseline data collection study for new OVC programs in Mozambique (Bryant et al., 2012). A third review of existing program evaluations was part of a multi-faceted USAID PEPFAR OVC portfolio review that included background data and literature review, analysis of data from surveys received from USG staff in 17 partner countries and OVC Task Force staff in 3 countries, and interviews with various stakeholders in 3 countries (Malawi, Tanzania, and South Africa) (Yates et al., 2011).

It was clear from these three reviews that the available pool of program evaluations is not comprehensive enough to lead to strong conclusions about effectiveness of PEPFAR OVC programs. In the Sherr et al. review, only eight evaluations used some form of comparison design. There was little, if any, baseline data to use to determine PEPFAR's impact on OVC well-being, in part due to PEPFAR's initial emergency response status with little focus on pre-trial data collection. There was also a lack of clear outcome and impact indicators, which hinders program evaluation. Nonetheless, despite these limitations, the three reviews taken together provide some consistent data across evaluations to indicate the effectiveness of several OVC program elements (Bryant et al., 2012; Sherr and Zoll, 2011; Yates et al., 2011).

The reviews of Bryant et al. and Sherr et al. both found positive effects on OVC well-being from at least three specific program elements: Support for school fees, child-centered clubs for females, and savings and loans programs. Support for school fees was found to have a positive effect on educational outcomes, such as school attendance and children's psychosocial outlook, though nonfinancial support such as books and supplies did not show any effects. The USAID review also concluded that keeping children in school is one measure clearly shown to have long-lasting positive effects on OVC well-being. However, the Bryant review stated some concern that these outcomes will not be long lasting and will not continue once external support stops. Government subsidization of school fees was noted as one way of continuing to support OVC educational outcomes as external donors cut back (Bryant et al., 2012; Sherr and Zoll, 2011).

Child-centered clubs were also found to have positive outcomes if they were well-organized with frequent activities and meetings. The reviews concluded that club support had

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consistently positive impacts on confidence and health attitudes of girls, while results of the impact on boys were not clear. Clubs that were poorly organized with insufficiently trained staff did not have any measurable effect, and evaluations of activities focused on providing psychosocial support outside of children's clubs showed inconclusive results (Bryant et al., 2012; Sherr and Zoll, 2011).

Economic strengthening in the form of savings and loan programs was also the subject of several evaluations, and the reviews concluded that these programs lead to increased engagement in income generating activities. The review by Sherr et al. found that caregiver access to local savings and loan schemes led to better outcomes for OVC by positively affecting health, nutrition, education, shelter, and psychosocial wellbeing. The evaluations in Bryant et al.'s review, however, did not show conclusive evidence of the positive impacts on broader development goals beyond increased engagement in economic strengthening activities. They suggested that this could be due in part to the fact that households with OVC are often very poor and thus often cannot invest enough to have substantial returns in the long run. Other avenues of economic support could thus supplement savings and loan programs for more effective results. The USAID review recommended that one way of strengthening families and supporting OVC well-being is through social services such as free or subsidized schooling and health care, and Bryant et al. similarly suggested cash transfers between the government and households for health, food, and nutrition (Bryant et al., 2012; Sherr and Zoll, 2011).

The evaluations reviewed by Sherr et al. also showed positive effects of other interventions: Consistent food supplements were seen to have a positive impact on nutrition in OVC household; consistent home visits and health education led to increased HIV testing and better ARV adherence; guardian group therapy reduced reports of child abuse and helped family relations, as did legal help in the form of birth certificates and will preparation; and shelter improvement improved OVC standards of living. The evaluations reviewed by Bryant et al. had inconclusive findings in these areas. In addition to the interventions already described, the USAID review added that good maternal and young child health programs have had some of the most cost-effective and positive results, and suggested that early childhood development be a focus of future programming (Bryant et al., 2012; Sherr and Zoll, 2011).

Finally, from the USAID PEPFAR OVC portfolio review it can be concluded that PEPFAR has been a forerunner in OVC programming, leading the way in terms of financing, capacity building, and human resources development for OVC well-being (Yates et al., 2011).

Evolution of PEPFAR's OVC Programs: Updated Programmatic Guidance

In July 2012, OGAC released new program guidance for OVC programs (OGAC, 2012a). The new guidance was released too late for this evaluation to assess its implementation process or its effects, but a review of the guidance document does serve as a reflection of the intended future directions of PEPFAR-supported OVC programs. Many of the recommendations around strategies and interventions in this guidance build on the 2006 guidance. However, there are a few key changes in the new guidance summarized here.

The guidance defines eligibility for OVC programs by stating that "intended beneficiaries of PEPFAR programs include 'Children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects'" (OGAC, 2012a), p.20). Ages 0-17 years old still is the *de facto* programmatic eligibility age range, but PEPFAR recognizes in the guidance that "the period of transition from adolescence to adulthood is critical" (OGAC,

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2012a), p.21) and does not specify a timeline for transitioning children from OVC programs. Further it recommends that a "young person who turns 18 while receiving OVC assistance should not be terminated from receiving assistance; rather, from the outset, programs should plan for appropriate transition strategies and be prepared to cover a buffer period for seamless transition" (OGAC, 2012a), p.21).

The core areas of intervention recommended in the guidance are re-organized by the following technical sectors: education, psychosocial care and support, household economic strengthening, social protection, health and nutrition, child protection, legal protection, and capacity building. Further, the guidance emphasizes the continuum of the response to address lifetime needs of OVC populations, and PEPFAR recommends the integration of OVC programs with HIV prevention, care, and treatment. The new guidance is based on the ecological model for child development, with a primary strategy of strengthening parents, caregivers, and families, rather than a child-focused approach, as well as setting OVC programs within coordinated systems of community- and facility-based services and providers.

In the new guidance PEPFAR also specifies that it does not require that programs provide a minimum package of services. Many programs understood the prior guidance to require that individual programs are required to provide a minimum package of services; which OGAC recognized may have led to NGOs providing services that were not their strengths, leading to challenges delivering quality services.

The new guidance also emphasizes the need to prioritize interventions. PEPFAR cannot address all needs, so programs need to identify what activities and interventions are most urgent and will have the biggest impact. The guidance does not prescribe priorities, but does provide illustrative guidance on prioritization of interventions relative to different scenarios of the epidemic. The guidance also provides a compendium of best practices.

In addition, country and community ownership is an important element in the new guidance, with a push for local community-based organizations and nongovernmental organizations to take on the role of prime partners, while still recognizing the role of larger partner organizations in helping implement programs. Other models to support smaller local partners include umbrella organizations and the use of private firms for financial administration and oversight.

Finally, the new guidance recommends that 10 percent of the OVC portfolio budget at the country level is allocated for M&E, in a manner to be determined by the Mission Team. The guidance emphasizes the need to support both innovation in OVC programming and evaluation of OVC programs. As described previously, in addition to the new OVC programming guidance, PEPFAR has also recently spearheaded an effort to develop, field test, and pilot methods for program evaluation to disseminate and implement in OVC programs.

PEPFAR'S PROGRAMS AND CHILD SURVIVAL

HIV programs, such as those implemented through PEPFAR, have the potential to reduce under-five mortality (Bourne et al., 2009; Ndirangu et al., 2010), and to contribute to Millennium Development Goal 4 (to reduce child mortality, and in particular to achieve a 2/3 reduction in the under-5 mortality rate between 1990 and 2015). The most direct programs that can be expected to affect child mortality are those for the prevention of maternal to child transmission and those for the successful identification and treatment of infected infants. In addition to these pathways, which were summarized previously in this chapter and discussed in more detail in chapters 5 and

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6, programs implemented through PEPFAR also plausibly contribute to child survival through the OVC programs described in this chapter when they result in improved access to and quality of non-HIV health services (such as well-child visits, immunizations, nutrition) and other nonclinical services. Finally, PEPFAR also conceivably contributes to child survival by averting orphanhood through reduced adult mortality and maintaining the health of parents through improved availability and coverage of ART and other care and support services; this positive effect on their caregivers is linked to the health and wellbeing of children (Mermin et al., 2008; Stover et al., 2008; UNAIDS, 2008; UNAIDS and WHO, 2009).

Although these are plausible pathways to reducing child mortality at the level of individual children, there are major limitations to directly assessing the effects of PEPFAR programs on overall population mortality in children. Cause-specific mortality is not often well-documented in children, but even the best estimates show that HIV/AIDS is only one of many contributors to child mortality, and in many countries it is not the leading cause of death in children. Even in countries where HIV is a leading cause, the rates of deaths due to HIV are often low enough that it would be unrealistic to expect to see a large discernible effect at the population level in many countries. Therefore, the committee was not able to draw definitive conclusions about the direct effects of PEPFAR on child mortality rates.

However, the committee did look descriptively at trends in estimated child mortality due to all causes and due to AIDS using data modeling AIDS deaths from HIV prevalence and prevention and treatment coverage (Liu et al., 2012). The committee selected the subset of nine PEPFAR countries where 15 percent or more of the child deaths were attributed to AIDS in 2000, before the initiation of PEPFAR, and in which it was therefore more likely to be able to discern an effect on estimated AIDs deaths. Of these countries, five were original focus countries when PEPFAR was initiated (Botswana; South Africa; Namibia; Zambia; Kenya) and four were not focus countries but did have some USG investment in HIV programs (Zimbabwe; Lesotho; Swaziland; Malawi). These four have become COP countries since the PEPFAR reauthorization in 2008.

The committee examined the trends in estimated child mortality in these nine countries from 2000 to 2010 using data from the Child Health Epidemiology Reference Group (CHERG), shown in Figure 7-2 (Liu et al., 2012). In all of these nine countries, the child mortality rates followed a downward trend in both all-cause and AIDS-specific deaths, with several showing relatively large declines during the time period after PEPFAR was initiated or scaled up. In most of these countries, the AIDS deaths and all-cause child deaths tracked downward in similar paths, suggesting that declines in AIDS death are contributing to the decline in overall child mortality, although it is not feasible to draw a causal inference and AIDS is not likely to be the sole contributor to the decline. In some exceptions, there is less consistency between the two. In Malawi, the all-cause deaths decreased more than the AIDS-specific deaths. In Zambia, an initial decline in all-cause deaths shifted to rise again more recently, while AIDS deaths continued to decline. This suggests that changes in overall child mortality may have been driven more by declines in causes of death other than AIDS, as is the case in most other countries examined in the CHERG analysis (Liu et al., 2012).

In all of these countries, PEPFAR has supported the activities and interventions described previously that could reasonably be expected to have contributed to improving child survival during the time period in which, for most of the countries, both overall child mortality and AIDS-specific child morality have trended downward. However, it is not feasible to draw

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conclusions that causally link these factors to the mortality trends described here, and it is not feasible to determine an attribution to PEPFAR investments in programs and services.

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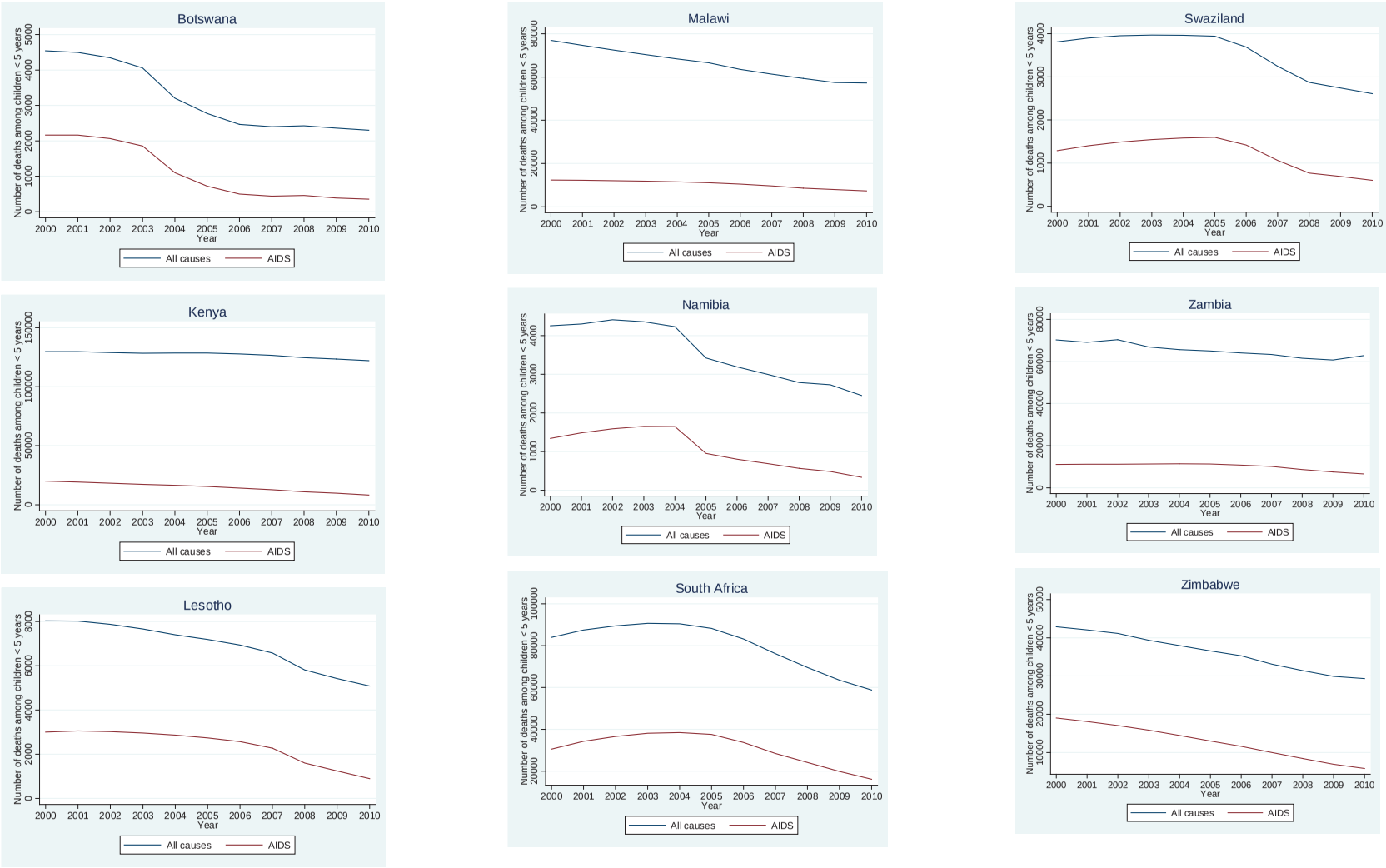

FIGURE 7-2 All-cause and AIDS deaths for children under 5 in select high-child-mortality-burden PEPFAR countries.
SOURCE: (Liu et al., 2012). Used with permission.

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SUMMATION

Conclusion: PEPFAR has positively affected the lives of children and adolescents living with or affected by HIV. PEPFAR has contributed to major scale up of services (OVC, pediatric care and support, pediatric treatment, and PMTCT) across delivery settings (facility-based, home-based, community-based, family support). With its explicit focus on orphans and vulnerable children, PEPFAR has elevated attention to and investment in meeting the needs of this population through programs and services that are informed by evidence. PEPFAR has also been instrumental in facilitating partner country consideration and adoption of policies, laws, and guidelines on behalf of children and adolescents, including OVC policies and frameworks, policies for pediatric testing and treatment, and efforts to strengthen legislation and enforcement for child protection.

Conclusion: Despite progress, there remain insufficiently met needs for the health and wellbeing of children and adolescents. Although it is not realistic to expect PEPFAR to meet all the need for children and adolescents in partner countries, there are particular areas where PEPFAR could strive to address these needs more fully. In particular, there remain gaps in coverage for PMTCT relative to PEPFAR's 85 percent goal; coverage of pediatric HIV care and treatment remains proportionally much lower than coverage for adults, despite the goal in the reauthorization legislation to provide care and treatment services in partner countries to children in proportion to their percentage within the HIV-positive population; and OVC programs struggle to adequately meet the needs of adolescents in particular. Across program areas, there is also a need to plan for long term sustainability of services and to build the capability of partner countries to continue the successes they have realized in addressing the needs of children and adolescents living with or affected by HIV.

Conclusion: The ability to assess the impact of PEPFAR-supported programs for children and adolescents is restricted by limitations in the available data. There are data insufficiencies in three key areas directly related to PEPFAR programs: disaggregation by both sex and age, with age subgroupings (for example, less than 1 year, 1-5 years, 6-17 years), to better understand what populations are receiving what services; baseline and longitudinal data to follow children and families and the effects of the services they receive over time; and data on effectiveness and outcomes to help identify the most effective PEPFAR OVC programs and models. In addition, there is a lack of data about the total population of children "in need," in part due to a lack of clarity and consistency both across countries and across programs within countries in how the population eligible for PEPFAR-supported services is defined (i.e. which children are defined as "vulnerable" or "affected by HIV").

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Recommendation 7-1: To improve the implementation and assessment of nonclinical care and support programs for adults[16] and children, including programs for orphans and vulnerable children, the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.

Further considerations for implementing this recommendation:

- For orphans and vulnerable children, the new OVC guidance and the ongoing developments for program evaluation already represent advances in addressing some of the challenges identified in this evaluation; this recommendation and considerations are intended to reinforce and further inform and support progress in achieving PEPFAR's goals for children and adolescents.
- Outcomes for consideration should be linked to the aims of OVC programs, and therefore could include, for example, increased rates of staying in school, decreased excessive labor, reduced rates of exposure to further traumas, increased immunization completion, and increased coverage of HIV testing and treatment. In continuing to focus on supporting developmentally-informed programs, consideration should be given to identifying appropriate core outcomes for different age groups and for achieving developmental milestones. The program evaluation indicators currently being developed already offer a reasonable opportunity to link measures to core target outcomes for OVC programs.
- The core key outcomes should also include quality of services and measures to reflect the potential sustainability of programs.
- To enable a shift to a more outcomes-oriented implementation model, partner countries will need support to define their prioritized outcomes and their target population and then conduct baseline assessments so that progress toward outcomes can be measured.
- PEPFAR U.S. Mission Teams should work with partner country stakeholders and implementers to assess country-specific needs and select a subset of the core key outcomes to focus on when planning, selecting, and developing evidence-informed activities and programs for implementation
- Prioritization is critical in the context of large need and finite resources. Planning with partner countries, PEPFAR should improve targeted coverage and quality of supported services for affected children and adolescents by not only prioritizing outcomes and activities but also by more explicitly, clearly, and narrowly defining the eligibility for PEPFAR-supported services. This prioritization should be based on an assessment of country-specific needs with a process that consistently applies considerations and criteria across countries and programs. This prioritization should be done in coordination across program areas that address the needs and vulnerabilities of children and adolescents. These areas, which may

[16] The discussion of nonclinical care and support for adults leading to this aspect of this recommendation can be found in Chapter 6.

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target and serve a broader eligible population of children and adolescents than is determined for specific OVC programs, include care and treatment, PMTCT, other prevention services, and gender programs.

- To improve the targeted coverage and sustainability for children and adolescents, PEPFAR and its implementing partners should continue to enhance services through existing systems and infrastructure and support national governments to expand social support services and the workforce to meet the health, education, and psychosocial needs of affected children and adolescents.
- OGAC should provide general guidance for country programs on continuous program evaluation and quality improvement to measure and monitor achievement of the key outcomes. This may include, for example, template evaluation plans and methodological guidance. To allow for comparability across countries and programs, evaluation plans should include (but not be limited to) the defined indicators or other measures of the core key outcomes. Evaluations should emphasize the use of in-country local expertise (e.g., local implementing partners/subpartners and local academic institutions) to enhance capacity building and contribute to country ownership. See also recommendations for PEPFAR's Knowledge Management in Chapter 11.
- PEPFAR should develop a system for active dissemination and sharing of evaluation outcomes and best practices both within and across countries that is driven as much by country-identified needs for information as by opportunities for exchange of information identified by headquarters-level leadership and Technical Working Groups. See also recommendations for PEPFAR's Knowledge Management in Chapter 11.

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8

Gender

Main Messages

- The scope and framing of PEPFAR's gender-focused efforts have evolved from a focus primarily on the HIV-related needs and vulnerabilities of women and girls to an expanded focus that aims to also address the vulnerabilities of men and boys (including men who have sex with men) that arise as a result of social and cultural norms about gender and sexuality. PEPFAR's efforts have also been scaled up over time from initial pilot programs to more central initiatives and country programming, with more financial and human resources devoted to them. This evolution is occurring in the context of a range of societal, cultural, economic, and other factors that affect gender norms in the countries in which PEPFAR is operating.
- The available data on differences between enrollment of women and men in antiretroviral therapy across countries indicate that there has been a successful scale-up of HIV treatment services for women as well as for men. Along with this success, both men and women continue to encounter barriers to accessing services. Men tend to have poorer health outcomes, in part due to enrollment in ART with later-stage illness.
- PEPFAR has placed a strong emphasis on addressing gender-based violence prevention and services. Continuing this focus is critical to changing one of the most important underlying structural drivers of vulnerability in the HIV epidemic.
- Over time PEPFAR has increasingly supported policy, data collection, and programming efforts for men who have sex with men that vary by country context and local need and are informed by available evidence. PEPFAR has only recently codified this support in programmatic guidance. Men who have sex with men continue to struggle with barriers to accessing care and treatment services and remain an important population at elevated risk for prevention programming. In addition, a more holistic and integrated approach to activities for men who have sex with men could be used in future programming given that their needs and challenges cut across the continuum of HIV-related services.
- There are currently insufficient mechanisms and data to give either OGAC or country programs an adequate assessment of the effectiveness of gender-focused programming and its impact on societal norms and health disparities. There is a need for PEPFAR to develop an adequate approach, through both the program monitoring system and a coordinated effort of periodic evaluation and other activities, to adequately assess what efforts are being implemented and the outcomes of these efforts across the full range of its programmatic portfolio for gender-focused activities.

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Overall Conclusion

- As PEPFAR's gender efforts have evolved and expanded, there have been positive effects of these efforts. However, the approach for how PEPFAR engages with gender-related factors that influence the HIV epidemic and response has been ad hoc. Although PEPFAR has articulated its framing of gender vulnerabilities and inequities and its overarching aims in its Gender and HIV Factsheet, it has not articulated the objectives that would need to be met in order to achieve those aims or the outcomes that would reflect success in these efforts. In addition, it does not provide guidance on intervention effectiveness or on approaches to establishing priorities for gender-focused efforts in different country settings and to developing strategic country-specific portfolios. Activities supported by PEPFAR central initiatives and through country operational planning vary widely in type and intensity of focus across the articulated gender aims and the populations that are addressed.

Recommendation Presented in This Chapter

Recommendation 8-1: To achieve PEPFAR's stated aim of addressing gender norms and inequities as a way to reduce HIV risk and increase access to HIV services, the Office of the U.S. Global AIDS Coordinator (OGAC) should develop and clearly state objectives and desired outcomes for gender-focused efforts. OGAC should issue guidance for how to operationalize, implement, monitor, and evaluate activities and interventions to achieve these objectives.

Further considerations for implementation of this recommendation:

- The objectives and guidance should be informed by the available evidence on how gender dynamics influence both HIV outcomes and the implementation of activities and services as well as by evidence on intervention effectiveness from the existing knowledge base, expert consultation, and experiences from pilot programs in partner countries.
- OGAC's guidance on gender-focused efforts should encompass programs specific to addressing gender norms and inequities and efforts to incorporate gender-focused objectives within prevention, care, and treatment activities.
- The development of guidance for gender-focused efforts should take advantage of lessons learned from the processes used for PEPFAR's recent updates to its guidance for prevention and OVC programs.
- PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to strategically plan, select, develop, implement, and measure evidence-informed activities and programs to achieve the gender-focused objectives.
- Strategic implementation of gender-focused efforts will require strong technical leadership, and as such additional capacity in gender expertise will be needed at both the OGAC and U.S. mission team levels. If gender efforts are to be appropriately integrated into all the aspects of service delivery and effectively implemented, this capacity cannot be limited to gender-specific experts but should also be incorporated as part of the core competencies of mission team staff across PEPFAR's programmatic areas.
- As an engaged participant with other global and partner country stakeholders, through its implementation PEPFAR should contribute to generating evidence to inform gender-focused efforts through research and evaluation. (See also recommendations for PEPFAR's knowledge management in Chapter 11).

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8

Gender

INTRODUCTION

The congressional charge for this evaluation, as laid out in the Lantos-Hyde Act of 2008,[1] requested that the Institute of Medicine (IOM), as part of its overall evaluation of PEPFAR, conduct an assessment of "efforts to address gender-specific aspects of HIV/AIDS, including gender-related constraints to accessing services and addressing underlying social and economic vulnerabilities of women and men."[2] In response to this charge, this chapter begins with a brief background discussion of gender-related aspects of the HIV epidemic and response before presenting the committee's assessment of PEPFAR's efforts towards its stated aim of addressing gender norms and inequities as a way to reduce HIV risk and increase access to HIV services.

The chapter reflects PEPFAR's articulated gender strategy with discussions of the main gender-focused programming areas: equity in access to services, addressing gender norms, reducing gender-based violence, and increasing women's access to economic resources and legal protections. This is followed by an assessment of PEPFAR's activities for men who have sex with men (MSM); although these activities are organized under PEPFAR's prevention portfolio, they must inherently be implemented in the context of cultural norms related to gender and sexuality and the resulting stigma and discrimination, which partly underlie the increased risk for HIV and barriers to accessing services experienced by this population. Finally, the chapter offers the committee's conclusions and recommendation for improving PEPFAR's gender-related efforts.

BACKGROUND

The AIDS epidemic always has been defined in part by issues of sex and gender. In the context of HIV, which remains primarily a sexually transmitted infection, sexual identity and sexual practices overlay sex and gender to influence how and which individuals and populations are affected. Fundamentally, then, HIV transmission, acquisition, and disease progression are

[1] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008), §101(c), 22 U.S.C. 7611(c)(1).
[2] *Ibid*., §101(c), 22 U.S.C. 7611(c)(2)(B)(iii).

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simultaneously affected by physiological, behavioral, and social realities related to sex and gender which must be understood and addressed as part of the AIDS response in order to optimize prevention, treatment, care, and support efforts for women and men alike.

Before the chapter presents the committee's assessment of PEPFAR's gender-related efforts, this section provides a very brief overview of some key factors in the interplay of sex and gender with the HIV epidemic and response, focusing on the areas of HIV transmission and acquisition, access to services, gender-based violence, and structural factors (e.g., social, economic, and political factors). These factors underlie the recognition by the public health community and PEPFAR, of the need to plan and implement programs from the perspective of gender as a social organizing principle for the creation of vulnerability; such an understanding of vulnerability must include the cultural and community norms and institutions that reflect and reinforce beliefs and practices that affect gender-associated differences in HIV risks and outcomes. This background section focuses primarily on the factors that influence differences between men and women; a subsequent section of this chapter provides a more in-depth background discussion on the factors affecting men who have sex with men in the HIV epidemic and response.

While "sex" and "gender" are often contested terms, *sex* is generally understood to mean the biological and physiological characteristics that define males and females, while *gender* is generally understood to mean the socially constructed roles, expectations, behaviors, and attributes that are ascribed to males and females in various cultures. As WHO notes, "aspects of sex will not vary substantially between different human societies, while aspects of gender may vary greatly" (WHO, 2012). However, for many issues related to the HIV response, this distinction between sex and gender becomes blurred. For example, as described below, there are purely biological contributors to the differences between men and women in HIV infection risk and health outcomes, and, in general, epidemiological and clinical measures tend to be referred to in terms of sex differences. However, as will also be discussed below, differences in the risk infection and in clinical outcomes from care and treatment are often influenced as much by social and cultural factors as by biological factors. For purposes of simplicity, in this chapter, rather than broker specific decisions about when to use the term "sex" and when to use "gender," the committee has chosen to have a low threshold for use of the term gender to refer to distinguishing between men and women for most issues discussed, recognizing that this choice does not apply to discussions of some specific populations, particularly transgendered persons.

HIV Prevalence, Transmission, and Acquisition

Globally, about half of all people living with HIV are women, and women continue to account for a disproportionate share of HIV-positive individuals in most key PEPFAR regions, making up an estimated 59 percent of people living with HIV in sub-Saharan Africa and 53 percent of people living with HIV in the Caribbean (WHO, 2011). There are exceptions to this however, as in Eastern Europe where the epidemic is driven by injection drug use and where men experience the greatest burden of disease and in other settings with concentrated epidemics where HIV has disproportionately affected men who have sex with men (WHO, 2011).

There are biological factors that facilitate a higher rate of HIV transmission from men to women than from women to men during heterosexual vaginal sex (Karim et al., 2010), and a variety of social and cultural factors also contribute to gender differences in vulnerability to HIV infection. As documented in the literature and also emphasized by interviewees during the committee's evaluation, cultural norms influence power dynamics between male and female

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sexual partners, frequently limiting women's abilities to negotiate safer sex practices such as condom use or enabling older men to engage in relationships with younger girls (116-24-USNGO; 240-06-USNGO; 272-16-PCNGO) (International Council of AIDS Service Organizations (ICASO), 2007).[3] On average, women become HIV infected five to seven years younger than men, which contributes to significant sex disparities in adolescent HIV infection rates; in sub-Saharan Africa this is driven in part by intergenerational relationships (Karim et al., 2010). Vulnerabilities associated with gender-based violence are also critical for understanding differential risks of HIV acquisition in women and men; these are discussed later in the chapter.

Access to HIV Services and Other Health Services

Access to and utilization of health services have important consequences for HIV-related outcomes, and can be influenced by gender-associated factors. However, limited data is available at the global level regarding the rates of access to HIV and other health services for women and men, especially for non-pregnant women. Some resources do provide this information at the country level, but the types of services measured and quality of data varies substantially by country and year (ICF International, 2012). Interviewees across countries identified access to health care as a challenge that was influenced by many varied cultural gender norms. Examples of challenges facing women included low health-seeking behaviors leading to less utilization of maternal care (240-19-USACA) and concern that for some services women were not comfortable using the same facilities as men (396-31-PCGOV). Women's lack of access to income also leads to increased vulnerability in many countries, as their ability to pay for transportation or user fees may limit their access to HIV care and treatment (Karim et al., 2010). In several countries interviewees also described gender-related barriers that prevented men from using health services, such as the accepted masculine norm that going to a health facility is a sign of weakness or is unnecessary (636; 272; 166; 461; 272-12-USNGO); one interviewee observed that '*men essentially do not go to health centers unless they are dying*'[4] (166-5-USG). Gender-related differences in enrollment in HIV care and treatment and in retention and outcomes are discussed briefly here and more detail in Chapter 6, Care and Treatment.

Gender-Based Violence

Sexual and physical violence and HIV risk are intricately linked. By some estimates women who are HIV positive are up to three times more likely to have ever experienced violence than women who are HIV negative (UN Trust Fund to End Violence Against Women, 2012). While, as noted above, the risk of HIV transmission during heterosexual vaginal sex is greater for women than for men (Karim et al., 2010), sexual violence can lead to female genital trauma,

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[3] Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Non-country Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO.

[4] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

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which can further increase a woman's risk of HIV acquisition (UN Trust Fund to End Violence Against Women, 2012). The fear of violence can lead to intimidation and make women less able to negotiate condom use or other safer sex practices (Dunkle et al., 2004; Jewkes et al., 2003; UN Trust Fund to End Violence Against Women, 2012). A study published by the World Health Organization in 2005 found that, on average, between 13 percent and 26 percent of women had experienced at least one episode of "severe" violence (defined as violence that is highly likely to cause injury), and between 10 percent and 50 percent of women reported having experienced sexual abuse, including having been forced to have sex against their will (WHO, 2005). One of the most common forms of violence against women is violence perpetrated by an intimate partner. Rates of intimate partner violence vary greatly across developing countries, as do the factors influencing the likelihood of experiencing violence (Hindin et al., 2008). In a 2008 analysis of Demographic and Health Survey data, younger age of women at marriage and men's alcohol use were found to significantly increase the rate of intimate partner violence in the majority of countries for which data were available (Hindin et al., 2008). Men and boys also experience physical and sexual partner violence and sexual abuse (Whetten et al., 2011); however, the data on these violence rates and health outcomes are more limited than those for women and girls.

Interviewees also spoke of the challenges related to gender-based violence, including harassment and sexual coercion (240-22- PCNGO; 587-05- PCGOV; 636-02- USG; 272-17- USG); gender-based violence was specifically identified as one of the '*underpinnings of the epidemic*' (272-17- USG). For example, women's inability to negotiate the use of condoms in relationships where they experience intimate partner violence was described as both a social challenge and a contributor to HIV transmission (461-01-USG; 934-07- PCGOV). In one country an interviewee noted, '*There is an expectation that girls would not say no to an older man and that men can be forceful if they want within the relationship*' (636- 02-USG). In addition, sexual violence against children has created further vulnerability within programs for orphans and vulnerable children (OVC) (587-21-PCNGO). Interviewees in several countries described the existence of legislation related to gender-based violence (331-19-USNGO; 587-5-PCGOV; 166-17-USG; 166-19-PCGOV; 272-17-USG; 636-6-USG 934-7-PCGOV); however, in general, where laws and policies existed related to gender vulnerabilities, interviewees reported that these laws and policies were not effectively implemented (240-22-PCNGO; 196-10-PCGOV; 196-23-USNGO; 636-6-USG; 166-17-USG; 272-17-USG; 461-18-USG; 934-7-PCGOV).

Structural Factors

Multiple studies have demonstrated the link between social, economic, political, and environmental elements, also called *structural factors*, and risks related to HIV (Coates et al., 2008; Gupta et al., 2008), and many of the inequities and barriers caused by structural factors are rooted in gender norms, such as a lack of access to education and income opportunities, the lack of legal protection, initiation rites for young girls and boys, and social norms that affect the power dynamics in sexual relationships. Data gathered during country site visits reinforced the important role that some of these structural factors play in the HIV epidemic. More broadly, interviewees in several countries identified discriminatory attitudes toward women and their roles in society as a challenge (240-6-USNGO; 331-9-PCNGO; 166-19-PCGOV; 636-2-USG): *"The message to women is to be quiet"* (331-9-PCNGO). As one interviewee stated:

> *"The decision making is quite low. They can't decide on anything. You'll be surprised to get to a village and find that some women*

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> *are taking treatment without their husband's knowing. And that makes it very much difficult for them; it's quite a problem."* (636-11-PCNGO)

Interviewees also described a contrast between cultural expectations related to women and their emerging role in professional and political environments, noting that despite the growing accomplishments of women, power differences continued to favor men (636-2-USG; 396-12-USG). There was an emphasis on the need to approach social norms not just by targeting women, but also by engaging men; this was exemplified by one interviewee's comment that '*women are not disempowered because of women, they are disempowered because of men*' (272-12-USNGO).

The recognition of the important role that structural factors play in HIV-related vulnerability has led to the development of interventions targeted to this area, especially in the field of HIV prevention (Gupta et al., 2008). Such interventions typically aim to create an enabling environment that will allow individuals to act in their own and their partners' best interests by effecting policy or legal changes, shifting harmful social norms through interventions targeting both men and women, catalyzing social and political change, and empowering communities and groups (Auerbach, 2009; Gupta et al., 2008). For example, in the IMAGE study which was a community randomized trial in South Africa, an intervention combining micro-credit, education, and community mobilization effectively reduced intra-partner violence, although the intervention was not effective in directly reducing HIV acquisition among women (Pronyk et al., 2006). A World Bank study in Malawi reported that a conditional cash transfer intervention resulted in a decrease in HIV and herpes simplex virus prevalence among young women (Baird et al., 2012). Examples of interventions to increase access to housing for HIV-positive persons, effect policy change regarding access to HIV prevention services, and empower community members at elevated risk of HIV have also been successfully implemented in developing countries, leading to reductions in HIV transmission (Gupta et al., 2008). These and other studies have contributed to the evidence that social and structural interventions can reduce the social determinants of HIV risk among women and girls (e.g., gender-based violence and economic dependence), sexual risk behaviors, and the rate of HIV infection.

PEPFAR'S APPROACH TO GENDER

Overview

Legislation and Strategy

The U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 highlighted the disproportionate impact that HIV/AIDS has had on women both as patients and as caregivers for those infected and affected by HIV. The legislation tasked PEPFAR with incorporating a focus on women into its planning, programming, and reporting. It required the establishment of and reporting on multiple strategies specifically aimed at addressing elements that could improve the lives of women living with or at risk of acquiring HIV.[5] These strategies

[5] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P. L. 108-25, 108th Cong., 1st sess. (May 27, 2003).

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included creating programs to educate women and girls about the spread of HIV/AIDS as well as developing specific strategies to:

- "meet the unique needs of women, including the empowerment of women in interpersonal situations, young people and children, including those orphaned by HIV/AIDS and those who are victims of the sex trade, rape, sexual abuse, assault, and exploitation"
- "encourage men to be responsible in their sexual behavior, child rearing and to respect women including the reduction of sexual violence and coercion"
- "increase women's access to employment opportunities, income, productive resources, and microfinance programs"[6]

In its second County Operational Plan Guidance PEPFAR listed five strategic areas to address the effects of gender norms on HIV: (1) increasing equity in services access, (2) addressing male norms, (3) reducing gender-based violence, (4) increasing women's access to economic resources, and (5) increasing women's legal rights and protections (OGAC, 2004b).

The 2008 reauthorization legislation reaffirmed the important role of addressing gender as a part of PEPFAR's HIV response, but it broadened the scope of PEPFAR in this area considerably. The legislation not only tasked the program to address gender-based violence and structural elements that contribute to the vulnerability of women and girls, but it also charged the program to develop a plan that addresses "the local factors that may put men and boys at elevated risk of contracting or transmitting HIV."[7] In addition, PEPFAR was directed to provide "clear guidance to field missions to integrate gender across prevention, care, and treatment programs."[8] Neither the authorizing nor the reauthorizing legislations, nor any of the subsequent guiding documents for gender-focused efforts, has laid out the sorts of programmatic targets or goals for gender that exist for PEPFAR's prevention, treatment, care, or OVC programmatic areas.

Thus, in the reauthorization legislation PEPFAR's original directive to focus on women was expanded to incorporate the needs of men made vulnerable as a result of gender norms. PEPFAR has recently defined gender and its relationship to the HIV epidemic in the following way:

> Gender—refers to the attributes, constraints and opportunities associated with being a man and a woman. The social definition and expectations of what it means to be a man or a woman varies across cultures and varies over time. The transformation of gender-related power dynamics is a key guiding principle of the PEPFAR gender program framework. Differences in power between and among men and women are evident within couples, families, and communities and in their relationships with the healthcare system and other stakeholders and institutions. Gender influences individuals' status within society, roles, norms, behavior, and access to resources—all of which influence dynamics of the HIV/AIDS epidemic and the success of programs to address it (OGAC, 2011d, p. 203).

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[6] *Ibid.*, §101(b)(3)(E-F).
[7] *Supra.*, note 1 at §101(a), 22 U.S.C. 7611(a)(21)(A).
[8] *Supra.*, note 1 at §101(a), 22 U.S.C. 7611(a)(20)(C).

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Consistent with this, the 2012 update to PEPFAR's Gender and HIV Factsheet rearticulates the original five strategic areas and also captures PEPFAR's more recent evolution to emphasize the gender expectations that affect HIV-related vulnerability and outcomes for men and boys. The 2012 update also emphasizes the reality that "gender norms around masculinity and sexuality also put men who have sex with men (MSM) at increased risk for HIV by creating additional stigma and discrimination that can prevent them from seeking and accessing services" (OGAC, 2012, p. 1).

Finally, it is noteworthy that PEPFAR's gender-focused programming has also been affected by its participation in the U.S. Global Health Initiative (GHI), announced in 2009 (US Global Health Initiative (GHI), 2010), which promotes a focus on women, girls, and gender equality within U.S. health and development programs. PEPFAR's second Five-Year Strategy, covering 2009–2013, contained an appendix outlining the incorporation of the GHI principles into PEPFAR activities (OGAC, 2009d) and reiterated the central role of the existing five-strategies approach. The document enumerated four new areas of increased focus for gender: (1) increasing partner government commitment for gender equity, (2) ensuring access through linkages with other non-HIV gender programming, (3) operationalizing gender principles within PEPFAR and country programs, and (4) improving monitoring and evaluation of gender activities (OGAC, 2009d).

Guidance

PEPFAR does not issue programmatic guidance specific to gender efforts. Its Gender and HIV Factsheet provides an overview of PEPFAR's aims, with some examples of activities (OGAC, 2012). Instructions to mission teams related to tracking gender efforts are provided as part of the annual Country Operational Plan (COP) guidance; these documents may also include information on how to implement gender activities, although this has varied over the history of PEPFAR, from negligible references to gender activities in FY 2004-FY 2006 to gradual increases in the acknowledgement and emphasis of the role of gender as an implementation consideration within the overarching programmatic areas of prevention, treatment, care, and strengthening health systems. In 2012, OGAC released a compilation of technical considerations in addition to its annual COP guidance that provided illustrative examples of gender-related activities that could be incorporated into country portfolios (OGAC, 2011d). However, neither the Factsheet nor the operational guidance provide information to country programs on how to select effective interventions and integration strategies, set priorities, develop strategic portfolios, or monitor and evaluate gender-focused efforts. Figure 8-1 summarizes how gender has been incorporated into PEPFAR guidance documents over the years.

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2003	2004	2005		2006	2007	2008
COP Guidance	**First Five-Year Strategy**	**COP Guidance**	**ABC Guidance #1**	**COP Guidance**	**COP Guidance**	**COP Guidance**
Women are mentioned only as targets for PMTCT services.	Gender inequality is noted within prevention as fueling the HIV epidemic and increasing women and girls vulnerability. GBV is highlighted.	The five-part gender approach is introduced as a key legislative activity for tracking. The description of potential policy activities includes gender.	The elevated risk of acquiring HIV for women and MSM is noted. Activities that address the specific needs of women and "vulnerable" populations are encouraged.	The five-part gender approach is included as a key legislative activity for tracking. The description of potential policy activities includes gender. Transgendered persons are introduced as a target population.	The five-part gender approach is included as a key legislative activity for tracking. The overlap between prevention activities and gender is noted. The description of potential policy activities includes gender.	Gender is described as a program priority area and the five-part gender approach is reiterated for tracking. The overlap between prevention, treatment, care, HSS, and policy activities and GBV is noted.

2009		2010	2011			2012
Second Five-Year Strategy (including annexes)	**COP Guidance**	**COP Guidance**	**COP Guidance and Appendices**	**Guidance for the Prevention of Sexually Transmitted HIV Infections**	**Combination Prevention for Men Who Have Sex with Men**	**COP Guidance and Appendices (including technical considerations)**
Addressing gender issues and providing services for vulnerable women are strongly emphasized within prevention. PEPFAR's contribution to the GHI is outlined describing how it will proceed with a women- and girls-centered approach.	Gender is described as a program priority area. For the first time countries are instructed to write a programmatic area narrative for activities addressing the five-part gender approach. The overlap between prevention, treatment, care, HSS, and policy activities and GBV is noted.	Gender mainstreaming and the five-part approach are described as program policy considerations and are identified as a key area for linking with other health and development programs. GBV is highlighted as a cross-cutting budget attribution.	Integrating a women- and girls-centered approach is defined as one of the core principles of the GHI, and addressing gender issues is described as a key program priority area. The five-part gender approach is reiterated and gender-based violence is highlighted.	Gender is emphasized as an essential contextual element for consideration across prevention interventions. Addressing gender equality and GBV are defined and highlighted as an available structural prevention approach. MSM are only mentioned as a population at elevated risk.	This is the first and only guidance document released to specifically address activities for MSM. It focuses on prevention and includes elements on stigma and discrimination and living with dignity.	The technical considerations that accompany COP Guidance include multiple lists of illustrative gender activities, broken down by program area.

FIGURE 8-1 Inclusion of gender in PEPFAR guidance documents over time, 2003-2012.
NOTE: Descriptions have been summarized for space considerations. COP = country operational plan; GBV = Gender-based violence; GHI = Global Health Initiative; HSS = health systems strengthening; MSM = men who have sex with men; PMTCT = prevention of mother-to-child transmission.
SOURCES: (OGAC, 2003, 2004a, c, 2005a, c, 2006b, 2007b, 2008b, 2009b, d, 2010b, 2011a, c, d, e).

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In addition to the different forms of guidance released by OGAC summarized in Figure 8-1, the U.S. Agency for International Development (USAID) has recently issued technical documents focused on the integration of gender strategies into HIV programs for populations at elevated risk (USAID, 2011c) and on integrating multiple PEPFAR gender strategies to improve HIV interventions (USAID, 2011b), as well as a compendium of gender programs in Africa (USAID, 2009). The publications support the expansion of the scope of gender-related activities within PEPFAR and provide some recommendations for programming. USAID has also released specific policy guidance on Gender Equality and Female Empowerment (USAID, 2012a). The policy aims to guide the integration of gender equality and female empowerment into USAID's existing work. Three outcomes goals are highlighted: reducing gender disparities in access to, control over, and benefit from resources, wealth, opportunities, and services; reducing gender-based violence and mitigating its harmful effects on individuals and communities; and increasing the capability of women and girls to realize their rights, determine their life outcomes, and influence decision making in households, communities, and societies (USAID, 2012a).

Operational Approaches

There are several operational approaches that PEPFAR uses to implement its gender programming. PEPFAR channels central funding into programs designed to address a specific gender-related component of HIV risk. Through this mechanism, PEPFAR has supported multiple gender central initiatives and, more recently, public–private partnerships, addressing either male norms or sexual and gender-based violence; these are described in greater detail in the relevant sections below. In addition there are gender-focused activities articulated as part of the country operational planning process that are managed by staff on the mission teams. In addition to managing PEPFAR-supported activities, interviewees in several countries noted that PEPFAR mission team members or implementing partners have worked directly to engage the national government or local organizations on topics related to gender; this work has included, for example, serving on or supporting national technical working groups (240-24-USG; 331-22-PCNGO; 196-18-PCNGO; 166-8-USG). In most countries there are not designated technical staff for gender, however, two country programs now have gender advisors as a part of their mission team. In support of all of these activities, one individual serves in the role of gender technical advisor at OGAC. PEPFAR also works closely with other U.S. development assistance efforts related to gender, such as the USAID Office of Gender Equality and Women's Empowerment and the State Department Office of Global Women's Issues (NCV-10-USG).

The following sections present the committee's limited assessment of PEPFAR's gender-focused efforts in the different areas articulated in PEPFAR's five-part gender strategy: equity in access to HIV services, gender norms, gender-based violence, and women's access to income generation and legal protection. Most of this assessment is focused on an understanding of the activities that PEPFAR has supported and, in some cases, the effects of those activities documented through published evaluations and the interview data collected for this evaluation. Given the limited availability of data, the committee was unable to determine whether PEPFAR's activities have had an impact on outcomes related to the aims laid out in PEPFAR's gender strategy.

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PEPFAR's Efforts to Address Equity in Access to HIV Services

There are few specific activities specified in PEPFAR's gender strategies that are designed to address inequity in service access, and PEPFAR's gender documents do not articulate what standards might be applied to define equitable access. Interviewees in multiple countries described outreach efforts to increase the utilization of health services; most of these were aimed at women, although as described, previously cultural norms also affect men's seeking of health services, and PEPFAR has also supported some efforts in this regard.

Interviewees stated that PEPFAR has increased women's access to health services (331-9-PCNGO; 636-6-USG; 396-21-USG; 240-13-PCGOV; 240-2-USG). These health services include HIV treatment, including antiretroviral therapy (ART) (240-2-USG; 240-15-USG), HIV testing (240-24-USG), antenatal care, and increased access to and integration of family planning services, which is further discussed in the services integration section of the service delivery building block in the health systems strengthening chapter (Chapter 9). Examples of mechanisms used to increase access included reducing fees for antiretroviral drugs (240-02-USG), increasing the number of female health workers through the development of a community health worker cadre (240-13-PCGOV), better integrating prevention of mother-to-child transmission (PMTCT) programs with other women's health needs and social services (587-5-PCGOV; 166-19-PCGOV), and creating mother-in-law groups to help support women who choose to go for treatment (636-11-PCNGO). However, women seeking services still face access challenges (240-13-PCGOV; 542-16-PCGOV; 331-5-ML; 272-14-PCNGO; 396-37-USNGO), and participants pointed to family planning and cervical cancer screening as existing gaps in service availability (587-3-USG; 272-20-PCNGO; 396-12-USG; 542-16-PCGOV).

Increasing coverage and utilization rates of PMTCT services is also an important component of PEPFAR's gender work because antenatal clinics are not only the entry point for many women into the health care system but are also where counseling and testing frequently occurs. PMTCT services should thus serve as an entry point not only for the prevention of vertical transmission but also into HIV care and treatment, including antiretroviral therapy, for the mother who is HIV-positive. A detailed discussion on service access successes and challenges specifically associated with PMTCT and linkages to care and treatment for women can be found in Chapter 5, Prevention as well as in Chapter 6, Care and Treatment.

Programmatic data from Track 1.0 partners[9] provided by the U.S. Centers for Disease Control and Prevention (CDC) indicate that the proportion of individuals newly enrolled in antiretroviral therapy was consistently at about 65 percent female and 35 percent male from 2005 to 2011.[10] These data represent the subset of patients enrolled during this time period in HIV care and treatment programs supported through four large PEPFAR implementing partners. The data are aggregated from programs in 13 countries and thus are not matched to country-specific information on the relative disease burden between men and women in these settings; they are also not matched to estimates of the need for antiretroviral therapy in men and women, which vary by country. However, given that women make up an estimated 59 percent of people living with HIV in sub-Saharan Africa (WHO, 2011), these treatment enrollment figures are broadly in

[9] Track 1.0 Partners in this report refers to four partners that were the primary large-scale implementers of ART in PEPFAR's centrally funded Track 1.0 program (for more information, see Appendix C, Methods). These partners also implemented other HIV services and programs, and there were also other centrally funded Track 1.0 partners in other program areas.

[10] The presentation of these data and a more comprehensive discussion can be found in Chapter 6, Care and Treatment. Additional information on data requests and the methods used by the committee can be found in Appendix C.

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line with the disparity of HIV infection rates between men and women in the largest generalized epidemics and the key PEPFAR-supported regions where these implementing partners are operating. Thus, within the limitations of interpreting this aggregated subset of the total population served by PEPFAR, the data do provide a sense that PEPFAR-supported provision of treatment services reflect the disproportionate burden experienced by women and that PEPFAR is supporting access to care and treatment programs for women.

Indeed, the programmatic data from Track 1.0 partners provided by CDC show that health care for men lags behind in these programs; men enter treatment at later stages of disease progression and have worse outcomes on average after starting ART regimens. One contributor to this discrepancy in health outcomes may be the influence of social-cultural norms that affect how men access and interact with the health system. Interviewees in multiple countries visited expressed an awareness of these challenges for men and indicated a goal of addressing them (636-6-USG; 272-12-USNGO; 461-17-PCNGO; 166-5-USG). As one interviewee noted, '*There is a bias towards women that PEPFAR is trying to balance, which is explained through the prevalence data that shows women are more vulnerable to HIV infection*' (636-6-USG). PEPFAR, through its implementing partners, has supported such activities as offering mobile counseling and testing and other services for men (272-12-USNGO; 461-17-PCNGO), providing technical assistance to train community workers to conduct health promotion services with men (272-12-USNGO), campaigns to encourage men to go for counseling and testing (166-5-USG), and efforts to engage men who accompany women to PMTCT services (636-9-USACA). In one country an interviewee described care and treatment programs that were focused on men in order to ensure that they received ART (636-6-USG). To some extent, addressing health-seeking behavior is also a part of PEPFAR's activities to respond to this and other HIV-related challenges influenced by gender norms, which are described further in the following section.

> **Conclusion:** The available data on differences between enrollment of women and men in antiretroviral therapy across countries indicate that there has been a successful scale-up of HIV treatment services for women as well as for men. Along with this success, both men and women continue to encounter barriers to accessing services. Men tend to have poorer health outcomes, in part due to enrollment in ART with later-stage illness.

PEPFAR's Efforts to Address Gender Norms

As previously described, cultural norms concerning gender underlie HIV-related experiences (vulnerability to infection; availability, access and utilization of services; and legal and human rights protections) in all countries. These norms are variable within and across country settings and govern social institutions (family, law, religion, politics, and media) that affect HIV epidemics and the responses to them. Thus, PEPFAR —and, by extension, OGAC— has an important and delicate role to play working in local communities and with partner country governments in undertaking activities to mitigate the harmful elements of cultural norms about gender. As outlined in its five-part gender strategy, PEPFAR's activities in this area are primarily defined in terms of addressing male norms. While addressing both the positive and negative consequences of male norms has received less attention within PEPFAR than other gender-associated factors that affect the HIV epidemic and response, there are several activities in these

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areas that are ongoing in partner countries, some of which are supported centrally from OGAC headquarters.

The PEPFAR Male Norms Central Initiative lasted for three years and came to a close in 2010. It was implemented through different, independent programs in Ethiopia, Namibia, and Tanzania; all of these programs attempted to build on knowledge gained from existing PEPFAR-funded gender activities in countries such as South Africa (Pulerwitz et al., 2010b; USAID, 2012c). In 2010 an evaluation of the initiative's work in Namibian prisons failed to indentify significant changes based on a survey conducted on self-reported behaviors, but follow-up in-depth interviews found that intervention participants did perceive changes in their behaviors and an awareness of gender dynamics (Pulerwitz et al., 2010b). In Ethiopia participants receiving interactive group education combined with community engagement activities had a lower risk of HIV than those who received community engagement activities alone; they also had partners who reported positive changes in their relationships, including increased sharing of household responsibilities (Pulerwitz et al., 2010a). There is no similar outcome evaluation available for the initiative in Tanzania.

PEPFAR activities to address male norms also include country-level programming, and partner country implementers identified two primary categories of effort: changing perceptions about gender roles and responsibilities (240-06-USNGO; 166-17-USG; 166-23-USG; 934-30-USNGO; 272-12-USNGO) and increasing male involvement in existing HIV and health care services (636-11-PCNGO; 636-6-USG; 461-21-ONGO; 935-20-PCNGO), including their engagement with their partners in PMTCT (331-27-PCGOV; 587-9-USG; 636-9-USACA; 116-15-USNGO). Although a few programs were well established and had been supported by PEPFAR for several years, many of the male-norms programs were described as being in the initial stages of development, either planned for implementation or recently started. Thus, there is limited information on outcomes. However, interview data show that PEPFAR-supported efforts have led to some observable changes in gender roles related to care giving and responsibility for household chores in partner country settings (240-06-USNGO; 934-30-USNGO). Despite these gains, the relatively narrow focus of PEPFAR's activities for shaping the cultural norms of men is not sufficient to comprehensively address the dynamic ways in which gender norms interact with and influence multiple aspects of prevention, treatment, and care in the HIV response.

PEPFAR's Work on Gender-Based Violence

PEPFAR identified the unique contribution of gender-based violence (GBV) to the transmission of HIV early in its priority setting (OGAC, 2004c). The authorizing legislation for the program specifically required that the first comprehensive Five-Year strategy include information related to reducing violence and coercion experienced by women.[11] As a result, activities in this area have received a large proportion of the focus and effort within the program's five-part gender strategy. In 2010–2011, PEPFAR invested approximately $155 million in activities related to gender-based violence, which makes it one of the largest investors in this area worldwide (OGAC, 2012).

OGAC's understanding of the contribution of GBV to HIV-related outcomes is presented in Figure 8-2.

[11] *Supra.*, note 5 at §101(b)(3)(F).

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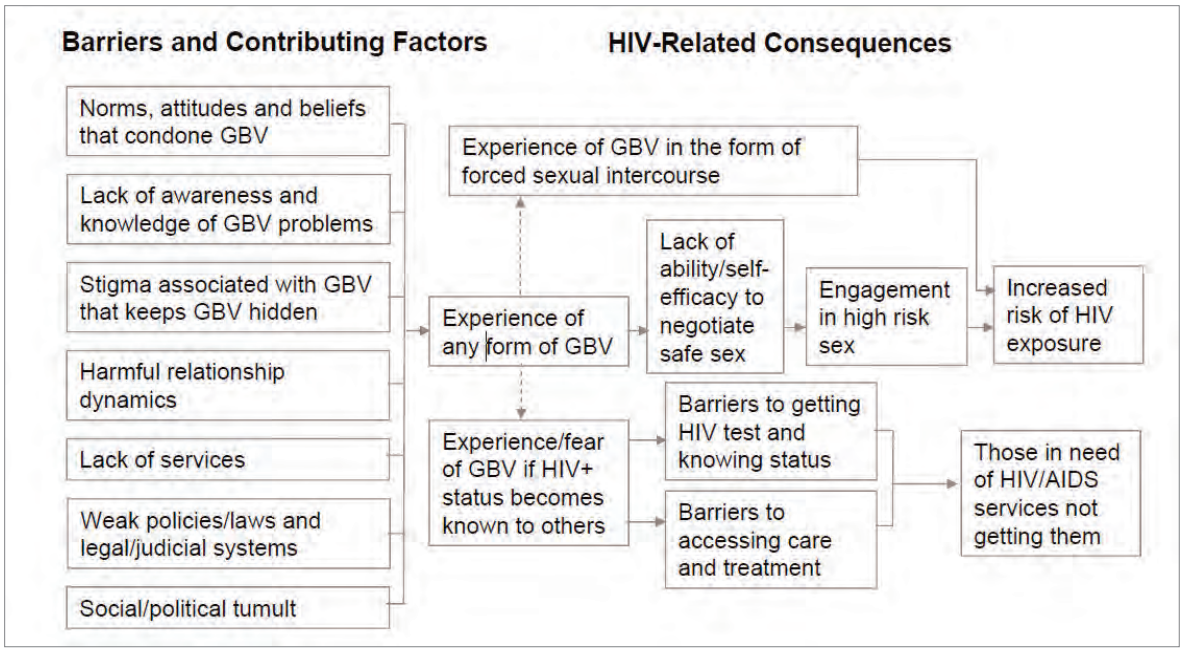

FIGURE 8-2 Gender-based violence (GBV) and HIV.
SOURCE: (USAID, 2011d).

Over time PEPFAR services to address gender-based violence have included prevention activities such as providing post-exposure prophylaxis to survivors of sexual assault and violence, behavior change communication and community mobilization, and the integration of services for survivors of gender-based violence into existing facilities or programs (OGAC, 2007b, 2008b, 2009b, 2011d). In 2006 PEPFAR released a congressionally requested report on gender-based violence and HIV/AIDS, outlining the efforts underway at the time and the progress that had been made to that point on scaling up services (OGAC, 2006c). The report was produced too early in the program to identify outcomes of gender-based violence activities, but it did provide several early benchmarks of GBV programming expansion, including as a part of country programs. The report noted that across the 15 focus countries, mission teams had identified 243 different activities that included at least one component designed to address GBV and that in FY 2005 activities that contained a GBV element represented just under one-third of all funded activities that reported addressing at least one of the five gender components (OGAC, 2006c).

PEPFAR Central Initiatives to Address Gender-Based Violence

PEPFAR also supports several central initiatives to address gender-based violence (USAID, 2012d), including one that has recently come to an end.

The Sexual and Gender-Based Violence Initiative The Sexual and Gender-Based Violence Initiative, which began in 2007 in Rwanda and Uganda, was a three-year effort to expand the available evidence base on interventions for sexual violence. The initiative highlighted the technical assistance needs of SGBV activities as well as the potential for country-to-country collaborations to be used in addressing violence. IT ultimately resulted in the development of "A Step-by-Step Guide to Strengthening Sexual Violence Services in Public Health Facilities" (Keesbury and Thompson, 2010).

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Currently PEPFAR is in the middle of scaling up three new central initiatives aimed at combating violence against women and girls, which not only continue to elevate the profile of gender-based violence efforts in PEPFAR, but also increase the available central funding available for GBV activities.

The Gender-Based Violence Response Scale-Up The Gender-Based Violence Response Scale-Up is an effort in three countries (Mozambique, Tanzania, and the Democratic Republic of the Congo) to build on existing GBV pilot programs. Within these countries the initiative attempts to provide comprehensive care to GBV victims, including post-rape services, and to support multisectoral GBV prevention efforts by working with law enforcement, education, and social services and addressing existing policy barriers within each of the three countries (OGAC, 2011b; USAID, 2011d).

The Gender Challenge Fund The Gender Challenge Fund provides matching resources from headquarters to those designated by participating mission teams in their budgets for GBV activities (OGAC, 2012). As of 2011, 15 countries had received additional funding through this program (OGAC, 2011b).

Together for Girls Together for Girls is a public–private partnership created to reduce sexual violence against girls through raising awareness of the problem and supporting increased data collection at the national level, as well as supporting policy and legal reforms for GBV at both the national and community levels (OGAC, 2011b, 2012). In the summer of 2012, in coordination with the 21st meeting of the International AIDS Society in Washington, D.C., the program announced an additional $5 million for the Together for Girls partnership (PEPFAR, 2012).

Country Program Activities to Address Gender-Based Violence

Interview participants from several countries identified multiple types of PEPFAR activities under way to address gender-based violence. These included efforts supporting female empowerment, education, and awareness (240-24-USG; 331-19-USNGO; 196-18-PCNGO; 636-06-USG; 272-17-USG; 166-17-USG); addressing alcohol use (240-24-USG); providing post-exposure prophylaxis to victims of rape (166-17-USG; 196-22-PCGOV; 935-17-USG); training healthcare workers in providing GBV services (166-17-USG); working with law enforcement (542-11-PCNGO; 166-17-PCNGO); helping women access the legal system after they have been victims of violence (166-17-PCNGO); and conducting surveys on populations with elevated risk and assessments of PEPFAR's in-country programmatic structure for gender (331-15-USG; 272-17-USG; 166-17-USG). There were also a number of GBV activities targeted at reaching men, including a "male network program" (587-21-PCNGO), a focus on male leadership and role models (636-06-USG), and a focus on partnership and addressing negative stereotypes about expected male norms in relationships with women (272-12-USNGO). While no interviewees explicitly indentified a reduction in the prevalence of gender-based violence, several described other successes resulting from PEPFAR-supported GBV programs. These included increased knowledge among women and girls regarding what to do if they experience violence (240-6-USNGO), an appreciation of the value of having a gender-based violence program as part of their portfolio (166-3-USG), and successfully increasing the availability of post-exposure prophylaxis (166-17-USG).

Conclusion: PEPFAR has placed a strong emphasis on addressing gender-based violence prevention and services. Continuing this focus is critical to changing one of the most important underlying structural drivers of vulnerability in the HIV epidemic.

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Women's Access to Income Generation and Legal Protections

The final two elements of PEPFAR's five key strategic approaches for gender are increasing women's access to income-generating activities and legal protections. These topics are important structural mechanisms to reduce women and girl's vulnerability, but they have received relatively limited attention in PEPFAR's programming over time (NCV-10-USG). However, once central initiative, while it had broader goals than just these two elements of PEPFAR's gender approach, did include an economic-strengthening component.

The Gender Special Initiative on Girls' Vulnerability to HIV (also called Go Girls!) was a 3.5-year central initiative that used a multilevel intervention approach, including mass media communication, life-skills building, training of school personnel, and economic empowerment, to reduce the risk of HIV infection among adolescent girls. The program was implemented in Botswana, Malawi, and Mozambique, and an assessment of the initiative conducted following its completion in 2011 showed that while addressing the economic needs of girls was key to reducing their vulnerability, it remains difficult to achieve in practice (USAID, 2012b).

Numerous interviewees emphasized that economic motivations and constraints are key drivers of gender imbalances. PEPFAR partners and staff described support for income-generating or employment activities for women in a number of countries visited (240-14-USPS; 196-9-USNGO; 166-27-PCNGO; 116-15-USNGO; 934-31-USNGO; 636-6-USG). Examples included supporting small-scale savings and loan programs (116-15-USNGO), supporting programs to offer vocational training for women engaged in sex work to find alternate sources of income (196-9-USNGO; 166-27-PCNGO; 935-16-USNGO), and providing life-skills training for young girls who were victims of abuse (934-31-PCNGO). In one country an interviewee described how income-generation activities at the household and village levels had resulted in positive changes in women's lives, with local women subsequently running small-scale businesses (116-15-USNGO), whereas in another country these were described as not effective (240-24-USG). There were also examples of activities designed to increase women's access to legal resources, but these were scarcer (166-27-PCNGO; 636-6-USG; 166-23-USG). Such activities included working to ensure that families understood the legal resources available to respond to sexual coercion (636-6-USG), helping young boys and girls with inheritance laws (166-23-USG), and supporting legal defense for victims of violence (166-27-PCNGO). Outside of PEPFAR's efforts to provide comprehensive services to survivors of gender-based violence, there are no central initiatives for legal protection. From the limited data available, it seemed to the committee that increasing women and girl's access to income-generating activities and legal protections are the least developed elements of PEPFAR's articulated five-part approach to gender programming.

Integration of Gender in Prevention, Care, and Treatment Programs

The previous sections have described efforts that, for the most part, seek to accomplish gender-focused outcomes through specific programs and activities that are designed to address one or more of the five aims of the gender strategy. Following the reauthorization legislation, PEPFAR has also identified an overarching aim of its gender efforts as "integrating gender throughout prevention, care, and treatment programs," with a focus on the same five aims (OGAC, 2012, p. 1). PEPFAR sometimes applies the term "mainstreaming" to efforts in partner countries to integrate gender considerations into prevention, treatment, and care activities. Some interviewees identified "mainstreaming" of gender into other programmatic areas as an element

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of their implementation approach (240-24-USG; 636-6-USG; 272-12-USNGO); one described mainstreaming as expecting '*women to benefit equally with men*' from services and that '*every technical person should be gender-sensitive*' and include gender assessments and gender concerns in proposals and programs in other technical areas (240-24-USG). However, it was difficult for the committee to make any assessment of this approach, given the difficulty of determining the specific objectives of these efforts or how they are currently operationalized within PEPFAR programs in partner countries.

Effects of PEPFAR's Gender Efforts Overall

As presented in the preceding sections on PEPFAR's gender-related work, the majority of data offered by in-country interviewees concerned inputs and activities for gender planning and programming; some limited information on the outcomes and impact of PEPFAR's gender efforts was also provided. Many of these outcomes were specific to one of the five gender focus areas articulated in PEPFAR's gender documentation, such as several positive changes in gender norms that occurred in two countries following efforts by PEPFAR implementing partners (240-6-USNGO; 934-30-USNGO), including an example where local religious leaders ceased blessing early marriages for young girls (240-24-USG), or the successful scale-up of care and treatment access and coverage for women in multiple PEPFAR countries. In addition to these focus-area-specific successes described above, interviewees in multiple countries described more cross-cutting gender outcomes, most notably an increased feeling of empowerment for women (240-6-USNGO; 116-15-USNGO; 331-9-PCNGO; 331-32-PCNGO; 636-6-USG), especially for girls (240-6-USNGO; 116-15-USNGO) as a result of participating in PEPFAR-supported programs. One implementer noted that they had '*seen changes where the girls start expressing themselves and have a vision of the future*' (240-6-USNGO), while another stated, '*Historically it has been a taboo to talk about sex. Now women can sit in a group and discuss sex issues and protection against HIV*' (636-6-USG). Finally, in several countries the positive benefits were expressed by organization staff members on behalf of the communities they served, as a result of being a part of PEPFAR's implementation across gender programming (331-22-PCNGO; 196-23-PCNGO). As one interviewee articulated:

> *'The [organization] would like to extend its appreciation to the…USG because through their support they feel as though they have been treated as humans and are able to be appreciated.'* (196-23-PCNGO)

One of the most common overarching challenges identified by interviewees was the need for longer project periods for gender initiatives in order to fully assess and address gender issues (240-24-USG; 636-6USG) and have time to see the program's effects.

Conclusion: The scope and framing of PEPFAR's gender-focused efforts have evolved from a focus primarily on the HIV-related needs and vulnerabilities of women and girls to an expanded focus that aims to also address the vulnerabilities of men and boys (including men who have sex with men) that arise as a result of social and cultural norms about gender and sexuality. PEPFAR's efforts have also been scaled up over time from initial pilot programs to more central initiatives and country programming, with more financial and human resources devoted to them. This evolution is occurring in the context of a range of societal, cultural,

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economic, and other factors that affect gender norms in the countries in which PEPFAR is operating.

MEN WHO HAVE SEX WITH MEN

Background

From the first identification and diagnosis of AIDS in the United States, men who have sex with men (MSM) have been significantly affected by the HIV epidemic. Work by Beyrer and colleagues has shown that, even where gay men and other MSM constitute a small proportion of a country's population, they bear a disproportionate burden of HIV disease. HIV prevalence for men who have sex with men is significantly higher than that of the general population in all regions of the world. In sub-Saharan Africa, approximately 18 percent of MSM are HIV-positive, compared with approximately 5 percent of the general adult population (see Figure 8-3) (Beyrer et al., 2012).

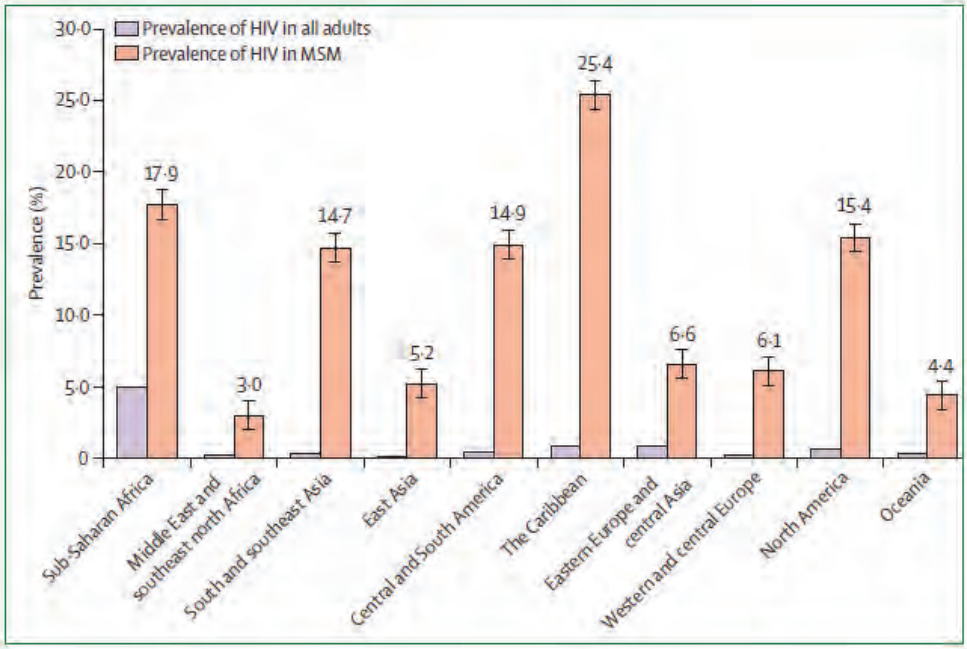

FIGURE 8-3 HIV prevalence in MSM compared to HIV prevalence in all adults in 2010. SOURCE: (Beyrer et al., 2012). Used with permission.

There are several factors that contribute to the increased rate of HIV infection in MSM. Biologically, there is an 18-fold increase in probability of HIV acquisition per sexual event through unprotected receptive anal intercourse as compared to unprotected vaginal intercourse (Grulich and Zablotska, 2010). Structurally, stigma and discrimination and criminalization of homosexuality or homosexual activity continue to prevent many MSM from accessing health services, including HIV testing, treatment, and care (AMFAR, 2010; Beyrer et al., 2012). More

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generally, from the perspective of interviewees the presence of laws that criminalized homosexuality or homosexual activity and the experience of stigma and discrimination made working with MSM a challenge in multiple PEPFAR partner countries. Criminalization contributed to fear among MSM and exacerbated stigma and discrimination. With or without criminalization, stigma was described as leading to the challenge of having '*hidden*' MSM who were difficult to reach with prevention and other efforts, and interviewees also reinforced the role of stigma and discrimination in affecting access to and the quality of health services for MSM. These issues were described as posing a similar and particularly difficult challenge for transgendered persons (196-25-PCNGO; 196-23-PCNGO; 116-28-USACA; 935-8-PCGOV; 331-22-PCNGO; 331-7-PCNGO; 331-44-USNGO; 196-9-USNGO; 396-47-USNGO). Interviewees also described cultural expectations to marry and stigma against openly identifying as MSM as factors contributing to individuals having sexual partners who are both men and women and typically do not disclose this to their female partners (272-24-USG; 196-23-PCNGO), which limits their sexual partners' knowledge of their risk of exposure to HIV.

PEPFAR Efforts Related to MSM

Guidance

While activities for MSM have been supported to varying degrees in PEPFAR countries since the beginning of the program, organized primarily through the prevention portfolios in country programs, the creation of specific programmatic guidance for this population at elevated risk is only a recent development. In 2011 PEPFAR complemented its new prevention of sexual transmission guidance with the *Technical Guidance on Combination HIV Prevention for Men who have Sex with Men* (OGAC, 2011e). Derived from the *UNAIDS Action Framework for MSM*, this document described six core components that will be supported by PEPFAR as part of a "comprehensive package of integrated HIV prevention activities for MSM and their partners" (OGAC, 2011e, p. 5).

- Community-based outreach
- Distribution of condoms and condom-compatible lubricants
- HIV counseling and testing
- Active linkage to health care and antiretroviral therapy
- Targeted information, education and communication
- Prevention, screening, and treatment for sexually-transmitted infections

The guidance also states that "PEPFAR supports efforts to further HIV prevention goals through laws, regulations and policies that improve the availability, accessibility and effectiveness of HIV prevention programs for MSM" (OGAC, 2011e, p. 9) and emphasizes the principles of equity, nondiscrimination, and confidentiality in each of the six core areas.

PEPFAR Activities and the Effects of PEPFAR's Support for Programming for MSM

There were no required PEPFAR programmatic indicators for monitoring prevention of sexual transmission efforts specifically for MSM until 2010 when, as a part of the Next Generation Indicators process, a new required measure for the number of persons reached with individual or small-group level interventions was introduced that included disaggregation by the population at elevated risk. As a result, there are no longitudinal program monitoring data on

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activities and outputs for this MSM available. However, data from semi-structured interviewees did provide insight into the types of activities supported by PEPFAR for MSM and into some of the effects of these activities.

Most countries visited identified some set of activities for MSM that are supported by PEPFAR; similar activities for transgendered persons were also described (240-9-USG; 331-07-PCNGO; 331-14-USG; 331-18-USNGO; 331-22-PCNGO; 331-32-PCNGO; 196; 166-5-USG; 196-21-PCGOV; 196-23-PCNGO; 196-25-PCNGO; 272-17-USG; 396-5-USNGO; 396-56-USNGO; 935-14-USG; 587-21-PCNGO; 542-3-USG; 461-1-USG). (The committee recognizes the distinction between MSM and transgendered persons, but PEPFAR's efforts for these populations are discussed together here due to the overlap in both the supported activities and the effects of those activities.) Participants in multiple countries identified steps that were being taken by PEPFAR to address the challenge of access to services, such as establishing a connection with a specific, trusted service provider or health facility and then making referrals directly to that provider (331-07-PCNGO; 331-22-PCNGO; 196-23-PCNGO; 196-21-PCGOV); linking facility providers with MSM-led community groups (331-44-USNGO; 196-23-PCNGO); or supporting mobile clinics (196-25-PCNGO). Multiple interviewees also described general prevention efforts for MSM as important components of their programs (240-9-USG; 331-14-USG; 331-18-USNGO; 166-5-USG; 396-5-USNGO), including activities to increase access to condoms (331-14-USG; 196-25-PCNGO), behavior change campaigns (331-14-USG; 166-5-USG), and prevention programs for male sex workers (196-25-PCNGO). Using peer educators was a common mechanism for delivering messages for MSM in PEPFAR countries. These peer educators were often also MSM, which interviewees stated both enables the educators to better connect with outreach efforts and empowers the peer educators themselves (331-07-PCNGO; 196-25-PCNGO; 587-21-PCNGO). In addition to increasing condom distribution, the goals of MSM outreach activities also included encouraging HIV testing and addressing stigma in local communities (331-07-PCNGO; 196-25-PCNGO). Civil society organizations and local NGOs are key elements in the HIV response for MSM, and PEPFAR's work with these organizations and populations in a variety of settings is an important success (AMFAR, 2010) (331-22-PCNGO; 331-32-PCNGO; 196-ES).

One major challenge noted by interviewees is that there is very little data on this population. In response to this challenge, in several countries PEPFAR has either supported or is planning to support special studies, surveillance activities, and pilot studies to obtain better population size estimates and other country-specific information on MSM (331-ES; 240-ES; 396-ES; 196-3-USG; 240-09-USG; 166-5-USG; 166-20-USG; 166-26-USG 396-09-PCGOV; 396-24-USNGO; 935-14-USG). For example, in Ghana PEPFAR partnered with the University of California, San Francisco, to support the Ghana Men's Study, and similar efforts are under consideration in Ethiopia (PEPFAR/Ethiopia, 2010; UCSF, 2012). These data collection activities, as well PEPFAR's engagement with local government and nongovernment stakeholders, were also highlighted for their important role in increasing attention to MSM in the planning and implementation of the national HIV response (240-ES; 331-14-USG; 331-27-PCGOV; 331-ES; 166-ES; 196-3-USG).

Despite notable improvements from PEPFAR's work with MSM, supporting policy progress and scaling up prevention, treatment, and care services to meet the range of HIV-related needs for this population remains an enormous unmet need. Interviewees described PEPFAR's MSM efforts as having variable coverage (542-5-USPS), and noted a rising HIV prevalence among MSM. One scale-up challenge identified by some interviewees was a divergence in the priorities of the national government and of PEPFAR (240-08-USG; 331-18-USNGO; 587-07-PCGOV; 587-12-USG), with the most common occurrence being that the country government wanted to focus on youth or the general population overall while PEPFAR mission teams and implementing partners identified and prioritized activities around populations at elevated risk, including MSM. In some cases this

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divergence was described as stemming from a lack of recognition by some in the government that MSM are present in the country (240-09-USG; 396-15-USNGO; 934-21-USG; 196-1-USG). One interviewee expressed concern for the future if PEPFAR's presence in their country diminished:

> *"[E]xpecting [the government] to pick up all of prevention particularly when it comes to target groups that have been so long stigmatized, there are still governments, parts of the provincial government partners who don't even recognize MSM, for instance. It would be much harder to expect them to suddenly do innovative programming for that group."* (396-15-USNGO)

Conclusion: Over time PEPFAR has increasingly supported policy, data collection, and programming efforts for men who have sex with men that vary by country context and local need and that are informed by available evidence. PEPFAR has only recently codified this support in programmatic guidance. Men who have sex with men continue to struggle with barriers to accessing care and treatment services and remain an important population at elevated risk for prevention programming. In addition, a more holistic and integrated approach to activities for men who have sex with men could be used in future programming, given that their needs and challenges cut across the continuum of HIV-related services.

MEASUREMENT AND EVALUATION OF GENDER EFFORTS

Tracking Gender-Focused Activities

The mechanisms that PEPFAR uses to track the implementation of activities addressing one or more elements of its gender approach have varied over time. From 2005 to 2010 gender efforts were considered a cross-cutting activity and were tracked primarily through the use of a checkbox in each Country Operational Plan (OGAC, 2004b, 2005c, 2006b, 2007b, 2008b, 2009b), though the number of activities captured through this system are no longer regularly reported publicly. In 2009, following a reorganization of the program area narratives (which had previously been tied to individual budget codes), countries were for the first time instructed to provide a program area narrative for their gender activities as a part of the supporting documentation submitted with their Country Operational Plans (OGAC, 2008c). In 2010 the gender-specific narrative was eliminated, and gender was referred to as a "key issue" tracked via a checkbox. However, mission teams were also instructed to incorporate a description of the gender-related elements of any activity that was identified as having a gender component (OGAC, 2009b). In 2011, as part of an overall effort to streamline the country operational plan document, a narrative section for the adoption of the Global Health Initiative's core principles was added, one section of which included providing greater detail on the types of gender activities underway and their expected effects related to each of the five components outlined in the gender strategy (OGAC, 2010b). These publicly available narratives provided a more organized, consistent view of country activities related to gender, although it is too early for the committee to assess if there will be any programmatic impact from their introduction. In 2012

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PEPFAR returned to a longer, more comprehensive country operational plan (intended to be submitted every two years), but the requirement to include a description of gender-specific efforts was maintained and incorporated into all technical area narratives (OGAC, 2011c). With respect to financial reporting, from FY 2004 to FY 2009 there were no budget codes specifically designed to track funding for gender-related efforts (OGAC, 2011f). However, one subcomponent of gender, gender-based violence, is currently considered one of seven "cross-cutting budget attributions" to be tracked, and estimated funding information was required to be reported to OGAC first in FY 2010 and again in FY 2012. In previous years this was referred to as a "cross-budget code," but the data were not reported centrally (OGAC, 2008b).

Program Monitoring Indicators Relevant to Gender-Focused Efforts

One component of measuring progress in gender-related efforts is program monitoring; this includes monitoring to understand the differences between men and women as well as to follow specific populations, as a part of both overall program monitoring efforts and monitoring of gender-focused programs.

PEPFAR states that it was the first international partner to disaggregate results data by sex (OGAC, 2006c), and the 2007–2008 PEPFAR program indicators included twelve measures with male/female sex disaggregation (Table 8-1) (OGAC, 2007c). These cut across the three major program areas of prevention, treatment, and care and were all intended to measure activities and outputs related to program implementation (OGAC, 2007c). In the Next Generation Indicators program monitoring guidance, five essential/reported measures require disaggregation by sex, and an additional indicator was added within prevention activities that requires disaggregation by populations at elevated risk, including men who have sex with men (OGAC, 2009c). Data with sex disaggregation are not collated centrally for annual reporting by PEPFAR to Congress in its public reporting mechanism (OGAC, 2005b, 2006a, 2007a, 2008a, 2009a, 2010a), although as described previously, a specific report on gender-based violence programs has been produced upon request (OGAC, 2006c). The indicator data that are not used for central analysis and reporting are available for use by country programs and implementing partners.

TABLE 8-1 Sex-Disaggregated Indicators Routinely Reported to OGAC

Routinely Reported Indicators, 2007	Next Generation Indicators (NGIs) – Essential/Reported
Number of individuals reached through community outreach that promotes HIV/AIDS prevention through abstinence and/or being faithful	Number of individuals who received testing and counseling services for HIV and received their test results
Number of individuals reached through community outreach that promotes HIV/AIDS prevention through abstinence	Number of eligible adults and children provided with a minimum of one care service
Number of individuals reached through community outreach that promotes HIV/AIDS prevention through other behavior change beyond abstinence and/or being faithful	Number of HIV-positive adults and children receiving a minimum of one clinical service
Total number of individuals provided with HIV-related palliative care (including TB/HIV)	Number of adults and children with advanced HIV infection newly enrolled on ART

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Routinely Reported Indicators, 2007	Next Generation Indicators (NGIs) – Essential/Reported
Total number of individuals provided with HIV-related palliative care (excluding TB/HIV)	Number of adults and children with advanced HIV infection receiving antiretroviral therapy (current)
Number of HIV-infected clients attending HIV care/treatment services that are receiving treatment for TB disease	
Number of registered TB patients who received HIV counseling, testing, and their test results at a USG-supported TB service outlet	
Number of OVC served by OVC programs	
Number of individuals who received counseling and testing for HIV and received their test results	
Number of individuals who received counseling and testing for HIV and received their test results	
Number of individuals newly initiating antiretroviral therapy during the reporting period	
Number of individuals who ever received antiretroviral therapy by the end of the reporting period	
Number of individuals receiving antiretroviral therapy at the end of the reporting period	

NOTE: ART = antiretroviral therapy; OVC = orphans and vulnerable children; TB = tuberculosis; USG = U.S. government
SOURCES: (OGAC, 2007c, 2009c).

Beyond the sex disaggregated indicators and the prevention indicator disaggregated by population, there are currently no indicators in the NGI guidance that are specific to outcomes for programs that address the five components of PEPFAR's gender approach. The guidance does include descriptions for four process indicators that are recommended but not required to be reported to OGAC (OGAC, 2009c). One effort that PEPFAR staff members have supported at the international level is the development of an indicator to track the prevalence of gender-based violence as a part of the UNAIDS biannual reporting process. Data from interviews with OGAC headquarters staff noted the contributing role that PEPFAR played through multiple iterations of indicator development (NCV-2-USG; NCV-6-USG; NCV-10-USG). This indicator will ultimately contribute to the understanding of trends in gender-based violence over time at the national level, but it is just the first step in obtaining a comprehensive global picture of the factors that contribute to gender-based violence and the resulting health outcomes, including HIV.

Perspectives from interviewees in partner countries varied on the use of and the need for PEPFAR indicators and other program data related to gender. While some interviewees cited examples of using data to track or inform gender programming (240-24-USG; 636-01-USG; 636-06-USG; 636-9-USACA; 116-1-USG; 331-43-USG), some also expressed a need for gender-specific program monitoring from PEPFAR (636-06-USG; 935-09-USG; 396-56-USNGO). Examples offered included a need to understand analytically how issues affect the sexes differently (636-6-USG) as well as the need to match their program activities by measuring changing norms, especially for young girls (935-9-USG). On the whole, interviewees indicated that sex disaggregation is not sufficient for gender program monitoring. As one interviewee noted, '*The guidance is there from OGAC, but there is a lack of indicators; this has led to gender programs being developed in an ad hoc manner*' (935-17-USG).

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The inclusion of sex disaggregation data and the participation in the development of the GBV indicator are elements of PEPFAR's response to the reauthorization legislation's mandate that the program develop a strategy that "includes specific goals and targets to address [gender] factors; …[and] sets forth gender-specific indicators to monitor progress on outcomes and impacts of gender programs."[12] However, the current program monitoring indicators are insufficient to give either partner countries or OGAC an adequate picture of the effectiveness of their gender-focused programming and its impact on societal norms and health disparities.

Beyond Program Monitoring Indicators

The programmatic reporting process may not always be the most needed or the most appropriate means of measuring and assessing gender efforts. In particular, one measurement challenge in gender-related reporting is that there is often a lack of data about the need. Without population size estimates for key subpopulations, for example, it is difficult to determine the scope of the need, to plan the scale of programming, and to assess whether the demand for services is being met. In many countries PEPFAR is, as a part of its programming, supporting a variety of one-time or follow-up surveys to provide a better estimate of the size of various populations in need of services; these are often done for specific populations, such as men who have sex with men and sex workers, as described in the previous section and in Chapter 5, Prevention. Similarly, tools beyond program monitoring may be needed for PEPFAR to appropriately and sufficiently evaluate the effectiveness and impact of its gender activities going forward.

PEPFAR has made efforts to share the lessons learned from some of its gender programming efforts. This is primarily accomplished through releasing various documents, such as the compendium of gender programs in Africa, as well as documents describing GBV, the integration of multiple PEPFAR gender strategies to improve HIV interventions, and populations at elevated HIV risk, which have been published through AIDStar-One (USAID, 2009, 2011a, b, c, d). PEPFAR also provides support for the website What Works for Women, which is a repository of information on a broad range of HIV interventions for women that is accessible to implementers worldwide (NCV-10-USG) (Gay et al., 2012).

Chapter 11 on PEPFAR's knowledge management contains a more detailed discussion of PEPFAR's reporting and evaluation elements, including a committee recommendation regarding the utility of periodic special studies to be carried out across partner countries. Gender-related special studies will be an important consideration for PEPFAR to improve its ability to assess the full range of its programmatic portfolio.

> **Conclusion:** There are currently insufficient mechanisms and data to give either OGAC or country programs an adequate assessment of the effectiveness of gender-focused programming and its impact on societal norms and health disparities. There is a need for PEPFAR to develop an adequate approach, through both the program monitoring system and a coordinated effort of periodic evaluation and other activities, to adequately assess what efforts are being implemented and the outcomes of these efforts across the full range of its programmatic portfolio for gender-focused activities.

[12] *Supra.*, note 1 at §101(a), 22 U.S.C. 7611(a)(20)(B) and (D).

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SUMMATION

PEPFAR's gender efforts have evolved from an initial focus that was primarily on the HIV-related needs and vulnerabilities of women and girls to an expanded focus that includes the vulnerabilities of men and boys (including men who have sex with men) that arise as a result of social and cultural norms about gender and sexuality. PEPFAR's efforts have also been scaled up over time from initial pilot programs to more central initiatives and country programming. There were limited data available to the committee concerning the scope, reach, effectiveness, and health impact of PEPFAR's gender work, but the committee concluded that these efforts have had positive effects. However, the approach that PEPFAR uses to address the gender-related factors that influence the HIV epidemic and response has been ad hoc. Although PEPFAR has articulated its framing of gender vulnerabilities and inequities and its overarching aims in its Gender and HIV Factsheet, it has articulated neither the objectives that would need to be met in order to achieve those aims nor the outcomes that would reflect success in these efforts. In addition, it does not provide guidance on intervention effectiveness or on approaches to establishing priorities for gender-focused efforts in different country settings and to developing strategic country-specific portfolios. Activities supported by PEPFAR central initiatives and through country operational planning vary widely in type and intensity of focus across the articulated gender aims and the populations that are addressed. Based on the findings and conclusions presented in this chapter, the committee makes the following recommendation:

Recommendation 8-1: To achieve PEPFAR's stated aim of addressing gender norms and inequities as a way to reduce HIV risk and increase access to HIV services for women and men, OGAC should develop and clearly state objectives and desired outcomes for gender-focused efforts. OGAC should issue guidance for how to operationalize, implement, monitor, and evaluate activities and interventions to achieve these objectives.

Further considerations for implementation of this recommendation:

- The objectives and guidance should be informed by the available evidence on how gender dynamics influence both HIV outcomes and the implementation of activities and services as well as by evidence on intervention effectiveness from the existing knowledge base, expert consultation, and experiences from pilot programs in partner countries.
- OGAC's guidance on gender-focused efforts should encompass programs specific to addressing gender norms and inequities and efforts to incorporate gender-focused objectives within prevention, care, and treatment activities.
- The development of guidance for gender-focused efforts should take advantage of lessons learned from the processes used for PEPFAR's recent updates to its guidance for prevention and OVC programs.
- PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to strategically plan, select, develop, implement, and measure evidence-informed activities and programs to achieve the gender-focused objectives.

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- Strategic implementation of gender-focused efforts will require strong technical leadership, and as such additional capacity in gender expertise will be needed at both the OGAC and U.S. mission team levels. If gender efforts are to be appropriately integrated into all the aspects of service delivery and effectively implemented, this capacity cannot be limited to gender-specific experts but should also be incorporated as part of the core competencies of mission team staff across PEPFAR's programmatic areas.
- As an engaged participant with other global and partner country stakeholders, through its implementation PEPFAR should contribute to generating evidence to inform gender-focused efforts through research and evaluation. (See also recommendations for PEPFAR's knowledge management in Chapter 11).

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9

Strengthening Health Systems for an Effective HIV/AIDS Response

Main Messages

- Health systems strengthening efforts were largely ad-hoc in PEPFAR I. Congressional reauthorization created opportunities for formal support of strategies in partner countries including integration of HIV services into existing country programs and systems**.** In PEPFAR II, OGAC adopted the six-building block framework articulated by WHO, around which the following main messages have been organized:

Leadership and Governance

- Many stakeholders affirmed that there is strong leadership in partner countries for the HIV/AIDS response, within both government and in nongovernmental sectors. However, in some countries there are still challenges related to governance and management capacity for the maintenance and sustainability of the HIV/AIDS response.
- Intergovernmental planning among partner country governments, other local stakeholders, and external donors is a critical activity that is needed for the current and future responses to HIV/AIDS. For the USG support for PEPFAR countries, it is the primary tool for ensuring leadership and governance, as well as a vehicle for joint planning efforts that support the principles of ownership, mutual transparency, and mutual responsibility and accountability.
- PEPFAR has increasingly provided stronger support for partner country planning and development of national frameworks, policies, and strategic plans over time. There is variable alignment or harmonization with partner country planning processes that are primarily driven by national government priorities. It is reasonable that the USG, like all donors, have its own considerations and requirements for funding decisions. Nonetheless, PEPFAR has made progress in making its considerations a part of a joint planning process rather than a displacement of country priorities.
- PEPFAR has supported training for management and leadership to build capacity for improved functioning of health systems with a variety of activities including curriculum development, mentorship, and shorter-term trainings and workshops. However, the focus and outputs of these training efforts are varied and it was difficult determine the impact of these efforts from the data currently available.
- PEPFAR's capacity building approach has been "holistic" and includes developing human resources; strengthening financial management; and building organizational capacity at national, provincial, district levels and across government, private, and civil society sectors. Despite these efforts, leadership and financial management capacity were frequently mentioned as challenges to effective HIV/AIDS responses.

Financing

- Data on partner country government expenditures for HIV/AIDS responses from National Health Accounts and National AIDS Spending Assessments for the 31 countries that are the focus of this evaluation were unavailable for many countries and years, making it difficult to examine trends in HIV/AIDS funding.
- Although there are nascent efforts in PEPFAR for costing of services and projecting of needs to help countries develop a costed HIV/AIDS response, PEPFAR has not yet systematically implemented assistance for partner countries to develop resource development plans, resource projections, costing, and identifying funding needs.

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Information Systems

- Despite initial PEPFAR-specific systems for program monitoring data, PEPFAR has worked with partner country governments to integrate and strengthen Health Information Systems, including achievements in strengthening partner country Laboratory Management Information Systems. However, ongoing support to strengthen partner country health information systems, and better alignment and integration with those systems, is needed to enhance timely data availability and quality for strategic program planning, resource allocation, and commodities procurement.

Medical Products and Technologies

- PEPFAR has improved the capacity of partner country governments to quantify, forecast, procure, store/warehouse, distribute, and track commodities; but challenges to assure consistent and reliable supply chain functioning remain in many countries. These challenges are a common issue across countries and are not PEPFAR-specific. Reliable supply chains will be critical for sustainable and cost-efficient HIV/AIDS responses and avoid disruptions to clinical care and treatment of people living with HIV/AIDS.
- PEPFAR's laboratory efforts have had a fundamental and substantial impact on laboratory capacity in countries. This laboratory infrastructure and capacity has been, and can continue to be, leveraged to improve the functioning of countries' entire health systems.

Workforce

- PEPFAR's contribution to health workforces in partner countries has over time been more appropriately directed to more pre-service production. Nonetheless, partner countries continue to have considerable need for health workforce development and retention. PEPFAR can contribute to that need by leveraging and maximizing its investments in collaborative efforts to build the capacity of health professional training schools, which would benefit the ability of countries to address not just HIV but the dual burden of infectious and non-communicable diseases that many high-burden countries increasingly face. Adherence by partner countries to the Global Code of Recruitment and follow-through on commitments to the Abuja Declaration could both support sustainability of their own health workforces and country ownership.

Service Delivery

- PEPFAR's impressive achievements in service delivery represent the success of a largely disease-specific approach, which had both positive and negative effects on partner country health systems. In some countries, an early emphasis on increasing volume of services to meet targets for service delivery resulted in vertical programming, which did not always facilitate service integration. PEPFAR has articulated the goal of increased integration of services and has had some success. Many stakeholders in partner countries have identified an interest and/or need for greater integration of HIV services into the general health system. The best practices for integrating services, such as HIV and TB, reproductive health, and primary care, need to be identified, evaluated, and scaled up.

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Recommendation Presented in This Chapter

Recommendation 9-1: To support the delivery of HIV-related services, make progress toward sustainable management of the HIV response, and contribute to other health needs, PEPFAR should continue to implement and leverage efforts that have had positive effects within partner country health systems. PEPFAR should maintain efforts in all six building blocks but have a concerted focus on areas that will be most critical for sustaining the HIV response, especially workforce, supply chain, and financing.

Further considerations for implementation of this recommendation:

- An important focus for PEPFAR's future activities and policies should be support for partner country capacity to locally produce and retain clinical, nonclinical, and management professionals whose training and scope of practice are appropriate and optimized for the tasks needed. MEPI and NEPI have provided a starting point for the training of physicians and nurses; however the training of associate clinician providers and other cadres will also be critical to sustainable management of the response. In addition, PEPFAR needs to augment its efforts to build partner country capacity to track the placement of trained workers, to promote retention, and to develop long term human resources plans (see also the discussion and recommendation for capacity building in Chapter 10 on Progress Toward a Sustainable Response).
- Building on the progress made through the public-private partnership with SCMS, PEPFAR should enhance and expand efforts with a greater focus on capacity building for accountable supply chain management in partner countries. The aim of this improved capacity should be to gradually shift to local or regional leadership, coordination, and management to ensure a reliable supply chain for essential medicines and commodities.
- Financing and leadership and governance are particularly critical for sustainable management of the HIV response; this area is addressed in Recommendation 10-1 (see Chapter 10).
- To contribute to the knowledge base for health systems strengthening, PEPFAR should include this area in its research and evaluation agenda and its knowledge dissemination efforts (see also recommendations for PEPFAR's Knowledge Management in Chapter 11).

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9

Strengthening Health Systems for an Effective HIV/AIDS Response

BACKGROUND AND CONTEXT FOR SYSTEMS DEVELOPMENT AND FUNCTIONING FOR HEALTH

A health system includes "all the organizations, institutions, and resources that are devoted to producing health actions. A health action is any effort, whether in personal health care, public health services or through intersectoral initiatives, whose primary purpose is to improve health" (WHO, 2000, p. xi). The primary objective of a health system is to improve health by achieving the best attainable average level of population health and minimizing the differences between individuals and groups. National governments are ultimately responsible for the performance of health systems and ensuring the wellbeing of their populations (WHO, 2000). To meet the ambitious goal of equitable access to health, member states of the World Health Organization (WHO) have committed to providing universal health coverage, defined as "access to key promotive, preventive, curative and rehabilitative health interventions," at an affordable cost for all members of a population (WHO Secretariat, 2005; World Health Assembly, 2005).

In the last decade, international donors (particularly high-income countries and multilateral institutions) provided more than $185 billion in development assistance for health to low- and middle-income countries (IHME, 2011). Much of this funding has been directed to programs and interventions for specific diseases (e.g., HIV/AIDS, tuberculosis, and malaria) and health focus areas (e.g., maternal and child health). Large global health initiatives such as PEPFAR, the Global Fund, and the Global Alliance for Vaccines and Immunization (GAVI) have facilitated the tremendous increase in development assistance for health, but there is concern about the effects, intended and unintended, of these initiatives on partner country health systems (Bärnighausen et al., 2012; Biesma et al., 2009; Grépin, 2012a; Levine and Oomman, 2009; Samb et al., 2009). There is widespread consensus within the global health community on the need to strengthen health systems in order to improve health outcomes and meet global targets such as universal health coverage and the health-related Millennium Development

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Goals[1] (Shakarishvili, 2009; Task Force on Global Action for Health System Strengthening, 2008; WHO, 2009). Many of the largest donors and multilateral organizations involved in global health have faced challenges scaling up services due to health systems weaknesses and have responded by supporting interventions specifically designed to strengthen components of the health system (Palen et al., 2012; Shakarishvili, 2009).

In 2007, WHO developed a framework for health systems strengthening (HSS) that identifies the following six building blocks which correspond with the essential functions of health systems to ultimately result in effective health services:

- Leadership and governance,
- Financing,
- Information,
- Medical Products, Vaccines, and Technologies (shortened to *Medical Products and Technologies* by the committee),
- Health workforce, and
- Service delivery (WHO, 2007a).

These building blocks are interdependent and the relationships between the building blocks deserve as much attention as the individual components (WHO, 2007a, 2009). Effective service delivery also critically depends on standards, guidance, and accountability mechanisms to ensure access to quality services characterized by the essential dimensions of —safety, effectiveness, integration, continuity, and people-centeredness (WHO, 2010b). The building-block framework, identified in Figure 9-1, has been adopted by the Office of the U.S. Global AIDS Coordinator (OGAC) and others stakeholders that are emphasizing prioritization, organization, and execution of activities in the essential area of strengthening health systems (Friedman et al., 2011; OGAC, 2009f).

[1] In 2000, world leaders committed to the United Nations (UN) Millennium Declaration and adopted eight Millennium Development Goals (MDGs) to reduce the most important determinants and consequences of poverty.

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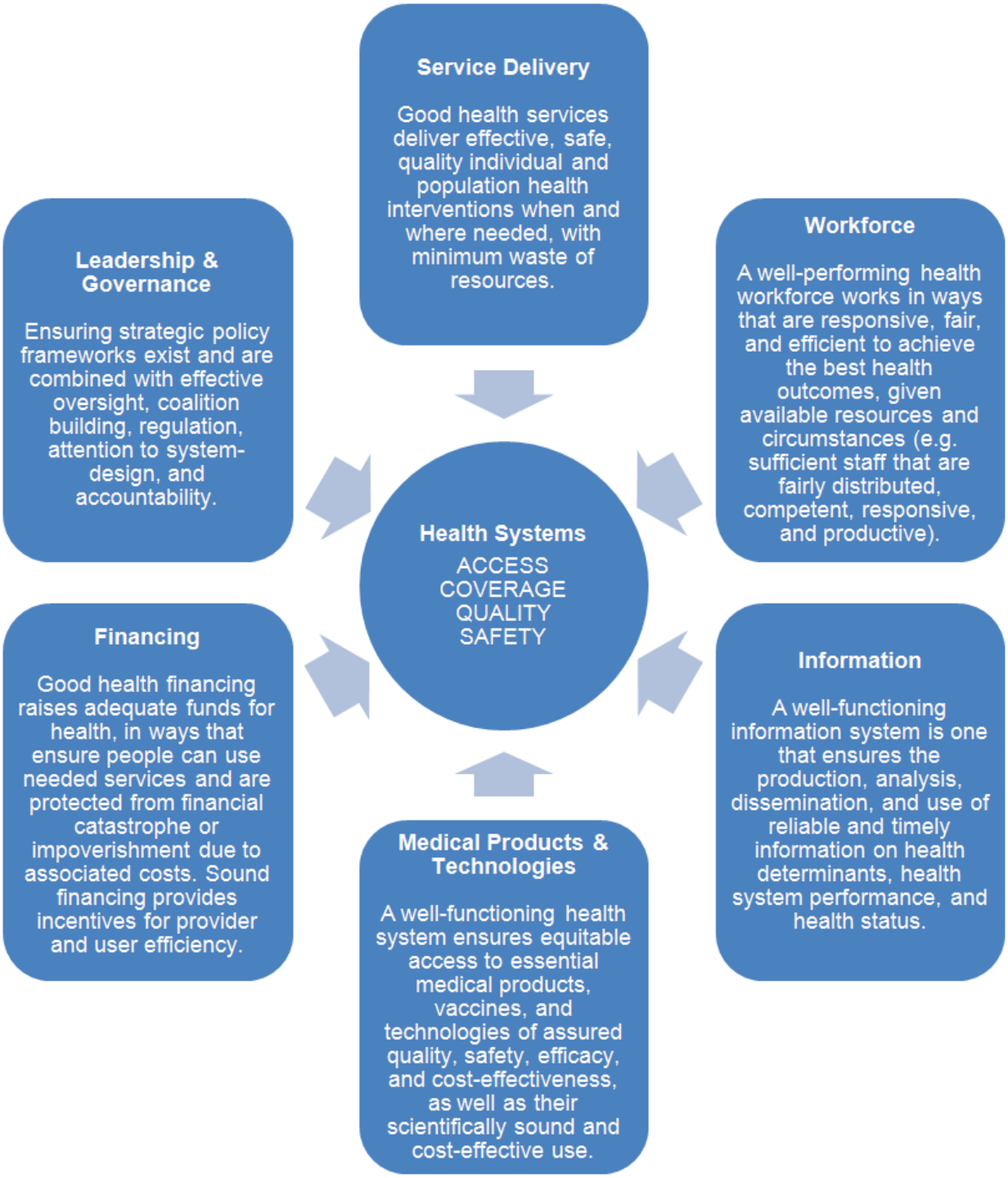

FIGURE 9-1 Representation of WHO's six building blocks for effective health systems.
SOURCE: Adapted from (IOM and NRC, 2010; WHO, 2007a).

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Large donor-funded global health initiatives interact with each building block within partner country health systems. Despite sharing the same goal — to improve health outcomes — initiatives such as PEPFAR can have both positive and negative effects on partner country health systems. Several studies have examined the effects of HIV/AIDS and broader global health initiatives on health systems. Positive effects have included strengthened infrastructure and laboratories, scale-up of HIV/AIDS service delivery, improved primary health care services, a slowing of HIV/AIDS-related deaths among the health workforce through provision of antiretroviral treatment, greater participation of stakeholder groups, and increased funding to nongovernmental organizations (NGOs) and faith-based bodies (Biesma et al., 2009; Samb et al., 2009; Yu et al., 2008). Negative effects on health systems include reallocation of or reduction in funding for other health or non-health priorities; attrition in the public health or primary care workforce as a result of increased incentives to work for donor-funded programs; and "distortion of recipient countries' national policies, notably through distracting governments from coordinated efforts to strengthen health systems and re-verticalization of planning, management and monitoring and evaluation systems" (Biesma et al., 2009, p. 239; Samb et al., 2009; Yu et al., 2008). In general, the evidence is mixed and limited for determining whether strengthening effects are positive or negative (Biesma et al., 2009; Samb et al., 2009; Yu et al., 2008). In recent years, there has been more research dedicated to the interaction between global health initiatives and health systems which has produced recommendations for ensuring that health systems are strengthened, not weakened by global health initiatives.

The ability of societies generally, as well as public health and clinical care entities specifically, to address the HIV epidemic is contingent upon functioning health systems. The term "health system" that is used in this report is intentionally broad, referring to all of the societal resources mobilized to achieve and preserve health and thus, a health systems approach to constraints offers a different lens from that of a disease-specific response (see Table 9-1) (Mills, 2007). Many scholars have argued that investments in response to scaling up disease-specific services could be more appropriately targeted to interventions that broadly strengthen health care systems (Mills, 2007; Travis et al., 2004; Yu et al., 2008). In 2009, the WHO Maximizing Positive Synergies Collaborative Group issued five recommendations to improve the joint effectiveness of large global health programs and partner country health systems: (1) prioritize health system strengthening, (2) agree on and track health system strengthening indicators, (3) align planning and resource allocation between global health initiatives and country health systems, (4) generate more reliable data for the costs and benefits of strengthening health systems, and (5) commit to increased national and global health financing that is more predictable to support sustainable and equitable growth of health systems (Samb et al., 2009). The challenge for global health donors is that health system interventions require long-term investments; the longer time lags between intervention and outcomes make such interventions more difficult to measure and evaluate (Bärnighausen et al., 2012).

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TABLE 9-1 Health System Constraints with Potential Disease-Specific and Health System Responses

Constraint	Disease-Specific Response	Health-System Response
	Financing	
Financial inaccessibility: inability to pay, informal fees	Permit exemptions or reduce prices for focal diseases	Develop risk pooling strategies
	Service Delivery	
Physical inaccessibility: distance to facility	Provide outreach for focal diseases	Reconsider plans for long term capital investment and planning for facilities
Poor quality of care among providers in the private sector	Provide trainings for private sector providers	Develop systems for accreditation and regulation
	Workforce	
Inappropriately skilled staff	Implement continuous education and training workshops aimed at developing skills in focal diseases	Review basic medical and nursing training curricula to ensure basic training includes necessary and appropriate skills
Poorly motivated staff	Offer financial incentives to reward delivery of priority services	Institute appropriate performance review systems, create greater clarity around performance roles and expectations, review salary structures and promotion procedures
	Leadership and Governance	
Weak planning and management	Provide continuous education and training workshops aimed at developing planning and management skills	Restructure ministries of health, recruit and develop a cadre of dedicated managers
Lack of intersectoral action and partnership	Create special disease-focused cross-sectoral committees and task forces at the national level	Build systems of local government that incorporate representatives from health, education, and agriculture as well as promote accountability of local governance structures to the people

SOURCE: Adapted from (Mills, 2007; Travis et al., 2004).

OVERVIEW OF PEPFAR'S HEALTH SYSTEMS STRENGTHENING ACTIVITIES

As part of the current IOM Evaluation of PEPFAR, Congress mandated an assessment of PEPFAR's effects on health systems, "including on the financing and management of health systems and the quality of service delivery and staffing."[2] This section provides a brief history of PEPFAR's approach to HSS; this is followed by a more in-depth discussion of PEPFAR activities related to each building block of the health system.

[2] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Public Law 110-293, 110th Cong., 2nd sess. (July 30, 2008), §101(c), 22 U.S.C. 7611(c)(2)(B)(ii).

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History of PEPFAR's Approach To and Increasing Focus on HSS

In PEPFAR's first Five-Year Strategy, OGAC articulated the importance of supporting national strategies, laboratory systems, workforce training, and information systems because these components of health systems were essential for scaling up quality services (OGAC, 2005b). Recognizing that partner country health systems were not prepared to support needed services, OGAC committed to providing "targeted technical assistance, training, and funding to improve and expand the infrastructure necessary to ensure optimal delivery of HIV/AIDS treatment services" (OGAC, 2004, p. 39). "Evidence demonstrates that scale-up of HIV services has produced stronger health systems and, conversely, that stronger health systems were critical to the success of the HIV scale-up" (Palen et al., 2012, p. S113). However, some have argued that the disease-specific nature of the PEPFAR program may have undermined a coordinated approach to health planning and delivery (Bärnighausen et al., 2012; Hanefeld, 2010; OGAC, 2009f).

OGAC has recognized the largely ad-hoc nature of HSS interventions during the first phase of the PEPFAR program (2004-2009) and the lack of a strategic focus on strengthening each building block of the health system (OGAC, 2009f). PEPFAR-supported HSS interventions were largely disease-specific or somewhere on the continuum between disease-specific and a broader health system response (see Table 9-1). The reauthorization legislation provided the opportunity and goals for PEPFAR to formally identify and support strategies to "strengthen overall health systems in high-prevalence countries, including support for workforce training, retention, and effective deployment, capacity building, laboratory development, equipment maintenance and repair, and public health and related public financial management systems and operations,"[3] as well as for PEPFAR and partner country government to commit to a "deeper integration" of HIV services into existing national programs and systems.[4] The reauthorization legislation stated goals for PEPFAR to strengthen health policies and systems for not only HIV/AIDS, but also tuberculosis and malaria, in support of increasing partner country ability for delivery of efficient, effective, and evidence-based services.[5] This enabled PEPFAR's engagement and promotion of other stakeholders, such as civil society, to participate in a country's HIV/AIDS response.

In its second phase (2009-2013), PEPFAR "emphasizes the incorporation of health systems strengthening goals into its prevention, care and treatment portfolios" with the goal of training and retaining "health care workers, managers, administrators, health economists, and other civil service employees critical to all functions of a health system" (OGAC, 2009d, p. 8). In response to the reauthorizing legislation's goals and objectives for health systems, PEPFAR's second Five-Year Strategy articulated not only its commitment to health systems in terms of activities and resources, but that it would also be cognizant and more considerate of health systems activities' effects when planning prevention, care, and treatment services within partner countries (OGAC, 2009f). The second Five-Year Strategy also articulated that PEPFAR could be a platform for improving other health conditions, especially due to its work in HSS to ensure quality and expanded care and treatment services, including antiretroviral therapy (ART) (OGAC, 2009d, p. 5). In 2009, PEPFAR developed a strategic framework to help PEPFAR

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[3] *Ibid*., §301(c)(5)(D), 22 U.S.C. 2151b-2(d)(6)(G)(ii).
[4] *Ibid*., §301(c)(6), 22 U.S.C. 2151b-2(d)(8).
[5] *Ibid*., §204(a), 22 U.S.C. 7623(a)(1)(A).

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mission teams plan HSS activities by identifying focused investments needed to achieve service delivery objectives, spillover effects, and targeted leveraging of other programs and donors (OGAC, 2009f). Specific OGAC guidance and PEPFAR activities related to each building block are described in the sections that follow.

PEPFAR Funding for HSS

Broadly, funding for PEPFAR HSS activities is captured in three budget codes: Health Systems Strengthening, Strategic Information, and Laboratory Infrastructure (see Box 9-1) (OGAC, 2011c). Although funding for Strategic Information and Laboratory Strengthening can be traced to HSS efforts in the Health Information and Medical Products and Technologies building blocks, funding cannot be disaggregated for efforts in the other building blocks. Over the years, PEPFAR's budget code definitions were revised, but HSS activities generally included broad policy reform efforts, system-wide approaches (e.g., supply chain, procurement, information), and capacity building for financial and program management (OGAC, 2008a, 2010a). Other activities that contribute to HSS, such as those associated with service delivery, especially human resources for health training (HRH), may not be reported in the HSS budget codes (Palen et al., 2012), so the amounts presented in Figure 9-2 may under-represent PEPFAR's investments in HSS.

BOX 9-1
PEPFAR Budget Code Definitions for HSS

Health Systems Strengthening – "include activities that contribute to national, regional or district level systems by supporting finance, leadership and governance (including broad policy reform efforts including stigma, gender etc.), institutional capacity building, supply chain or procurement systems, [strengthening of local coordinating mechanisms for implementation of] Global Fund programs [or other external grants,] and donor coordination." (OGAC, 2011c, p. 184)

Laboratory Infrastructure – development and strengthening of laboratory systems and facilities to support HIV/AIDS-related activities including: strengthening of laboratory leadership and management; purchase of equipment and commodities; strengthening of laboratory supply and equipment management systems; promotion of quality management systems, laboratory monitoring and evaluation, and laboratory information systems; and provision of staff training and other technical assistance." (OGAC, 2011c, p. 156)

Strategic Information – "Aims to build capacity in country for HIV/AIDS behavioral and biological surveillance, facility surveys, monitoring program results, reporting results, supporting health information systems, supporting countries to establish and/or strengthen such systems, supporting training and retention of local cadres of personnel needed to direct all SI activities, and related analyses and data dissemination activities fall under strategic information." (OGAC, 2011c, p. 165)

SOURCE (OGAC, 2011c).

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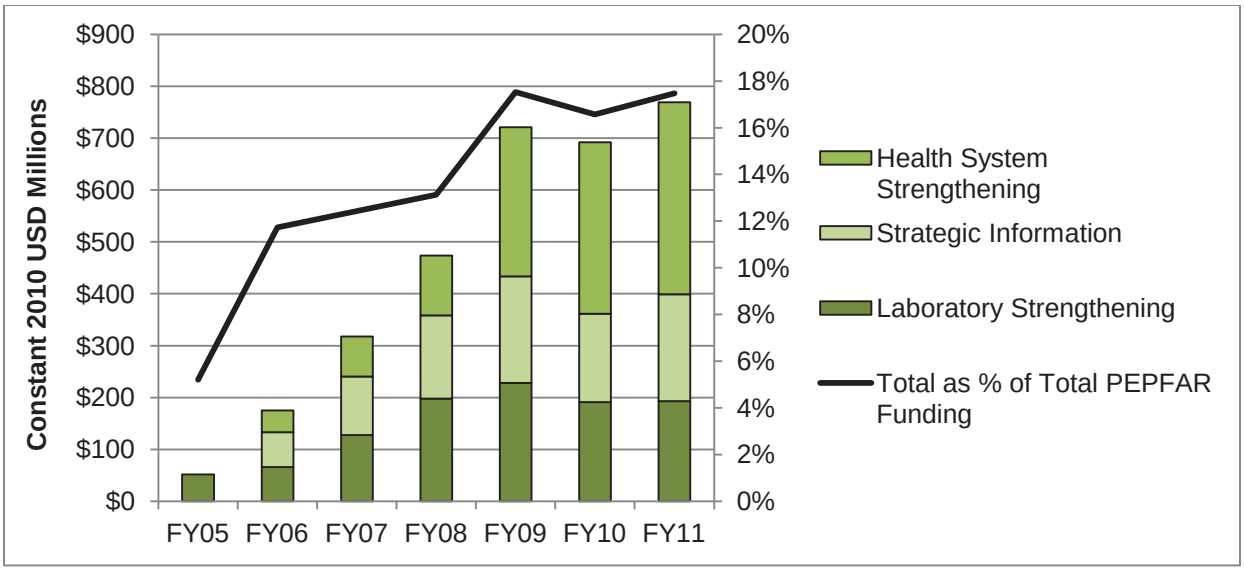

FIGURE 9-2 PEPFAR funding for HSS (country activities) (constant 2010 USD millions).
NOTE: These data represent funding for country activities planned through the Health Systems Strengthening, Strategic Information, and Laboratory Strengthening budget codes. For FY 2005, data were not reported for the Health Systems Strengthening and Strategic Information budget codes. To compare data most accurately over time, data are presented in constant 2010 USD. These totals do not include the MEPI and NEPI initiatives supported by PEPFAR.
SOURCE: (OGAC, 2005a, 2006b, 2007c, 2008b, 2010b, 2011d).

Over time, as shown in Figure 9-2, funding for the three budget codes most directly related to HSS as a proportion of all PEPFAR funding has increased from nearly 12 percent in FY 2006 to nearly 18 percent in FY 2011 (data for two of the three budget codes were not reported in FY 2005) (OGAC, 2006b, 2007c, 2008b, 2010b, 2011d). Funding for these three budget codes increased from $175 million in 2006 to $769 million in FY 2011. Initially, Strategic Information and Laboratory Strengthening activities received a greater share of funding, but over time, more funding has been directed to the Health Systems Strengthening budget code. From FY 2006-FY 2011, 38 percent of PEPFAR funding for HSS was directed to the Health Systems Strengthening budget code, 33 percent to Laboratory Strengthening, and 29 percent to Strategic Information.

Committee's Approach to the Assessment of PEPFAR by Health Systems Building Block

The committee systematically collected and analyzed data about PEPFAR activities and effects for each health systems building block; these data included semi-structured interviews with key stakeholders, programmatic and financial data, and other published information including: peer-reviewed and grey literature, PEPFAR/OGAC guidance documents, and a targeted review of 2008 and 2010 PEPFAR Country Operational Plans (COPs) for a subset of countries. Based on those analyses, the section below describes PEPFAR's inputs and activities within each of the WHO health systems building blocks. PEPFAR inputs include funding for HSS activities and the strategic documents (such as the authorizing and reauthorizing legislation, five-year strategies, and programmatic guidance) that provide direction for HSS activities. Although funding information is not disaggregated by each building block's activities, it is presented where available. Reflecting the interdependent nature of the building blocks, many of PEPFAR's activities overlap building blocks. In the following sections,

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PEPFAR activities are discussed within the context of the most relevant building block, considering the intent of the activities as they were described in semi-structured interviews and guidance documents. Finally, the committee drew upon these data to outline PEPFAR's historic and current achievements and made recommendations for future directions for HSS efforts.

LEADERSHIP & GOVERNANCE

Introduction

The Leadership and Governance building block represents the most critical function of the health system — stewardship (WHO, 2000, 2007a). Broadly, stewardship has been defined as the "careful and responsible management of the well-being of the population" (WHO, 2000, p. viii). The stewardship function in health systems is quite complex and has been difficult to operationalize since its proposal by the WHO in 2000. In 2001, WHO organized a technical consultation through which experts recommended several considerations for a refined definition of stewardship and for conceptualizing "more tangible elements for better assessment of stewardship in a particular country" (WHO, 2001, p. 2). In their redefined definition, stewardship incorporates much of what is described as governance with an emphasis on the role of government, but differs from governance more in its style or approach to particular tasks rather than in its scope. Stewardship should be ethical, inclusive, and proactive. By reflecting the cultural, political, and societal norms in each country's context, stewardship could facilitate addressing interactions between the health system and other aspects of society, as well as influence other stakeholders in the private and other sectors. These multisectoral and multi-stakeholder stewardship interactions should enable change that not only addresses today's challenges, but also longer-term views that can build capacity and foster continuous improvement to address future problems (WHO, 2001).

For health systems, stewardship includes priority setting, strategy and policy development, multisectoral collaboration and coalition building, oversight and guidance for the whole health system (public and private), and regulation of all actors involved in the health system (WHO, 2007a). Although national governments are ultimately responsible for the performance of health systems, other entities and institutions from the private sector and civil society may be involved in or carry out some of the functions of stewardship (IOM and NRC, 2009; WHO, 2000, 2007a).

Leadership and Management

In 2007, WHO organized another international consultation on improving leadership and management for health. Reports from that consultation stated that leadership and management are also complex concepts relevant to many different parts of the health system and recognized the different, yet complementary roles of leaders and managers. Leaders were identified as essential for setting a strategic vision and planning and mobilizing efforts toward realization of that vision, while skilled and motivated managers work throughout a health system to "ensure effective organization and utilization of resources to achieve results" and meet the objectives set forth in the strategic vision (WHO, 2007b, p. 1). Good leadership and management were described as key to effectively using resources devoted to health to achieve measurable results, particularly by "providing direction to, and gaining commitment from, partners and staff, facilitating change, and achieving better health services through efficient, creative and

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responsible deployment of people and other resources" (WHO, 2007b, p. 1). Additionally, the report stated that countries needed to develop and implement overall plans for leadership and management and external donor assistance should coherently support these plans.

Governance

In the broadest sense, "[g]overnance refers to the structures, rules, and processes that societies use to organize and exercise political power to identify and achieve objectives [...] Governance includes, but is not synonymous with, government [...] National governance refers to the way in which a country organizes political power within its territory and controls interactions among local, sub-national, and central governmental authorities" (IOM and NRC, 2009, p. 206). Governance for the health system has been defined by WHO as "the wide range of functions carried out by governments as they seek to achieve national health policy objectives" and includes identifying the health needs of a population, setting priorities, strategic planning, policy development and implementation, and regulation of different types of actors within the health system (WHO, 2012c). To achieve good governance, governments must have the capacity to "plan, manage, and regulate policy, financial resources, and service delivery" with efficiency, effectiveness, openness, transparency, and accountability (Brinkerhoff and Bossert, 2008; Fox et al., 2010, p. 12).

Effective governance of the HIV/AIDS response requires a multisectoral approach that is responsive to and inclusive of other government sectors, as well as the private sector and civil society (Brinkerhoff and Bossert, 2008). HIV/AIDS impacts all the social and economic sectors within a country, so to be truly effective, national responses to HIV/AIDS must be multisectoral (Piot and Coll Seck, 2001). The health sector may be the focus of a country's HIV/AIDS response (and donor support), but comprehensive responses involve other sectors, such as finance, education, labor, transportation, military/policy, women, and young people (UNAIDS, 2009). Frameworks and principles for good governance seem to be rooted in historical development from postwar conflicts and other activities that have threatened the principles of democracy, security, and the rights of people around the globe. While there are emerging theories and frameworks for global health governance, current frameworks for good governance are described as building on the "fundamental values of human rights, the rule of law and democracy, [and the] principles of equity, participation, accountability and solidarity" in addition to promoting stability, preventing conflict, and facilitating social and economic progress (COE, 2005; Committee of Ministers, 2010, p. 391).

Entities in many PEPFAR countries are receiving a considerable amount of donor funding for health and development issues and governance includes the management of these resources "in ways that promote national leadership, contribute to the achievement of agreed policy goals, and strengthen national management systems" (WHO, 2012c, p. 1). As one of the functions of stewardship for health systems, national governments are expected to responsibly and transparently manage all resources for health and HIV/AIDS—what it contributes as well as resources from external donors—whether it goes directly to government institutions or is provided to NGOs. It is worth noting however that not all donor funds, including PEPFAR's, go directly to governments in these countries; this can create a disconnect wherein governments are asked to manage and oversee funds that they do not directly control and provide leadership and management of funds that they do not directly receive. The challenges to governance associated with the mechanisms and approaches of donor funding are discussed further in the Financing building block and in Chapter 10.

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There are many examples of strong government engagement in and management of HIV/AIDS responses in low-and middle-income countries. In the 1980s and 1990s, the Government of Uganda, led by President Museveni, brought together government institutions and civil society organizations (CSOs) to form a nationally-integrated response that eventually became known as the "multisectoral approach" (Grebe, 2009). In Rwanda, the government is "fully engaged and in command" of the HIV/AIDS programs within the country, it "insists on ownership of all development plans[,] and has asked all partners to adhere to them" (Logie et al., 2008a). The Ministry of Health coordinates donor assistance for health through the Health Sector Cluster Group (HSCG) and "health sector partners, including the USG, are signatories to the Sector-Wide Approach (SWAp)" (PEPFAR/Rwanda, 2010).

The Role of Nongovernmental Leadership

Although partner country governments bear the primary responsibility for HIV/AIDS responses, "the complexity of the disease requires broad societal partnerships" (Grebe, 2009). In many countries, CSOs provide a critical stewardship function by enabling "access and facilitating participation of societal groups" (Brinkerhoff and Bossert, 2008, p. 3). Global advocacy for HIV/AIDS as well as donor-funded global health initiatives have catalyzed stronger involvement of civil society in decision-making processes (Yu et al., 2008). The Global Fund requires that funding proposals be developed with representatives from all sectors, including government, civil society, the business sector, and PLHIV through broad partnerships called Country Coordinating Mechanisms (CCMs) (The Global Fund, 2012). PEPFAR's Partnership Framework process also requires the participation of key partners from civil society, community-based and faith-based organizations, the private sector, other bilateral and multilateral partners, and international organizations (OGAC, 2009a). In addition to direct involvement in planning and decision-making processes, civil society can also play an important role in advocating for government action or resources, as well as monitoring for good governance and responsiveness to the needs of marginalized or vulnerable populations (Grebe, 2009; Samb et al., 2009).

The private and nongovernmental sectors also play an important role in the delivery of health services, particularly those supported through donor funding (OGAC, 2009a; Yu et al., 2008). PEPFAR and the Global Fund channel considerable amounts of funding to nongovernmental and community-based organizations which has expanded the delivery of services beyond the public sector. The increased involvement of civil society has also contributed to the decentralization of health management and highlighted the need for capacity building to ensure legitimacy, accountability, and transparency by nongovernmental service providers (Samb et al., 2009).

Perspectives on Partner Country Context

Most partner country governments have embraced HIV/AIDS as a health priority and multiple stakeholders who were interviewed asserted that governments are engaged in leading the response (272-1-USG; 272-12-USNGO; 240-5-PCGOV; 240-33-USG; 636-2-USG; 461-8-PCGOV; 461-25-ML; 396-7-PCGOV; 396-18-USG; 166-25-USG; 934-7-PCGOV), particularly in Ministries of Health (240-1-USG; 240-3-USG; 272-20-PCNGO; 461-16-USG; 934-28-PCNGO; 331-6-CCM; 636-3-USG).[6] Interviewees attributed the success of national

[6] Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type

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HIV/AIDS responses to robust leadership and in particular, confirmed its importance for mobilizing national responses to HIV/AIDS and raising support from external donors (461-8-PCGOV; 240-7-PCGOV):

> *'The President asked all leaders in the nation and communities to "not sit down" about HIV' (461-8-PCGOV).*[7]
>
> *'MOH definitely drives the agenda and programming, even when partners have disagreements' (636-3-USG).*

Where strong leadership was absent, HIV/AIDS programs were described as having been built outside the government (272-1-USG).

In contrast to what the committee heard about the presence of high-level leadership in many partner countries, it also heard about gaps in national leadership and management skills (240-19-USACA; 587-22-USG; 196-11-USNGO; 636-9-USG; 116-7-USG; 116-11-PCGOV; 166-13-PCGOV; 935-2-USG; 935-12-USPS; 935-24-USNGO); a lack of a government commitment to the HIV/AIDS response (196-19-PCNGO; 196-20-PCNGO; 196-6-USNGO; 461-13-USACA; 636-9-USG; 636-21-USNGO); persistent challenges with leadership at the sub-national level (272-1-USG; 240-3-USG; 587-22-USG; 636-9-USG; 166-13-PCGOV; 116-23-USPS; 935-12-USPS); authoritarian leadership (587-3-USG), lack of capacity for implementation (331-43-USG; 116-2-USG; 461-4-USG; 461-8-USG; 240-22-PCNGO; 272-20-PCNGO; 935-14-USG), poor coordination and/or collaboration among government entities or programs (196-11-USNGO; 461-19-USG; 240-33-USG; 636-21-USNGO), and *'diminishing'* leadership (196-7-PCNGO; 542-11-PCNGO; 461-7-PCNGO; 461-25-ML).

> **Conclusion:** Many stakeholders affirmed that there is strong leadership in partner countries for the HIV/AIDS response, both within government and in nongovernmental sectors. However, in some countries there are still challenges related to governance and management capacity for the maintenance and sustainability of the HIV/AIDS response.

PEPFAR Inputs

Guidance

PEPFAR's authorizing legislation recognized the importance of "determined national leadership" for addressing HIV/AIDS epidemics.[8] This legislation supported building leadership capacity, particularly at the community level, and articulated training and "the

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Non-country Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Non-Governmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO.

[7] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

[8] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong., 1st sess. (May 27, 2003), §2(15).

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development and implementation of national and community-based multisectoral strategies and programs" as mechanisms to achieve improved capacity.[9] In its first Five-Year Strategy, PEPFAR pledged to coordinate programs with partner country policies and strategies and identified four strategies to build leadership at all levels of the HIV/AIDS response:

- Engaging heads of state and other government officials through bilateral diplomatic interventions and multilateral forums
- Reaching out to a broad range of community and religious leaders and private institutions to generate multisectoral leadership and responses to HIV/AIDS
- Using the tools of public diplomacy and communications to inform and engage new partners, including media, in the fight against HIV/AIDS
- Using diplomatic interventions in bilateral and multilateral forums with donor nations, and communications tools with the public and private institutions, to raise additional resources for global AIDS (OGAC, 2004)

Partnership Frameworks

As articulated in the reauthorization legislation, the focus of PEPFAR II shifted from an emergency response to ensuring sustainability of programs and activities.[10] The reauthorization legislation permitted a joint, intergovernmental framework for cooperation between the USG, partner country governments, and other partners as a mechanism to support the transition from an emergency response to a "public health and development approach to HIV/AIDS."[11] Originally called "compacts" in this legislation, these mechanisms are known as Partnership Frameworks (PFs). "The purpose of a Partnership Framework is to provide a 5-year joint strategic framework for cooperation between the USG, the partner government, and other partners to combat HIV/AIDS in the country through technical assistance and support for service delivery, policy reform, and coordinated financial commitments. At the end of the five year time-frame, the expectation is that, in addition to results in the prevention, care and treatment of HIV/AIDS, country governments will be better positioned to assume primary responsibility for the national responses to HIV/AIDS in terms of management, strategic direction, performance monitoring, decision-making, coordination, and, where possible, financial support and service delivery" (OGAC, 2009a, p. 3). PFs were framed as an opportunity to accelerate PEPFAR's "transition of PEPFAR support from direct service provision to increased provision of technical assistance to governments" (OGAC, 2009a, p. 4). Though the PFs are not legally binding in either country, they are guided by the following principles:

- Country ownership
- Sustainability
- Support for coordination of country resources
- USG interagency collaboration
- Engagement and participation
- Strategic framework

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[9] *Ibid*., §101(b)(3)(D) and §301(a)(2), 22 U.S.C. 2151b(d)(6)(B).
[10] *Supra.*, note 2 at §4, 22 U.S.C. 7603(1)(C).
[11] *Supra.*, note 2 at §301(c)(6), 22 U.S.C. 2151b-2(d)(8) and §301(d)(2), 22 U.S.C. 2151b-2(e)(1)(B).

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- Flexibility
- Progress towards policy reform and increased financial accountability
- Integration of HIV/AIDS into strengthened health systems and a broader health and development agenda
- Monitoring and evaluation
- Collaborative but not transactional
- Transparency
- "Do no harm" (highlighting PEPFAR's continued support of existing implementing partner service delivery systems while the transition to county ownership occurs over time) (OGAC, 2009a)

Within the context of these principles, PFs provide a broad overview of the goals, contributions, and targets for PEPFAR and partner country actors to address HIV/AIDS in accordance with the national HIV/AIDS strategy. An additional document, the Partnership Framework Implementation Plan (PFIP), provides more detail on the scope of activities to be carried out; the indicators that will be used to set targets and monitor progress; 5-year targets; specific commitments of the USG, partner country, and other partners; and a plan for monitoring progress. Together, the PF and the PFIP, once signed, are to serve as the basis for annual PEPFAR Country Operational Planning (OGAC, 2009a). As of July 5, 2012, 19 countries and 2 regions have signed PFs. Fourteen of these countries have completed the next step of the process and have drafted Partnership Framework Implementation Plans (PFIPs), but only four PFIPs had been signed as of July 2012 (OGAC, 2012a). Once signed by the partner country government and the USG, PFs were intended to be executed as the primary planning vehicle for the respective roles and contributions of governments and other stakeholders for the country's HIV/AIDS response. The committee learned from OGAC and implementing partners that when extenuating circumstances hindered the development of PFs (e.g. political turmoil in a country), strategic plans could be submitted in lieu of PFs (NCV-9-USG; 542-13-USG). The committee acknowledged the purpose of the PFs as a primary tool for PEPFAR to contribute to strengthening and ensuring leadership and governance of the HIV/AIDS response within partner countries. These strategic planning mechanisms are further discussed in Chapter 10 of this report on Progress Toward Transitioning to a Sustainable Response.

PEPFAR Activities

Since its beginning, PEPFAR has supported partner country leadership and governance primarily through technical assistance (TA), defined by OGAC as "the identification of need for and delivery of practical program and technical support," and training of human resources (OGAC, 2007b, p. 97). In response to request for programmatic data, OGAC provided the data from PEPFAR I for three indicators that measure the number of local organizations that received TA and three indicators that measure the number of individuals trained in activities related to leadership and governance.

Technical Assistance

PEPFAR implementing partners have provided TA to governmental and nongovernmental entities involved in leadership and governance of national HIV/AIDS responses in order to build capacity for designing, implementing, and evaluating HIV/AIDS

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programs (OGAC, 2007b). PEPFAR collected data on three categories of TA, many of which overlap with other health systems building blocks (see definitions in Box 9-2). Since this TA was intended to strengthen some key stewardship functions, the indicator data are presented here and the concepts discussed in later sections that incorporate examples from the interview data. From FY 2006 to FY 2009, PEPFAR-supported partners more than tripled the total number of local organizations receiving technical assistance, from more than 11,000 to almost 36,000 (respectively) (see Table 9-2).

BOX 9-2
OGAC Definitions of Technical Assistance (TA) related to Leadership & Governance

"TA should *include regular technical communications and information dissemination sustained over a period of time*. TA can be provided through a combination of strategic approaches and dissemination strategies including individualized and on-site peer and expert consultation, site visits, ongoing consultative relationships, national and/or regional meetings, consultative meetings and conferences, conference calls and web-casts, development and implementation of training curricula." (OGAC, 2007b, p. 97)

TA for **HIV-related policy development** includes "activities that aim to broaden and strengthen political and popular support for HIV/AIDS policies and programs; improve the operational environment for these programs, including better planning and financing; ensure that accurate, up-to-date information informs policy decisions; and build in-country and regional capacity to participate in policy development." (OGAC, 2007b, p. 101)

TA for **HIV-related institutional capacity building** may include strategic planning; registration; financial management; human resource management; networks development; commodities, equipment and logistics management; infrastructure development. (OGAC, 2007b, p. 102)

TA for **strategic information** refers to "activities that aim to strengthen HIV/AIDS surveillance, HMIS and M&E. Examples include providing local organizations with technical assistance in the following areas: developing or improving M&E models, methods and tools for collecting, analyzing, disseminating and using data; establishing or improving information systems; developing or improving program monitoring, planning and or conducting targeted program evaluations including operations research; monitoring and disseminating best practices to improve program efficiency and effectiveness; and/or improving data quality." (OGAC, 2007b, p. 97)

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TABLE 9-2 PEPFAR Indicators Related to Leadership and Governance (Organizations)

Number of local organizations (in thousands) provided with technical assistance for:	FY04	FY05	FY06	FY07	FY08	FY09
For HIV-related policy development (14.1)	3.5*	2.9*	2.2	2.5	7.0	7.3
For HIV-related institutional capacity building (14.2)			5.5	6.8	10.9	13.8
For strategic information activities (13.1)	--	--	3.7	8.5	11.2	14.5

NOTE: Local organizations refer to governmental or nongovernmental organizations with headquarters in a country or region served by PEPFAR. Data are presented in thousands. Indicator 13.1 was not reported prior to FY 2006.
* In FY 2004 and FY 2005, indicators 14.1 and 14.2 had not yet been separated by OGAC and were reported as a single result.
SOURCE: Program monitoring indicators provided by OGAC.

Interviewees described PEPFAR support for Ministries of Health (461-8-PCGOV; 240-1-USG; 240-19-USACA; 935-24-USNGO; 542-5-USPS), HIV/AIDS coordinating bodies (461-8-PCGOV; 240-1-USG; 935-22-PCGOV), Global Fund CCMs (331-6-CCM; 587-6-CCM; 636-3-USG), and other ministries involved in the HIV/AIDS response (461-8-PCGOV; 272-17-USG; 636-3-USG; 935-10-USG; 935-14-USG; 935-19-USG). It was highlighted in one country visit that PEPFAR is the only external donor that provides support for governance capacity building, specifically by working with the country's Global Fund CCM (587-6-CCM). Other examples of PEPFAR-supported technical assistance included supporting capacity building of partner country governments to oversee and/or regulate both the public (331-28-PCGOV) and the private sector (240-12-USG). In some countries, PEPFAR seconds staff or provides salary support for key technical positions in the Ministries of Health (240-19-USACA; 116-7-USG; 116-11-PCGOV; 166-6-USG; 166-15-USACA; 166-30-ONGO). Several stakeholders identified investment in management personnel as the greatest priority for country ownership, which PEPFAR was supporting (396-55-USG; 272-2-USG; 166-13-PCGOV; 116-23-USPS; 935-4-PCGOV).

PEPFAR has also supported capacity building for NGOs and CSOs that include faith-based organizations (FBOs) and community-based organizations (CBOs) (196-9-USNGO; 636-3-USG; 935-10-USG; 935-14-USG; 542-5-USPS; 331-34-USNGO). PEPFAR support has enabled a network of AIDS service organizations to coordinate activities across districts through a secretariat and community councils (636-11-PCNGO) and enabled CSOs to plan and fiscally manage programs including reporting on activities (587-21-PCNGO). In several countries, PEPFAR partners sub-contract with local governments and other entities and are devoting time and resources to building management and administrative capacity so these implementing partners will be able to sustain the HIV/AIDS response (NCV-5-USACA; NCV-6-USNGO; NCV-16-USNGO).

Training

In conjunction with TA, PEPFAR also supports training for individuals in HIV-related policy development, institutional capacity building, and stigma and discrimination reduction (see Table 9-3). Training for HIV-related policy development and institutional capacity building serves the same purposes as TA (see definitions in Box 9-2). Again, some of these trainings may overlap with other building blocks.

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TABLE 9-3 PEPFAR Indicators Related to Leadership and Governance (Individuals)

Number of individuals (in thousands) trained:	FY04	FY05	FY06	FY07	FY08	FY09
In HIV-related policy development (14.3)	24.1*	45.9*	28.3	26.9	21.1	23.5
In HIV-related institutional capacity building (14.4)			45.4	69.6	83.5	102.6
In HIV-related stigma and discrimination reduction (14.5)	--	--	63.6	186.1	168.0	103.6

NOTE: "A training must have specific learning objectives, a course outline or curriculum, and expected knowledge, skills and/or competencies to be gained by participants;" to be counted, individuals must attend the full training. Double counting of individuals is to be avoided (OGAC, 2007b, p. 33). Data are presented in thousands. Indicator 14.5 was not reported prior to FY 2006.
*In FY04 and FY05, indicators 14.3 and 14.4 had not yet been separated by OGAC and were reported as a single result.
SOURCE: Program monitoring indicators provided by OGAC.

Interpretation of these data are difficult; one individual may have received training (and been counted) in more than one area and the same individuals may have been trained or retrained in multiple years. Although output indicators are the only data available from OGAC, during country visits, the committee heard several examples of PEPFAR-supported activities and initiatives to increase health workforce capacity for leadership and management, including educational exchange programs (166-3-USG; 166-11-USG), integrating leadership and management skills and training into public health curricula (240-8-USG; 934-38-PCGOV), mentorship (166-11-USG; 116-7-USG), support for sub-national (e.g., district) management teams (935-4-PCGOV; 935-24-USNGO; 116-7-USG), and training programs/workshops (331-43-USG; 934-38-PCACA; 116-7-USG; 116-4-USG; 196-1-USG; 586-13-USG; 240-12-USG).

Policy Development

PEPFAR is also supporting capacity building for policy development to support implementation of HIV/AIDS services and activities. Contributions to policy development and strengthening, as a part of leadership and governance to plan and oversee a national response, can occur through direct negotiations with national counterparts or through less direct efforts to influence dialogue around topics or issues with policy implications. Throughout the course of its interview data-gathering, the committee heard several examples of efforts by PEPFAR mission teams and implementing partners to shape or influence policy in the countries in which they work. Examples included successfully supporting the recognition of populations at elevated risk in national HIV strategy documents (331; 166); supporting the development of national guidelines related to PMTCT (240-24-USG; 636-9-USG), palliative care (116-13-PCNGO), counseling and testing (461-18-USG); and bolstering efforts to improve the rights of women, including protection against gender-based violence and support and vocational training for sex workers, particularly adolescent girls (272-12-USNGO; 166-17-USG; 166-27-PCNGO).

> *'The studies that partners do and the influence [that] PEPFAR has been able to bring to policies, guidelines, and standards is tremendous and has been a major impact.'* (272-22-USG)

However, the committee found that even where new policies and laws have been adopted or enacted, implementation was reported to be very limited or difficult (240; 331; 196; 636; 166; 272; 461). Some examples of laws and policies that are particularly challenging to implement

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and/or enforce included those protecting or addressing women's land rights (240-22-PCNGO), laws protecting PLHIV (331-11-PCNGO), HIV prevention with sex workers (196- 10-PCGOV), and guidelines for procurement (166-22-USPS). One interviewee (461-18-USG) specifically highlighted policy implementation as an area that PEPFAR could help address. There was not one consistent reason given across different interviewees for why policy implementation had not occurred in their country. One reason offered was that government lacked commitment to policies ensuring women's access to services (e.g., educating women about their rights or expanding service delivery), so there was no budget for implementation activities (240-22-PCNGO). Lack of local and national ownership of law and policies was attributed to the lack of enforcement by officials (196-7-PCNGO; 196-10-PCGOV; 196-23-PCNGO).

Across the partner countries visited by the evaluation teams, data use emerged as an important theme for program planners and implementers at the national level. Some interviewees noted a lack of useful data available for policy formation, however the reasons for this limitation varied by partner country. Specifically, interviewees cited the need to conduct more surveillance or surveys due to a dearth of comprehensive data on specific populations (166-5-USG; 240-9-USG), lack of formal processes for utilizing the results of assessments (587-9-USG), weak linkages between national academic and research institutions and the Ministry of Health (116-23-USPS), and the failure to use data if it doesn't support the government's priorities (587-2-USG). In contrast, in different countries, there were conscious attempts by the national government to use data to inform program and policy decisions (196-01-USG; 116-8-USG; 934-24-PCGOV; 331-24-PCGOV; 272-6-ML; 396-9-PCGOV). The introduction of data in discussions around health policy was also mentioned by interviewees as a way of bringing awareness to sustainability challenges (116-23-USPS).

At the national level within partner countries, PEPFAR has played varying roles in creating more supportive policy environments. However, this hasn't been achieved in every partner country and PEPFAR's engagement has varied with respect to different topics. There is evidence of successful engagement for policies related to clinical services and labs, but its efforts on broader structural issues are more mixed.

Strategic Planning

National strategic plans for the HIV/AIDS response can be used to capture or bring together multiple partners and stakeholders (331-27-PCGOV). Interviewees from PEPFAR mission teams and implementing partners described PEPFAR support for a wide range of national frameworks and strategic plans related to the HIV/AIDS response (272-12-USNGO; 272-1-USG), including those for laboratories (396-22-USG; 396-55-USG; 240-21-PCGOV; 331-17-USG) and human resources for health (240-12-USG; 934-38-PCACA).

Across countries, interviewees mentioned PEPFAR-supported TA to assist the national government with planning, budgeting, rollout, and coordination (272-17-USG; 935-2-USG; 935-10-USG; 935-19-USG; 116-7-USG; 166-3-USG; 166-16-PCGOV). For example, PEPFAR was part of a task force for developing a new national strategic plan for the HIV/AIDS response in one country (240-7-PCGOV). PEPFAR partners are also supporting sub-national levels of the government (e.g., regions, districts) with planning tools such as costing and resource mapping to help prioritizing, planning, and budgeting of implementation activities (240-12-USG; 272-17-USG; 272-20-PCNGO; 196-1-USG; 196-6-USG; 116-7-USG).

Interviewees identified challenges to national strategic planning, including turnover within ministries and sub-national departments of health, resulting in loss of skills and requiring retraining and rebuilding relationships (116-7-USG; 116-11-PCGOV; 542-8-USNGO; 542-21-USNGO; 196-6-USG; 272-

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16-PCNGO); turnover within PEPFAR mission teams, including high-level leadership positions within a U.S. Mission (116-6-USG; 116-26-USG; 116-27-USG); and differing time frames or cycles for PEPFAR and partner country budget years and multiyear strategic plans (166-13-PCGOV 166-ES; 396-6-PCGOV; 396-7-PCGOV; 196-6-USG; 461-16-USG).

The 2007 IOM evaluation of PEPFAR I recommended increased support for country leadership through improved coordination with partner country governments, with a focus on transparency and participation during the annual planning process (IOM, 2007). In PEPFAR II, OGAC has instructed PEPFAR mission teams to align and harmonize PEPFAR planning documents (e.g., PFs and the COPs) with national strategies through consultations with partner country governments; ultimately, partner country governments must approve the strategic direction of the PEPFAR program (OGAC, 2011a).

However, PEPFAR mission teams struggled to collaborate with partner country governments with competing health priorities or specifically those that did not view the HIV/AIDS response as a priority (542-2-USG; 396-18-USG). Some interviewees noted that PEPFAR was providing considerable funding for the HIV response while the government really needed or wanted funding for a broader approach to health (240-1-USG; 934-5-USG). For example, when PEPFAR and Global Fund funding comprised the overwhelming majority of the government's total budget for health, the partner country government felt like PEPFAR was driving the priorities of the HIV response (240-21-PCGOV). Interviewees identified some challenges to joint strategic planning, including unrealistic targets or expectations for funding (240-33-USG) and situations when the priorities of the partner country government do not align with OGAC/USG guidance or PEPFAR focus areas (935-17-USG; 196-11-USNGO; 636-3-USG). Although there were examples of misalignment of priorities between the USG and partner country priorities (240-1-USG; 240-7-PCGOV; 331-6-CCM), there were also many instances in which PEPFAR was supporting the government's vision (240-2-USG; 636-3-USG; 331-15-USG; 116-16-PCGOV). Many stakeholders believed that strategic alignment had improved during PEPFAR II (240-20-ML; 935-8-PCGOV; 116-16-PCGOV; 166-13-PCGOV) and some PEPFAR partners mentioned forming agreements or signing memorandums of understanding as tools to ensure alignment with government priorities (272-15-PCNGO; 166-30-ONGO).

This evaluation committee learned from interview data that cooperative planning has had an evolving definition over time ranging from joint planning before resources are allocated, to review and adoption of select activities from the strategic plans that donors decide they wish to support, and to partner country governments taking the lead in instructing donors about the priorities needed for their HIV/AIDS responses (see Chapter 4 on Funding).

PEPFAR Achievements

PEPFAR supports strengthening partner country leadership and governance primarily through training and technical assistance and collaborates with partner countries to improve strategic planning and develop policies to guide national HIV/AIDS responses. Several interviewees felt that PEPFAR had a positive effect on leadership and management capacity (331-1-USG; 587-2-USG; 116-16-USG 116-23-USPS; 240-12-USG; 935-13-PCGOV; 935-14-USG), but the committee had no data to understand the impact of these activities. The committee reached several conclusions regarding leadership and governance:

> **Conclusion:** Intergovernmental planning among partner country governments, other national stakeholders, and external donors is a critical activity that is needed for the current and future responses to HIV/AIDS. For the USG support for

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PEPFAR countries, this type of planning is the primary tool for ensuring leadership and governance, as well as a vehicle for joint planning efforts that support the principles of ownership, mutual transparency, and mutual responsibility and accountability.

Conclusion: PEPFAR has increasingly provided stronger support for partner country planning and development of national frameworks, policies, and strategic plans over time. There is variable alignment or harmonization with partner country planning processes that are primarily driven by national government priorities. It is reasonable that the USG, like all donors, has its own considerations and requirements for funding decisions. Nonetheless, PEPFAR has made progress in making its considerations a part of a joint planning process rather than a displacement of country priorities.

Conclusion: PEPFAR has supported training for management and leadership to build capacity for improved functioning of health systems with a variety of activities including curriculum development, mentorship, and shorter-term trainings and workshops. However, the focus and outputs of these training efforts are varied and it was difficult for the committee to determine the impact of these efforts from the data currently available.

Conclusion: PEPFAR's capacity building approach has been "holistic" and includes developing human resources; strengthening financial management; and building organizational capacity at national, provincial, district levels and across government, private, and civil society sectors. Despite these efforts, leadership and financial management capacity were frequently mentioned as challenges to effective HIV/AIDS responses.

FINANCING

Background and Context

Health financing includes the "mobilization, accumulation, and allocation of money to cover the health needs of the people, individually and collectively, in the health system," and encompasses two goals: "(i) to raise sufficient funds and (ii) to provide financial risk protection to the population" (WHO, 2010c, p. 72). In most developing countries, resources for health come from both domestic and external sources. Domestic sources include private spending (typically out-of-pocket expenditures) and public spending (national and local government expenditures). External sources include official development assistance for health (DAH) from both bilateral and multilateral sources, as well as funding from private donors and philanthropic organizations. Ideally, financial risk protection involves combining elements of prepayment schemes (and less reliance on out-of-pocket expenditures), risk pooling (such as health insurance), and incentives for health care providers to offer priority interventions efficiently (WHO, 2000). In 2010, the WHO's World Health Report addressed health financing for

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achieving universal access to health services.[12] The report identified three challenges for achieving universal access: the availability of resources, an overreliance on direct payments at the time people need care, and the inefficient and inequitable use of resources (WHO, 2010e).

The Financing building block overlaps significantly with Leadership & Governance. This section of the report presents some information on the availability of resources for health in PEPFAR countries, followed by a discussion of PEPFAR efforts to build capacity for health financing in partner countries. Accountability and transparency are two governance functions of particular importance for health financing. Transparency, or the sharing of/access to information regarding the allocation of resources is a necessary mechanism for accountability (Brinkerhoff and Bossert, 2008). Partner country governments, as well as donors, need to be able to account for the use of financial resources for health, as well as the outcomes and results achieved with such resources (WHO, 2010c). For example, in 2012, the Kaiser Family Foundation's Global Health Policy Report and VOA News reported that there are concerns from country residents about how the funds raised from Zimbabwe's AIDS levy are being used (KFF, 2012; Mhofu, 2012).

Context of Domestic Financing

Since 2000, domestic spending on health in developing regions has increased dramatically; in 2009, government spending on health was $411 billion in developing regions, nearly 16 times as much as total DAH (IHME, 2011). Domestic spending is critical for achieving health goals and funds core components of health systems, such as infrastructure and salaries, whereas donor funding is often earmarked or directed to specific diseases (e.g., the Global Fund and PEPFAR) (IHME, 2011) (240-1-USG; 240-2-USG; 934-5-USG). Many governments have recognized the importance of increasing domestic funding for health in order to achieve universal access to essential health services and to achieve the health-related Millennium Development Goals (MDGs).

In 2001, African Heads of State gathered at a conference in Abuja, Nigeria and pledged to increase spending on health to at least 15 percent of government spending in what became known as the Abuja Declaration (OAU, 2001). The Abuja Declaration recognized that AIDS was a “state of emergency in the continent” and African leaders committed to mobilize the resources necessary to combat HIV/AIDS, tuberculosis, and other infectious diseases (OAU, 2001; WHO, 2011). According to a recent report on progress towards the commitments made at Abuja, only one country—Tanzania—had met the Abuja goal by 2009, reflecting a lack of “appreciable progress in terms of the commitments the AU [African Union] governments make to health” (WHO, 2011, p. 5). The report acknowledges that it is also important to consider a country’s overall level of spending for health in addition to the proportion of government spending on health. Between 2000 and 2010, per capita expenditure on health increased in all 31 PEPFAR countries considered during the committee’s evaluation (see Table 9-4). In 16 of the 29 countries for which data are available, external resources for health as a percentage of total health expenditure also increased between 2000 and 2010. Figure 9-3 presents external resources for health as a percentage of total health expenditure for 2010.

[12] Universal access is defined as ensuring that “all people have access to services and do not suffer financial hardship paying for them” (WHO, 2010e, p. ix).

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TABLE 9-4 Total Expenditure on Health Per Capita at Exchange Rate

	2000	2010	% Increase
Angola	$15.8	$123.2	680.1%
Sudan	$12.2	$83.9	588.7%
Ukraine	$35.7	$234.4	555.7%
Rwanda	$9.0	$55.5	513.9%
Russian Federation	$96.0	$525.3	447.5%
Ghana	$12.3	$ 67.0	444.0%
China	$43.4	$220.9	408.9%
Indonesia	$15.1	$76.9	408.1%
Lesotho	$26.6	$108.9	308.7%
Zambia	$18.0	$72.9	305.0%
Botswana	$151.8	$614.6	304.9%
Viet Nam	$20.9	$82.9	296.7%
Nigeria	$17.1	$62.8	267.0%
Tanzania	$10.1	$30.9	206.0%
Uganda	$15.6	$46.7	199.2%
Ethiopia	$5.3	$15.7	195.5%
Guyana	$54.3	$158.8	192.5%
Namibia	$126.0	$361.3	186.6%
India	$19.6	$54.2	177.2%
Malawi	$9.4	$25.6	172.3%
Thailand	$66.0	$179.1	171.5%
Swaziland	$75.3	$203.1	169.7%
South Africa	$251.3	$648.7	158.1%
Cambodia	$18.6	$45.2	142.6%
Kenya	$19.0	$36.8	93.6%
Côte d'Ivoire	$31.8	$59.7	88.0%
Dominican Republic	$174.8	$323.3	85.0%
Haiti	$25.7	$46.4	80.7%
Mozambique	$14.1	$21.3	51.3%
Democratic Republic of the Congo	$13.3	$15.8	18.4%
Zimbabwe	$60.0	…	…

NOTE: Data represent total health expenditure per capita expressed at average exchange rate for that year in US$. Total health expenditure includes government and private expenditure on health and may include donor funding. Countries are sorted by the percent increase from 2000 to 2010. Data have been rounded. No data were available for Zimbabwe after 2001.
SOURCE: (WHO, 2012b).

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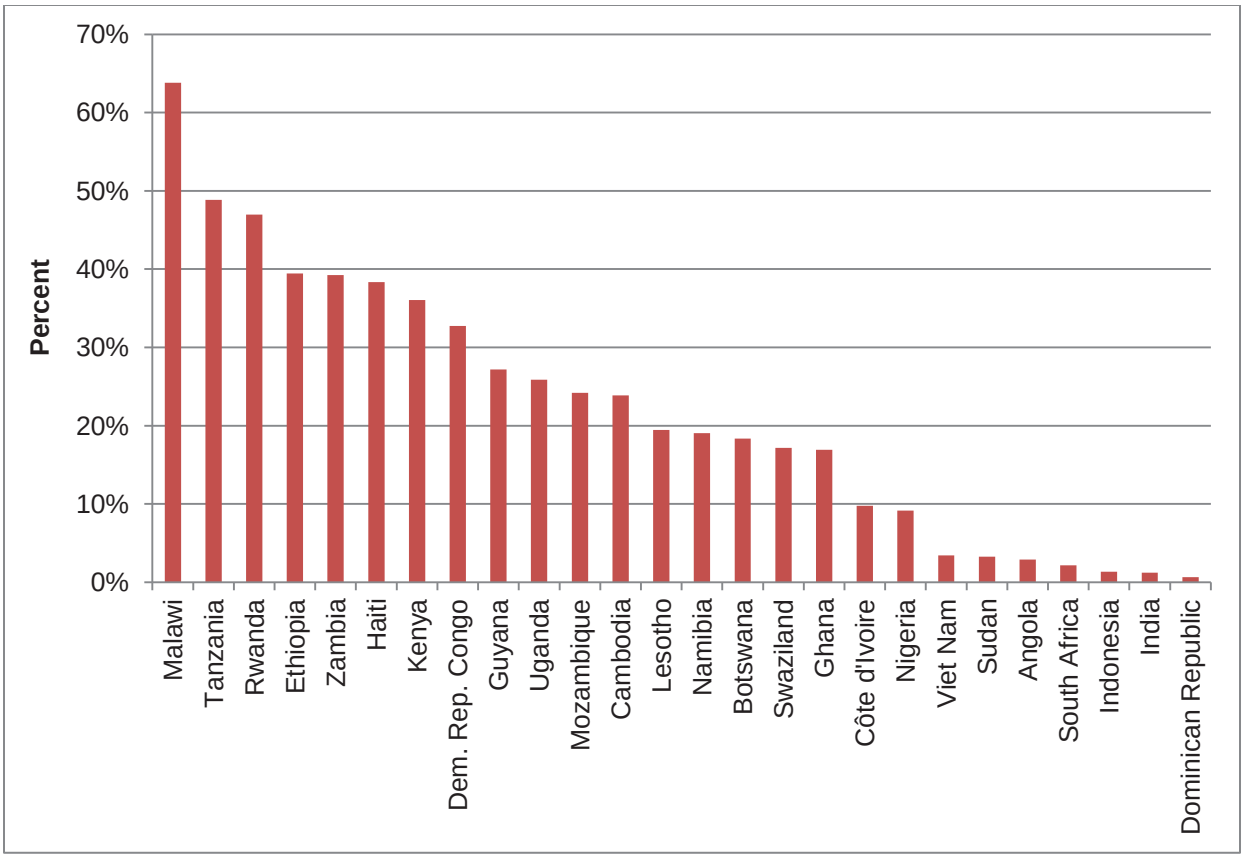

FIGURE 9-3 External resources for health as percent of total health expenditure, 2010.
NOTE: Russia and Zimbabwe have been excluded from the figure because there are no data available. China, Thailand, and Ukraine have been excluded from the figure because less than 0.5 percent of total health expenditure comes from external resources.
SOURCE: (WHO, 2012b).

The committee sought data on partner country government expenditures for HIV/AIDS responses from National Health Accounts and National AIDS Spending Assessments for the 31 countries that are the focus of this evaluation. However, data were unavailable for many countries and years, so the committee was unable to examine trends in HIV/AIDS funding. In a descriptive analysis of HIV/AIDS and health expenditures from 65 countries, Amico et al. found wide regional variability in HIV/AIDS expenditures. In 2007, sub-Saharan Africa countries directed nearly 19 percent of total health expenditure ($4.08 per capita) to HIV/AIDS related activities. Central and South American countries spent $2.63 per capita on HIV/AIDS activities, but this comprised just slightly more than 1 percent of total health expenditure. Amico et.al., also found that a one unit increase in prevalence predicted a nearly $4 million increase in HIV/AIDS funding after controlling for total health spending, foreign direct investment, GDP, and population (Amico et al., 2010).

Context of External Funding

External assistance has become an important source of funding for health for many countries. Annual DAH from bilateral donors and multilateral organizations increased from approximately $11 billion in 2000 to nearly $28 billion in 2011 (IHME, 2011). DAH doubled between 2000 and 2008, but slowed in recent years due to the global economic recession

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(IHME, 2011). In the United Kingdom and the United States, high domestic unemployment and economic uncertainty has prompted discussions about reducing development assistance (IHME, 2011).

Debt relief is another form of external assistance that can be used for health financing. Many heavily-indebted poor countries (HIPCs) qualify for debt relief through the HIPC Initiative and the Multilateral Debt Relief Initiative (MDRI). In eligible countries, bilateral and multilateral creditors agree to forgive some of their national debt burden which reduces spending on debt service (e.g., interest) and increases the availability of domestic resources for social spending on issues like health and education (IMF, 2012). In a recent report on progress toward Abuja Declaration commitments, WHO suggested that countries can increase their investment in health by "making larger claims on their funds from debt relief" (WHO, 2011, p. 4). Of the 31 countries addressed in the committee's evaluation, 12 qualify for assistance under the HIPC Initiative.

Although external assistance is a primary source of resources for health and HIV/AIDS in developing countries, there are serious concerns about the sustainability of donor funding. The question of whether PEPFAR and other donor funds have led to a displacement of government funding for HIV continues to be an open question empirically (Garg et al., 2012; Lu et al., 2010). In some of the countries visited, the committee heard from a variety of interviewees that partner country governments had diverted domestic resources away from health due to the contributions of donors (166-13-PCGOV; 461-4-USG; 461-15-USG; 461-17-PCNGO; 935-2-USG). Donor dependency and other challenges associated with sustainability of national HIV/AIDS responses are discussed in Chapter 10.

Coordinating Financial Resources for the HIV/AIDS Response

Many developing countries receive external assistance for HIV/AIDS from multiple donors and funding mechanisms (see Chapter 4 for more information). Bilateral and multilateral donors may provide funding directly to partner country governments, while others fund projects implemented by civil society or faith-based organizations. Coordinating these resources can be a challenge for partner country governments, a theme the committee heard often during country visits (935-14-USG; 461-12-PCGOV; 542-6-ML), but several structures have been proposed to improve coordination (Spicer et al., 2010). In the late 1980s, the WHO's Global Programme on AIDS introduced the concept of National AIDS Commissions and as introduced in Chapter 1, the "Three Ones" principles call for National AIDS Coordinating Authorities to take responsibility for coordinating resources for and implementation of national HIV/AIDS responses (HLSP Institute, 2006; Spicer et al., 2010; UNAIDS, 2004). In 2002, the Global Fund introduced the concept of CCMs—broad partnerships with representatives from all sectors, including government, civil society, the business sector, and PLHIV—to coordinate the development of Global Fund proposals and implementation of grants (The Global Fund, 2012). In some countries, one or more of these entities have been integrated, but in others, the existence of parallel coordination structures is a challenge for effective governance of the HIV/AIDS response (331-9-PCNGO) (Spicer et al., 2010).

The way that donor funding is provided can affect the ease of a government's ability to coordinate and manage donor resources. Some donor funding is provided as budget support—this funding goes directly to government treasuries and may or may not be earmarked for specific purposes. Many countries have a basket funding mechanism through which donors contribute resources to a common pool and the government is able to allocate resources as

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needed to support national priorities. Finally, some donors provide project-based funding, which may bypass government accounting and budgeting systems and go directly to implementing partners (USAID, 2007). Donors may provide aid through any or all of these approaches. In some countries, partner country governments struggled to successfully coordinate donor funding, implement projects, and ensure accountability with multiple streams of funding (935-14-USG; 461-12-PCGOV; 396-16-PCGOV; 166-ES). Partner country governments also reported to other interviewees that it was difficult to coordinate the response without control over the money (542-6-ML; 396-16-PCGOV). Across countries, interviewees agreed that funding provided through budget support or basket funding mechanisms was preferable to project-based funding. Many interviewees identified direct budget support as a means for increasing country ownership of the response (NCV-9-USG; 240-21-PCGOV; 240-33-USG; 166-34-PCGOV; 542-6-ML), building capacity (240-5-PCGOV; 240-21-PCGOV; 240-23-PCGOV; 331-4-PCGOV; 166-22-USPS; 166-34-PCGOV; 461-25-ML), and ensuring sustainability (331-4-PCGOV).

Several countries use basket funding to increase coordination of donor resources (and some coordinate resources and activities through a Sector-Wide Approach (SWAp) mechanism, which is a type of basket funding approach (166-13-PCGOV; 166-16-PCGOV; 116-18-PCNGO; 461-19-USG; 935-2-USG; 331-ES; 934-29-USNGO; 934-ES; 196-ES). Interviewees described basket funding as an approach to avoid fragmenting the national strategy by funding streams (461-5-PCGOV), reduce transaction costs associated with funding from and reporting to multiple donors (116-5-PCGOV), and to allow donors to support the priorities set by the government (461-21-ONGO). In one country, basket funds were used to support planning for and delivery of services by district health councils (935-24-USNGO), in another, this mechanism of funding was used to support CSOs that provide HIV/AIDS services (461-19-USG; 461-12-PCGOV). In a few countries, the governments wanted to have partners contribute to a basket fund or pooled funding mechanisms, but donors refused or were wary based on concerns of government mismanagement or inefficient use of the money with the most severe consequence of donor withdrawal from this mechanism where attempted (331-29-PCGOV; 636-4-PCGOV; 461-12-PCGOV; 166-22-USPS; 116-ES).

PEPFAR Inputs

PEPFAR funding is external assistance for partner country HIV/AIDS responses and is delivered in different ways in different countries. PEPFAR funds are not generally contributed toward basket funding mechanisms because the U.S. Congress has placed legislative requirements/limitations on how PEPFAR resources may be used (NCV 9-USG). Since it is difficult to account for how basket funding is used (and report on indicators related to such funding), most PEPFAR mission teams do not provide direct PEPFAR funding to such funding mechanisms. There are some exceptions, where PEPFAR contributes to a funding pool that supports a partner country AIDS coordinating authority or a sector-wide approach to health (116-18-PCNGO; 196-12-PCGOV). As described in Chapter 4, some PEPFAR funding is provided to partner country governments and other local entities directly as prime partners or indirectly as sub-partners. The committee's assessment of prime partner funding from FY 2004 to FY 2010 revealed that during this time period, 9 percent of PEPFAR funding was provided to partner governments as prime partners and 24 percent was provided to nongovernmental entities based in partner countries (including nonprofit organizations, for-profit firms, and academic institutions) (see Chapter 4 for more information about PEPFAR prime partners). In general, PEPFAR has been criticized for "a lack of willingness to coordinate with other donors" (Spicer et al., 2010, p. 3). Interviewees also described coordination with PEPFAR as a challenge (166-10-

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USNGO) but representatives from multilateral and other bilateral donors stated that *"they face the same challenges as each other in terms of coordination"* (166-9-USG/OBL/ML).

Guidance

OGAC has highlighted capacity building for governmental and nongovernmental organizations as one of its strategies to ensure sustainability and country ownership, and some of the key activities for capacity building include improving financial management and accounting systems, as well as strategic information activities that inform financial management (OGAC, 2004, 2008a, 2009f). In particular, the PEPFAR's first Five-Year Strategy called for the strengthening of financial, administrative, and management systems for implementing partners, particularly NGOs and CBOs, to build capacity for delivery of HIV/AIDS services (OGAC, 2004). The capacity building activities will be discussed in this chapter, while the implications for sustainability and country ownership will be discussed in Chapter 10.

The reauthorization legislation authorized the U.S. Treasury "to provide assistance for advisors and partner country finance, health, and other relevant ministries to improve the effectiveness of public finance management systems in partner countries."[13] In its second Five-Year Strategy, PEPFAR identified the long-term (3-5 years) objective of strengthening partner country governance and financing of the health system to contribute to country ownership and sustainability (OGAC, 2009f). "PEPFAR's long-term goal is to see more management and operation of bilateral programs conducted by the countries themselves, with financial support through the Global Fund. In order to promote this goal, PEPFAR is working to improve grant performance, quality, and consistency of services, and transparent and accountable financial management" for both PEPFAR and Global Fund grants (OGAC, 2009e, p. 14-15).

PEPFAR Activities

Technical Assistance/Capacity Building

Across countries, PEPFAR funding has supported TA to partner country governments for planning, budgeting, and coordination (272-17-USG; 116-11-PCGOV). Often, this TA is directed to both national and sub-national levels of the government (240-12-USG; 272-17-USG; 935-14-USG; 116-23-USPS; 166-22-USPS).

PEPFAR partners have also been working to strengthen financial management capacity of partner country NGOs (272-11-PCNGO; 240-12-USG; 240-19-USACA; 935-14-USG; 196-9-USNGO; 542-5-USPS), FBOs (240-26- PCNGO; 196-20-PCNGO), and service providers (331-34-USNGO; 636-15-PCNGO; 934-8-USNGO; 272-3235-PCNGO). Often, partner country governments and other entities will be sub-partners of PEPFAR prime partners that actively work to build capacity for grants and financial management (240-12-USG; 196-9-USNGO; 116-4-USG; 272-16-PCNGO). One prime partner mentioned regular visits to recipient organizations in order to transfer skills about proper procedures for reporting and keep track of funding (NCV-5-USACA). Another prime partner sub-contracts directly with district-level governments in partner countries and works through government systems to build financial and management capacity (NCV-6-USNGO). Other strategies include incorporating health financing topics into the economics curriculum at local universities (116-23-USPS), and mentoring district health personnel and management teams (116-7-USG; 935-12-USPS), and seconding staff to national and regional governments (240-12-USG) .

[13] *Supra.*, note 2 at §204(a), 22 U.S.C. 7621(b)(1).

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Generating and Mobilizing Domestic Resources

Many partner country governments have committed to (240-3-USG; 331-5-ML; 331-15-USG; 587-1-USG; 272-5-PCGOV) or have already begun increasing domestic resources for the HIV/AIDS response (396-2- PCGOV; 331-28-PCGOV). In some situations, the government takes financial responsibility for specific components of the response, such as procurement of ARVs (272-22-USG; 934-25-USPS; 196-10-PCGOV; 542-9-PCGOV) or salaries for health care workers (240-2-USG; 331-15-USG; 636-7-PCNGO; 196-7-PCNGO). However, several interviewees noted that partner country governments are unable to take over total financing for the response (587-14-PCGOV; 587-22-USG), particularly at the current level supported by donors (240-3-USG; 272-3235-PCNGO; 272-36-USG; 461-8-PCGOV; 935-10-USG) and that in some cases, governments are unwilling to contribute more resources due to competing health and development priorities (331-6-CCM; 461-15-USG; 396-18-USG).

Interviewees from partner country governments recognized the need to mobilize existing resources and generate new domestic resources to ensure sustainability of the HIV/AIDS response (461-6-PCGOV; 331-28-PCGOV; 331-29-PCGOV; 240-7-PCGOV; 196-10-PCGOV; 116-5-PCGOV; 116-13-PCGOV). In a few countries, additional resources have been mobilized through requirements that government ministries or agencies dedicate a specific portion of funding to the HIV/AIDS response (331-27-PCGOV; 636-4-PCGOV; 636-11-PCNGO; 166-16-PCGOV). Interviewees identified the need for greater advocacy to government to increase resources (542-8-USNGO; 935-12-USPS; 461-19-USG). Through an international workshop, PEPFAR has supported partner country organizations (governmental and nongovernmental) to advocate for more government investment in the HIV/AIDS response (461-19-USG). In some countries, PEPFAR is training CSOs to advocate for more funding to local government, as well as supporting them to mobilize resources from non-USG sources (196-9-USG).

> *'PEPFAR needs to help countries look at ways to make this a sustainable domestic response, for example how to mobilize domestic resources. The direction is that countries will be required to invest'* (461-5-PCGOV).

In order to generate new domestic resources for the HIV/AIDS response, several countries are exploring or are interested in exploring innovative financing mechanisms such as AIDS trust funds or levies (934-7-PCGOV; 934-10-PCGOV; 934-46-PCGOV; 934-42-PCACA; 331-6-CCM; 331-27-PCGOV; 166-34-PCGOV; 461-5-PCGOV), but the committee found limited evidence that PEPFAR is supporting such mechanisms (see Box 9-3). A few stakeholders mentioned expanding health insurance as another mechanism for increasing resources for health (116-13-PCGOV; 272-5-PCGOV; 116-23-USPS). PEPFAR support for insurance schemes is described below in the section that discusses removing financial barriers to access.

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BOX 9-3
Select Innovative Financing Mechanisms from Committee-Collected Interview Data

Interviewees expressed interest in the following strategies to increase domestic resources available for the health sector and/or HIV/AIDS activities:

- Tax credit/rebate OR increased taxes from private/corporate sector (331-6-CCM)
- Value Added Tax (VAT) to support national health insurance (331-6-CCM)
- National Fund (331-6-CCM); HIV/AIDS fund is necessary so government has a dedicated pot of money for HIV (331-27-PCGOV)
- AIDS trust fund (935-8-PCGOV; 331-40-PCPS); National HIV/AIDS Trust Fund funded through tax on consumer commodities (461-5-PCGOV; 116-16-PCGOV)

Global Fund–Related Support

As described in Chapter 4, PEPFAR and the Global Fund are the largest donors for HIV/AIDS worldwide, and many countries receive both PEPFAR and Global Fund support. Chapter 4 also describes some of the ways in which PEPFAR and Global Fund activities are aligned in partner countries. Interview data revealed that in most countries, partner country governments are the Principal Recipients of Global Fund grants so this money moves through the government systems (116-11-PCGOV; 240-7-PCGOV). Several countries have experienced delays in disbursements or had Global Fund applications rejected due to:

- Lack of absorptive capacity (331-47-USG)
- Pipeline issues (396-15-US NGO)
- Supply chain management/procurement problems (lack of capacity) (542-21-US NGO; 636-3-USG; 166-3-USG; 166-31-USG)
- Failure to meet deadlines (116-11-PCGOV)
- Lack of capacity to complete Global Fund M&E/reporting requirements (166-9-ML)
- Financial management/mismanagement (166-3-USG; 166-31-USG; 934-12-CCM)
- Failure to expend funding in a timely manner (636-16-USG)

> *'One of the challenges in terms of the Global Fund is the issue of grants management by the MOH; moving money is an issue as the MOH sits on the funding'* (636-16-USG).

Turnover within high-level government leadership has also affected ability to access funding, particularly when staff with grant management experience are lost (116-11-PCGOV; 166-22-USPS). To address these issues, PEPFAR mission teams in 19 countries include Global Fund Liaisons (GFLs) or Advisors that support partner country management and implementation of Global Fund resources (240-8-USG; 166-31-USG; 196-6-USG; NCV-11-USG). A portion of the USG's contribution to the Global Fund is withheld each year to support technical assistance with CCMs, NACs, MOHs, and Global Fund Principal Recipients to increase productivity and improve management of and structures related to Global Fund resources (Bilimoria, 2012) (NCV-11-USG; 331-6-CCM; 196-6-USG; 542-5-USPS; 166-3-USG). The Grant Management Solutions (GMS) project, led by Management Science for Health (MSH), provides support in multiple areas, such as "governance and leadership challenges; financial and grants management; procurement and

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supply management; monitoring, evaluation, and reporting; and improving the skills and participation of civil society organizations and local consultants" (MSH, 2009). In 2011, OGAC announced the Country Collaboration Initiative, through which additional funding was available to PEPFAR mission teams to increase coordination and collaboration with Global Fund–supported activities within countries and "to optimize Global Fund grant performance" (Goosby, 2011; OGAC, 2012b, p. 60).

The committee heard about specific examples of Global Fund–related support during interviews with partner country stakeholders. In one country, PEPFAR supports the salary of a Global Fund coordinator who works with various departments in the MOH that implement Global Fund–supported projects. This coordinator ensures that everyone stays on schedule and that reporting deadlines are met (116-11-PCGOV). In another country, a PEPFAR partner helped the MOH set up a Global Fund Management Unit to support the financial management, monitoring and evaluation, and supply chain management of Global Fund grants (166-22-USPS). PEPFAR funding also supports the secondment of technical staff that work directly with the MOH staff in the Global Fund Management Unit (166-22-USPS; 166-31-USG). In some countries, staff from PEPFAR mission teams sit in on or are members of the Global Fund CCM (331-6-CCM; 636-3-USG; 934-12-CCM; 196-26-USG; 166-31-USG; 396-12-USG).

PEPFAR has supported the development of Global Fund proposals and applications (240-20-ML; 331-6-CCM; 331-47-USG; 542-21-USNGO; 116-8-USG; 196-ES). PEPFAR has also supported the strengthening of systems and quality necessary to implement programs with Global Fund resources (331-47-USG), including CCMs (587-6-CCM; 240-12-USG; 934-12-CCM). In some countries, PEPFAR supports capacity building of NGOs that are Principal Recipients of Global Fund money (240-12-USG; 240-29-USNGO; 542-2-USG).

In addition to supporting partner countries, the USG, through OGAC/PEPFAR, has been instrumental in the formation of the Global Fund and the structures through which it operates (NCV-16-USG). The USG holds a permanent seat on the board of the Global Fund, which is currently held by Ambassador Eric Goosby. PEPFAR provides "critical guidance to and oversight of" the organization (Bilimoria, 2012, p. 1416). More recently, OGAC has established a PEPFAR-funded position based in Geneva to serve as a liaison between PEPFAR and the Global Fund to assist with day-to-day coordination (NCV-21-ML). PEPFAR has also been working with the Global Fund to provide country information to facilitate decision making, since PEPFAR has a greater presence on the ground in countries through PEPFAR mission teams (NCV-11-USG).

Tracking Resources

The ability to measure and track government expenditure on health allows governments to be transparent about resource allocation and "identify opportunities to improve resources flows" (OGAC, 2009f, p. 21). Access to this information enables civil society to hold governments accountable, but the data on government health spending are often incomplete, of poor quality, or unavailable (IHME, 2011). At least 15 PEPFAR countries (out of 31) have costed national HIV/AIDS plans (WHO, 2012a). However, in several countries, interviewees identified the lack of expenditure and/or costing data as a challenge to planning and sustainability (331-10-PCGOV; 587-6-CCM; 935-4-PCGOV; 166-5-USG).

In recent years, PEPFAR has increased support for partner country governments to quantify expenditures and project funding needs through National Health Accounts (NHAs), National AIDS Spending Assessments (NASAs), costing efforts, and GAP analysis (Goosby,

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2012b; Holmes et al., 2012; OGAC, 2009f). PEPFAR partners have supported costing and modeling efforts that have contributed to governments to project costs and resource needs (240-12-USG; 331-10-PCGOV; 587-7-PCGOV; 587-10-USG; 272-22-USG; 272-36-USG; 396-16-PCGOV; 935-2-USG; 461-15-USG; 934-25-USPS). Some of these efforts have contributed to increased partner country capacity to forecast procurement needs for ARVs and other commodities (331-10-PCGOV; 272-1-USG; 272-20-PCNGO). PEPFAR supported-partners have also provided training and technical assistance to build capacity for partner country governments to track health and HIV/AIDS expenditures through NHAs or NASAs (587-10-USG; 116-23-USPS; 461-15-USG). However, a specific country example was described as a cyclical problem with many of those trained in data collection for NHAs had left the MOH and frequent turnover made it difficult to institutionalize the NHA process and use of the data (116-23-USPS).

Interviewees frequently mentioned the lack of transparency regarding PEPFAR funding as a challenge for understanding HIV/AIDS expenditures in partner countries. Partner country governments have been frustrated by not knowing where the PEPFAR money was going (240-5-PCGOV; 240-7-PCGOV; 240-20-ML; 331-4-PCGOV; 331-10-PCGOV; 542-6-ML; 935-8-PCGOV; 116-2-USG; 116-16-PCGOV). Some interviewees wondered how the government could be expected to hold implementers accountable if they did not know where the money was going (935-8-PCGOV; 461-11-PCGOV). Interviewees described challenges in tracking PEPFAR expenditures by implementing partners (331-4-PCGOV; 116-16-PCGOV) and for particular services/activities (240-5-PCGOV; 240-7-PCGOV; 240-20-ML; 331-4-PCGOV; 331-10-PCGOV; 116-16-PCGOV; 935-8-PCGOV). They want to know more than what's been planned in the COPs—they want to know where (geographically) the money is going and what services are being supported so that they can identify unmet needs. This has opened the door for increased dialogue with partner country governments (NCV-9-USG).

In at least one country, this situation was reversed; the PEPFAR mission team described difficulties in planning activities due to lack of transparency from the partner country government (636-3-USG). Representatives from other donors and multilateral organizations stated that donors other than the USG often are not transparent with the partner country governments about the amount of funding donors will provide (331-5-ML; 587-2-USG), and acknowledged instances where the partner country government is also not transparent about the amount of money it will invest in health, specifically the HIV/AIDS response until they know what external donors will commit in terms of funding its national priorities.

Removing financial barriers to access

Direct payments, or payment required for a service at the time it is delivered, are one of the largest barriers to access to health services. To reduce reliance on direct payments, governments should encourage risk-pooling, prepayment approaches in which "payments made in advance of an illness, pooled in some way and used to fund health services for everyone who is covered—treatment and rehabilitation for the sick and disabled, and prevention and promotion for everyone" (WHO, 2010e, p. xiv; Xu et al., 2007). In some countries visited by the committee, access to HIV/AIDS services is free (240-15, 196-17; 935-12; 935-13; 636-4-PCGOV), but in others a fee is assessed in order to acquire the drugs needed to survive, serving as a financial barrier to access (240-15, 935-19; 396-25; 934-1516). Transportation costs were also described as a financial barrier for accessing services (935-19; 396-25); it was seen that there was a large uptake of services when the fees were eliminated (240-1).

Some PEPFAR countries have or are moving toward national health insurance programs (331-5-ML; 240-12-USG; 272-5-PCGOV; 272-20-PCNGO; 166-13-PCGOV), but these are not always sufficient to

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reduce financial barriers to access (WHO, 2010e). In Rwanda, the government has implemented a community-based insurance scheme called *Mutuelles* which has improved utilization of maternal and child care services and reduced catastrophic household spending on medical expenses (Lu et al., 2012). Other PEPFAR partner countries rely on the private sector to provide access to insurance (116-23-USPS) or have a mixed system where private insurers cover some of the population, and the government covers the poor (396-4-PCGOV). However, HIV/AIDS treatment or ARVs are not always covered through these insurance schemes (331-6-CCM; 396-16-PCGOV) and PLHIV struggled to pay the monthly premiums and this was a barrier to accessing care (331-6-CCM; 331-32-PCNGO; 331-38-USPS).

PEPFAR is supporting access to insurance in several partner countries by supporting implementation of national insurance schemes (240-12-USG), piloting social insurance strategies (240-12-USG), piloting a membership-managed insurance fund (935-14-USG), piloting group insurance scheme (935-14-USG), costing of health services for incorporation in insurance benefits (396-16-PCGOV), or exploring potential insurance providers (636-4-PCGOV).

PEPFAR Achievements

In few countries, stakeholders have been able to utilize information from PEPFAR-supported NHAs and NASAs for policy decisions and evidence-based advocacy (116-23-USPS). In one country, NHA data have contributed to an understanding of the source of health resources and affected policy decisions regarding resource allocations (116-23-USPS). Data from NHAs reflected low rates of insurance contribution and stakeholders have used this information to advocate that employers should contribute more to the health of their employees (116-23- USPS). PEPFAR-supported costing studies in one country have also improved the government's ability to plan and budget (935-2-USG). PEPFAR has supported capacity building for financial management and resource mobilization at multiple levels and across sectors. As a result of increased capacity, local implementing partners have transitioned from sub-partners to prime partners and have received direct PEPFAR funding in a few countries (NCV-5-USACA; NCV-6-USNGO). However, support to improve financial management capacity and accountability is still needed in many countries. Interviewees identified the need for increased financial management capacity at national (240-3-USG; 331-30-USPS; 166-13-PCGOV; 461-12-PCGOV; 636-16-USG) and sub-national levels (240-19-USACA; 116-23-USPS; 196-13-OGOV; 196-28-USG).

Conclusion: Although there are nascent efforts in PEPFAR for costing of services and projecting of needs to help countries develop a costed HIV/AIDS response, PEPFAR has not yet systematically implemented assistance for partner countries to develop resource mobilization plans, conduct costing activities and resource projections, or identify funding needs.

HEALTH INFORMATION

Background and Context

A health information system (HIS) is a set of components and procedures organized to generate sound and reliable health information "to enable decision-makers at all levels of the

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health system to identify problems and needs, make evidence-based decisions on health policy and allocate scarce resources optimally" (WHO, 2010c, p. 44). In addition to data generation, the key functions of an HIS are data compilation, analysis and synthesis, and communication and use of data (WHO, 2010c). Although HISs are sometimes equated with program monitoring and evaluation, an HIS serves broader objectives, such as supporting patient and health facility management, enabling planning, and providing information for situational and trends analyses (WHO, 2010c). However, having an HIS in place is essential for being able to successfully carry out monitoring and evaluation of health programs (WHO, 2010c).

The Health Metrics Network, which helps countries and other partners strengthen HISs for evidence-based decision making, has developed an HIS framework made up of six components broken down into three categories: inputs, processes and outputs. These components include HIS resources, indicators, data sources, data management, information products and dissemination and use of information (see Figure 9-4 below). HIS resources include the legislative environment and resources that are put into the HIS. Indicators are used to measure effectiveness of health systems and should reflect change over time. Data sources for the HIS can vary from facility level information to periodic nationwide surveys, however, gathering the appropriate data can be challenging because it requires coordination across sectors (Health Metrics Network, 2008) (see Figure 9-5). Use of information generated by the HIS can vary from day-to-day operational decisions to longer-term strategic decision making; therefore, having multiple data sources is necessary (see Figure 9-5).

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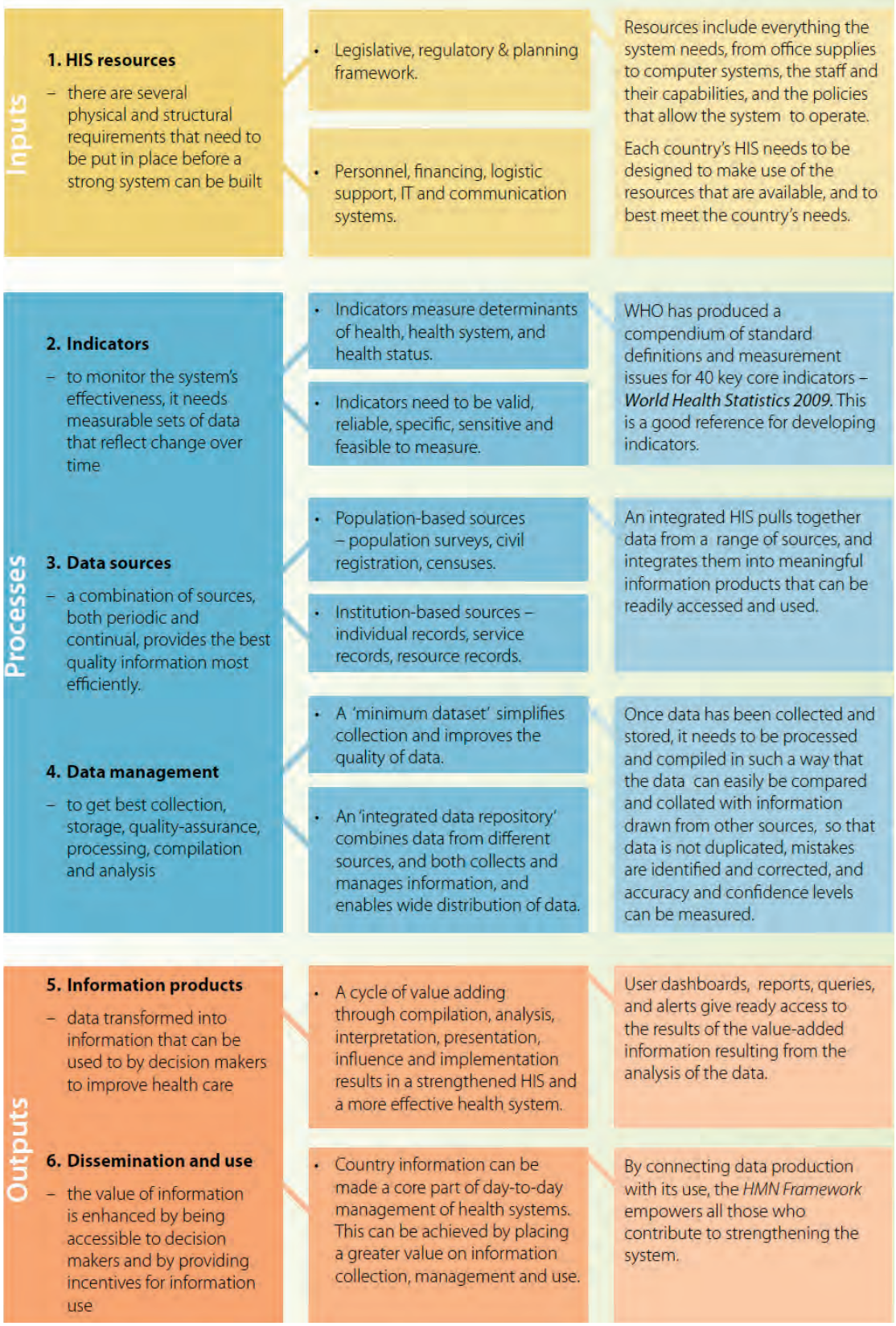

FIGURE 9-4 Components of health information systems (HIS).
SOURCE: (Health Metrics Network, n.d.).

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Data management, information products, and dissemination and use rely heavily on having a skilled workforce to analyze and interpret health information. Sharing and analyzing data for use in decision making can be a challenge when there are limited available resources and capacity for these processes, as is the case in many low-income countries. Because each component of and HIS requires infrastructure and skilled human resources, it is not surprising, that in many countries, HISs continue to be inadequate for meeting stakeholder needs (AbouZahr and Boerma, 2005).

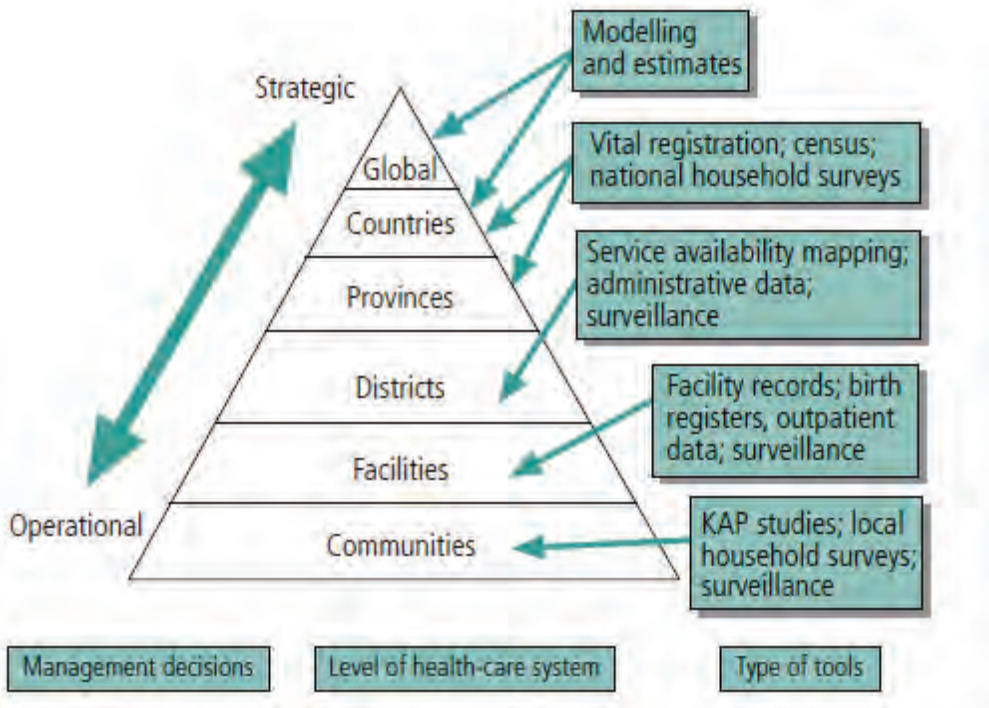

FIGURE 9-5 Data needs and sources at different levels of the health care system.
NOTE: KAP = Knowledge, attitudes, and practices.
SOURCE: (AbouZahr and Boerma, 2005).

PEPFAR Inputs

Guidance

In 2004, PEPFAR's first Five-Year Strategy recognized that in many partner countries, existing HISs lacked the capacity to provide the information necessary to monitor and manage interventions. The strategy called for the design of "country-appropriate HIV management information systems," to be built from the ground up, and for the integration of these systems into regional or national HISs (OGAC, 2004, p. 73). The strategy planned to develop and improve partner country capacity to collect client-level, facility-level, district-level, and surveillance information (OGAC, 2004, p. 73). During PEPFAR I, support for information systems, surveillance, and monitoring and evaluation was referred to as "upstream support" because it was often provided at the national level and benefitted multiple sites and programs (OGAC, 2005b).

From FY 2006 to FY 2011, 4 to 5 percent of total funding for PEPFAR country activities was budgeted for strategic information activities (OGAC, 2005a, 2006b, 2007c,

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2008b, 2010b, 2011d). Until FY 2011, strategic information activities included monitoring and reporting PEPFAR partner results, as well as surveillance, surveys, and efforts to strengthen partner country information systems (OGAC, 2008a, 2009b, 2010a). The FY 2012 COP guidance advised mission teams that activities planned under the strategic information budget code should aim "to build individual, institutional, and organizational capacity in country" for strategic information activities (OGAC, 2011b).

PEPFAR Activities

Through technical assistance/support and capacity building, PEPFAR mission teams and partners have supported the development of national plans/frameworks for monitoring the HIV/AIDS response (240-23-PCGOV; 166-1-USG) and supported and/or participated in national-level M&E working groups (636-1-USG; 587-9-USG; 396-1920-USG) (PEPFAR/Ethiopia, 2007; PEPFAR/Thailand, 2009). PEPFAR has also supported building capacity for national health management information systems (HMIS), national M&E/reporting systems for HIV/AIDS (240-19-USACA; 636-ES), the integration of various national data systems (196-8-ML; 196-11-USNGO) (PEPFAR/Botswana, 2009), and surveys and surveillance (934-21-USG; 331-1-USG; 240-8-USG). See Chapter 11, Knowledge Management, for additional information on PEPFAR's support of surveys and surveillance.

Given the limited capacity for collecting and using strategic information at the onset of and during PEPFAR I, mission teams invested in strategic information capacity building efforts focused on strengthening HIV/AIDS-related M&E and surveillance (OGAC, 2005b, 2006a). Mission teams reported on two PEPFAR indicators to monitor capacity building for strategic information activities (including M&E, surveillance and/or HMIS). From FY 2004-FY 2009, the number of individuals trained and local organizations provided with TA for strategic information activities with PEPFAR support greatly increased (see Table 9-5). Interpretation of these data is difficult as individuals may have been trained or retrained in multiple years and local organizations may have been provided with TA in multiple years.

TABLE 9-5 PEPFAR Indicators Related to Strategic Information/Information Systems

	FY04	FY05	FY06	FY07	FY08	FY09
Maximum countries contributing toward results, n	15	15	28	30	31	31
Number of individuals (in thousands) trained in strategic information (13.2)	9.3	18.0	42.6	38.7	53.0	64.5
Number of local organizations with technical assistance (in thousands) for strategic information activities (13.1)	--	--	3.7	8.5	11.2	14.5

SOURCE: Program monitoring indicators provided by OGAC. Data are presented in thousands.

Most of PEPFAR's investments in strengthening HISs have been related to training and analytics, supply chain issues, human resource information systems, laboratory information management systems, patient record management systems, and electronic health records (see Box 9-4 for examples PEPFAR-supported information systems). There are few examples of integration of these systems, which reflect disciplinary and structural barriers within partner countries, as well as software interoperability issues.

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BOX 9-4
Select Examples of PEPFAR-Supported Information Systems

- Human Resource Information System (HRIS) (240-12-USG; 166-12-USG; 116-7-USG)
- Patient Information Management System (PEPFAR/Botswana, 2009)
- EMRs (166-15-USACA; 166-ES; 116-ES; 116-9-PCNGO; 636-1-USG; 461-13-USACA)
- Commodities/Logistics/Supply Chain Management System (240-2-USG; 240-5-PCGOV; 331-12-USG; 331-43-USG; 331-38-USPS; 166-12-USG). In one partner country, a PEPFAR-supported local partner has developed an electronic medical record system and shared relevant data for drug procurement in order to quantify drug needs (116-9-PCNGO).
- Pharmaceutical Information Management (542-21-USNGO; 240-5-PCGOV)
- Laboratory/Laboratory Management information systems (166-11-USG; 166-12-USG; 331-15-USG; 331-17-USG; 331-38-USPS; 396-22-USG; 636-14-USNGO)

SOURCES: PEPFAR/Botswana (2009) and country visit interview data.

When PEPFAR began, partner country information systems were often fragmented and it was difficult for PEPFAR mission teams to integrate and/or strengthen existing parallel systems. In many countries, PEPFAR originally set up and/or supported parallel information systems rather than strengthening existing national HISs (331-24-PCGOV; 587-2-USG; 537-9-USG; 636-1-USG; 636-9-USACA; 166-4-USG; 166-12-USG; 166-34-PCGOV; 272-27-USG; 461-11-PCGOV; 396-ES), often due to challenges associated with national systems. Interviewees noted that partner country HISs often did not capture the information needed by PEPFAR mission teams to report to OGAC (636-9-USG; 166-1-USG; 166-12-USG; 166-10-USNGO; 272-27-USG; 461-15-USG; 461-20-PCPS; 934-21-USG; 116-12-PCNGO).

Routine monitoring of HIV/AIDS service delivery at the facility or patient level requires more indicators than are collected by many HISs, which also contributed to the development of M&E systems for HIV/AIDS that operate outside broader HISs (166-10-USNGO; 461-11-PCGOV; 934-46-PCGOV). Some of the challenges identified with these parallel systems include: some stakeholders bypassing the national system (461-11-PCGOV; 934-21-USG) and reporting only to funders (461-11-PCGOV), while other partner countries had no way to aggregate the data collected through parallel systems (331-5-ML; 331-10-PCGOV; 331-24-PCGOV).

HIV/AIDS M&E Systems

Although M&E systems represent a subset of an HIS, efforts to strengthen M&E systems can contribute to strengthening the overall HIS. In many partner countries, PEPFAR has supported capacity building at the national level through support for national M&E plans and frameworks (636-18-ONGO; 331-1-USG; 461-16-USG; 934-46-PCGOV) and technical support (636-18-ONGO; 331-1-USG; 166-12-USG; 934-21-USG). PEPFAR has also supported sub-national (636-18-ONGO; 240-12-USG; 461-15-USG), and organization/facility (636-18-ONGO; 196-11-USNGO; 116-12-PCNGO; 166-12-USG) levels to strengthen national M&E systems. The development of M&E guidelines and processes (240-23-PCGOV; 934-21-PCGOV; 196-11-USNGO), data collection and management tools (934-21-USG; 934-46-PCGOV; 196-11-USNGO; 331-23-USNGO; 331-34-USNGO; 935-ES; 587-14-PCGOV) (PEPFAR/Botswana, 2007), data quality management (196-11-USNGO; 636-18-ONGO), and national reporting systems (196-11-USNGO) have also been supported by PEPFAR. Finally, PEPFAR partners also supported M&E training for health care workers (doctors, nurses, etc.), as well as data clerks (636-18-ONGO) and government employees (331-1-USG;

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331-15-USG). See Chapter 11, Knowledge Management, for additional information on PEPFAR's activities related to HIV/AIDS M&E systems.

Health Management Information System (HMIS)

An HMIS provides information to assist in the management and planning of health programs, rather than the delivery of services (WHO, 2004). Although parallel information systems for the collecting and reporting of PEPFAR indicators were created in many countries, PEPFAR has also supported the development and implementation of national health management information systems (HMIS) (396-1920-USG; 196-ES). In the developing world, most HMISs collect only cross-sectional patient data with few systems collecting longitudinal, patient-based data, which can affect the strategic planning and management of health programs. Lack of more comprehensive data reported in a timely manner across sectors, among levels, and from many providers to the central depository in the countries, will also affect program planning and management including efforts for quality assurance or improvement. Many interviewees felt that strengthening national HMISs would improve the availability, quality, and use of data for decision making (934-38-PCACA; 934-46-PCGOV; 240-8-USG; 272-22-USG).

Formats of HMISs in PEPFAR partner countries vary; some are paper-based (116-12-PCNGO; 934-21-USG), some are electronic, and some are a mix (331-15-USG). Transitioning to an electronic HMIS requires significant financial resources (934-21-USG). In several countries, PEPFAR has supported partner country governments to plan for (PEPFAR/Botswana, 2009) and rollout/implement national HMISs (636-1-USG; 116-16-PCGOV; 934-21-PCGOV; 196-11-USNGO; 587-9-USG; 331-3-USG; 240-8-USACA; 240-19-USACA; 240-20-ML) (PEPFAR/Botswana, 2007, 2009). PEPFAR has also supported capacity building for increased or improved workforce capacity for HMIS, such as through *'pre-service training at regional health colleges for health information technicians'* (240-12-USG) or support for in-service training when new systems were initiated (636-1-USG).

As part of strengthening partner country systems, PEPFAR has supported the development of Laboratory Information Management Systems (LIMS), in many cases, introducing electronic LIMSs. PEPFAR has generally supported an incremental approach within partner countries—introducing LIMSs in a few larger laboratories and then gradually expanding to additional laboratories (396-22-USG; 240-16-USG; 636-14-USNGO). For example, in one partner country, PEPFAR supported an integrated LIMS at four labs, expanding to an additional five laboratories the following year (636-14-USNGO). In another partner country, PEPFAR focused on developing a LIMS for hospital laboratories and HIV testing laboratories, working in 10 sites (396-22-USG). In a country with the greatest level of integration described, the LIMS was automated and interfaced to standard software and all databases networked, feeding into a central repository of data to serve not only as backup, but also as a means for data to be available at the national level so that the laboratory services could make informed decisions about procurement and larger policy decisions (636-14-USNGO). To build capacity and manage the LMISs, PEPFAR has provided training for cadres of workers as well as salary support for key LMIS staff (636-14-USNGO; 166-11-USG). For additional information about PEPFAR's efforts related to laboratory strengthening, see the Laboratory section later in this chapter under the section of Medical Products and Technologies.

Integration of Information Systems

Partner countries often have multiple yet separate health information sources. Some interviewees expressed a desire to integrate information, monitoring and evaluation, and

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surveillance systems for HIV and other diseases (636-18-ONGO; 934-46-PCGOV; 331-24-PCGOV; 240-ES; 116-ES; 116-9-PCNGO; 116-16-PCGOV; 935-ES; 196-8-ML), and PEPFAR has provided considerable support to streamline/integrate multiple information/reporting systems (196-ES; 196-11-USNGO; 240-2-USG; 934-10-PCGOV). In one partner country, PEPFAR supported combining parallel district HISs into one national HMIS in order to make data available centrally (331-24-PCGOV). One country's MOH choose to use the HIV information system as a model for bringing together disparate components of health information (196-11-USNGO). However, integration of information systems was not always seen as the best approach (116-16-PCGOV; 196-8-ML). As described by one interviewee, '*Integration would be difficult—there is very different data collected for communicable diseases, like HIV*' (196-8-ML).

Individual Capacity Building

In some countries, SI skills were new competencies introduced in the country's workforce (587-10-USG; 461-16-USG) or were nascent efforts that, even with very little training, made the workers marketable and afforded them different job opportunities (272-3235-PCNGO; 166-12-USG; 587-7-PCGOV). PEPFAR II has supported training for HISs, M&E, and surveillance at all levels: national government (636-1-USG), sub-national levels of the government (396-9-PCGOV; 116-7-USG; 166-7-PCGOV; 331-15-USG) (PEPFAR/Botswana, 2009), and facilities/partners (240-17-PCGOV; 240-8-USG; 396-29-PCGOV; 196-21-PCGOV; 636-15-PCNGO). However, interviewees from at least one country mentioned that due to attrition of staff trained in M&E (M&E skills make them more marketable), they were continuously training (934-21-PCGOV; 934-46-PCGOV). PEPFAR has also provided salary support for key health information positions within national (166-30-ONGO) (PEPFAR/Botswana, 2009) and sub-national institutions (166-15-USACA).

PEPFAR has also supported efforts to strengthen health workforce capacity for M&E, HMIS, surveillance, and use of health information through support for partner country education programs and institutions by supporting the integration of SI skills into pre-service curricula at local universities and colleges (331-1-USG; 331-15-USG; 331-34-USNGO; 240-12-USG) (PEPFAR/Botswana, 2007), MPH programs (934-38-PCACA; 396-55-USG), programs for health information technicians (240-12-USG), certificate programs for HMIS (PEPFAR/Ethiopia, 2007), and supporting the Field Epidemiology and Laboratory Training Programs (see the Workforce building block in this chapter for more information on these programs).

Challenges

Despite PEPFAR's efforts to build national and individual capacity to plan for, collect, manage, and use HIV/AIDS and other health information, interviewees across countries mentioned challenges common to any organization's efforts to strengthen HISs including: inadequate financial resources for HISs (166-5-USG); lack of national level capacity (196-8-ML; 166-1-USG; 461-11-PCGOV; 461-16-USG; 934-46-PCGOV; 396-19-USG; 396-20-USG), which was exacerbated by attrition of skilled/trained employees (934-21-PCGOV; 331-5-ML; 196-1-USG; 396-ES; 272-ES); and lack of national-level commitment (587-25-ML; 636-ES).

Issues related to human resources were also described as challenges for increasing data collection and management, including inadequate number of trained professionals (396-9-PCGOV; 934-46-PCGOV; 587-ES; 461-ES), lack of capacity (skills/knowledge) (461-11-PCGOV; 587-9-USG; 331-34-USNGO), lack of incentives (331-6-CCM; 396-9-PCGOV), and low salaries (331-23-US NGO; 396-9-PCGOV). Interviewees also mentioned infrastructure-related challenges to collecting and managing information, such

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as transportation/roads (636-1-USG), electricity (587-9-USG), internet access (934-21-PCGOV; 116-12-PCNGO), and technology (hardware and software) (934-5-USG; 934-21-PCGOV; 587-9-USG). In some countries, challenges with timely reporting of data from sub-national to national levels impaired the use of data for programs/policies (934-46-PCGOV; 166-12-USG).

Another challenge identified, which was more specific to PEPFAR's approach, was that strengthening HIV/AIDS information systems did not always result in strengthening the overall HIS system (166-12-USG; 461-11-PCGOV; 396-2-USG; 934-25-USPS).

> *"I think that PEPFAR remains constrained by the fact that, and this is changing again, to some extent, but it's still HIV. So still, when you talk about health system strengthening, it's not health system strengthening. And I think that's more obvious here because HIV was pulled out of the health system, in a way. But it's also true in other countries where people have been maneuvered into I think more basically HIV systems that overlap with broader health systems. [..] you can strengthen those, but they're still at the cost of the other systems unless you really look at staffing across the system, look at skill-based, allocation of staffing."* (396-45-USNGO)

However, a contrasting view presented in another country pointed out that, despite the fact that PEPFAR has an HIV mandate, most of the activities of that partner country's mission team SI Technical Working Group were broad health sector strengthening projects (166-12-USG).

PEPFAR Achievements

Despite contributing to parallel systems for collecting health information, PEPFAR has supported capacity building for national information systems across countries and improved the availability of quality information regarding HIV/AIDS (Samb et al., 2009). In several instances, interviewees credited PEPFAR support for improved HMIS (240-2-USG; 240-3-PCGOV; 240-7-PCGOV; 240-20-ML; 461-4-USG; 587-9-USG). As a partner country government and an USG interviewee in the same country stated:

> *'Before PEPFAR, HR capacity was very low, HMIS was very poor, and the laboratory and health system in general was very poor, very weak. PEPFAR has contributed to strengthening the health system.'* (240-7-PCGOV)

> *"Before PEPFAR, HMIS was a challenge—used to be very weak. PEPFAR has helped to strengthen, pilot, and implement a system, which has now been rolled out to almost all facilities. PEPFAR has streamlined all information systems. The government is leading this effort, but PEPFAR has supported the government in leadership at every level."* (240-2-USG)

Over time, there has been a shift in PEPFAR's dialogue around alignment of PEPFAR's M&E system with national HISs. In some countries, interviewees described increased efforts to align PEPFAR monitoring indicators with national HISs (240-20-ML; 331-18-USNGO; 636-9-USACA; 636-18-ONGO; 166-12-USG; 461-18-USG). Interviewees perceived that capacity building for and strengthening of national information systems increased during PEPFAR II (166-22-USPS). As one interviewee

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stated, *'PEPFAR has supported a lot of information systems and better management of data but, "there is still a long way to go"'* (587-9-USG).

> **Conclusion:** Despite initial PEPFAR-specific systems for program monitoring data, PEPFAR has worked with partner country governments to integrate and strengthen Health Information Systems, including achievements in strengthening partner country Laboratory Management Information Systems. However, ongoing support to strengthen partner country health information systems, and better alignment and integration with those systems, is needed to enhance timely data availability and quality for strategic program planning, resource allocation, and commodities procurement.

MEDICAL PRODUCTS AND TECHNOLOGIES

Commodities and Supply Chain Management

Background and Context

Consistent access to diagnostic reagents, medicines, vaccines and technologies requires a system of links that run from unprocessed raw materials to the delivery of the finished product commonly referred to as a supply chain (CSCMP, 2012). Supply chain management encompasses operational components such as quantification, procurement, inventory management, distribution, and data collection and reporting, as well as "the coordination and collaboration of staff, levels, and functions" (USAID DELIVER Project, 2011, p. 1). Effective supply chains require "an understanding of patient needs, captured in forecasts and supply plans, which then guide procurement and supply to satisfy those needs" (SCMS, 2012, p. 4).

However in many settings in low-income countries, considerable challenges remain in achieving and maintaining well-functioning supply chain management, from the macro level (infrastructural issues including laws related to importation of commodities, regulatory policies and approaches for pharmaceuticals, and local drug manufacturing capacity that could play a contributory role to sustainability) to the micro level (poor tracking systems within clinical care systems). It is critically important to manage the supply chain effectively and efficiently, particularly with a lifelong infection like HIV, to ensure that there are no stockouts of essential medications such as antiretrovirals and other drugs to prevent or treat opportunistic infections. In order to avoid such stockouts and emergency shipments, accurate planning and forecasting must be established; requiring coordination, transparent financing, and procurement plans for the necessary goods (Lalvani et al., 2010). A practical and efficient warehouse must also be constructed in a methodical way to hold the stocks of quality goods (e.g. HIV test kits, ARVs, etc.) in the appropriate temperature and settings (USAID DELIVER Project, 2011). In-country technical capacity for freight and logistics will help maintain an organized schedule of deliveries, and coordination between supply-chain managers and program-service managers can create continual availability of the necessary commodities on a regular and consistent basis (OGAC, 2011c). Accountability is also necessary to protect against the misuse of products and ensure product reliability. Procurement capabilities should be coordinated with national programs to create a central and transparent system, and with an accurate amount of supplies in place at all times, there will be support among HIV/AIDS patients on treatment for optimal

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adherence of the drugs (OGAC, 2011c). A smooth transition from one link in the supply chain management system to the next helps to ensure proper product delivery and use, creating more successful HIV/AIDS programs through the areas that need it the most.

PEPFAR Inputs

Guidance The first PEPFAR Five-Year Strategy articulated the necessity of effective supply chain management in order to provide diagnostic reagents, drugs, materials, and equipment for HIV/AIDS programs. In order to support effective supply chain management, the strategy committed to training supply chain management personnel and strengthening health logistics systems. The strategy also pledged to coordinate supply chain management systems to "reduce and eliminate diversion, counterfeiting, and the sale of HIV/AIDS products and supplies on the black market" (OGAC, 2004, p. 12-13).

The FY 2009 COP guidance identified improving commodity distribution and control as key area for building capacity in both the governmental and nongovernmental sectors (OGAC, 2008a). The FY 2012 COP guidance identified the following activities to address multiple components of the supply chain to ensure continued availability of key health commodities:

- Support/encourage the development and implementation of a national strategic plan for supply chain.
- Contribute to an adequately trained and well-performing supply chain workforce, including capacity building activities and transitioning roles and responsibilities to partner government counterparts.
- Coordinate with other donors, and leverage other donor inputs, for supply chain system strengthening activities.
- Improve the availability and use of information within the supply chain system for decision making (OGAC, 2011b).

PEPFAR Activities

Historically, PEPFAR procurement of ARVs enabled the rapid scale-up of HIV treatment. To address challenges with partner country supply chain infrastructure and systems, in 2005, OGAC established the Supply Chain Management System (SCMS) (SCMS, 2012). SCMS is managed by the Partnership for Supply Chain Management, a nonprofit organization that consists of two managing partners (JSI Research and Training Institute, Inc. and Management Sciences for Health) and 13 member organizations from the non-profit, commercial private, and academic sectors (PFSCM, 2010) (see Box 9-5). SCMS works in three areas:

1. Procurement and distribution of essential medicines and supplies
2. Technical assistance to strengthen existing supply chains
3. Collaboration with in-country and global partners to coordinate efforts in these areas (PFSCM, 2010)

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BOX 9-5
SCMS Member Organizations

- Booz Allen Hamilton
- Crown Agents USA, Inc. (CA-USA)
- i+solutions
- JSI Research & Training Institute, Inc.
- Management Sciences for Health
- The Manoff Group
- MAP International
- North-West University
- Northrop Grumman
- RTT
- UPS Supply Chain Solutions
- Voxiva
- 3i Infotech

SOURCE: (PFSCM, 2010).

Capacity building for supply chain management To build partner country capacity for supply chain management, SCMS provides technical assistance for the strengthening of local supply chains (Jamieson, 2011). SCMS is working with partner country educational institutions in seven countries to "incorporate supply chain management modules into health worker training curricula" (SCMS, 2012, p. 6).

Interviewees described various PEPFAR-supported capacity building efforts at many levels of the supply chain. At the national level, PEPFAR partners have provided support for the development and implementation of policies related to pharmaceuticals (such as National Medicines Policies and Essential Medicines Lists) (636-20-PCGOV; 542-5-USPS; 196-11-USNGO) and for strengthening regulatory authority to ensure drug quality (542-21-USNGO; 240-12-USG). PEPFAR is supporting human resource capacity at all levels of the supply chain system, from providing direct salary support (116-2-USG; 934-5-USG; 934-25-USPS) and technical assistance (636-20-PCGOV; 331-38-USPS; 116-2-USG; 116-4-USG; 166-3-USG; 461-18-USG; 587-6-CCM; 587-10-USG; 935-9-USG; 542-21-USNGO) for key national-level positions (e.g., in the MOH) to training, supportive supervision, and mentorship for health care workers (636-20-PCGOV; 240-12-USNGO; 461-13-USACA; 331-30-USPS) including study tours abroad to learn skills for proper supply chain management (587-11-PCGOV). PEPFAR partners have contributed to strengthened supply chains through development of standard operating procedures and dissemination of best practices (240-29-USNGO; 542-21-USNGO; 636-20-PCGOV; 166-32-USPS; 331-38-USPS) (Ministry of Health, 2012). In several countries, PEPFAR is supporting the National/Central Medical Stores to improve warehousing/storage capacity (461-13-USACA; 461-15-USG; 166-6-USG; 166-32-USPS; 935-9-USG). PEPFAR has also supported innovative distribution systems (934-25-USPS) and purchased vehicles to expand distribution capacity (240-5-PCGOV; 934-25-USPS).

PEPFAR partners have also supported data collection and data management activities to monitor the drug supply and provide information for quantification (166-6-USG), including electronic data systems for capturing and reporting data (636-20-PCGOV; 542-21-USNGO; 331-38-USPS; 166-32-USPS). PEPFAR support for information needed for forecasting/procurement is also discussed in the Information building block in this chapter.

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Procurement In most countries, PEPFAR funding supports procurement of ARVs in coordination with other donors and domestic resources, but these types of arrangements vary. In a few countries visited by the committee, Global Fund procures first-line ARVs and PEPFAR procures second-line ARVs and/or pediatric formulas (240-5-PCGOV; 587-13-USG; 587-22-USG; 461-13-USACA). In most countries, the majority of ARVs are procured with Global Fund (116-11-PCGOV; 331-16-USG; 935-4-PCGOV) or PEPFAR (461-4-USG; 166-13-PCGOV; 396-4-PCGOV; 396-7-PCGOV) funding, but in some countries, the government has taken partial to complete responsibility for funding ARVs (636-4-PCGOV; 542-2-USG; 542-9-PCGOV; 272-1-USG; 196-10-PCGOV; 934-25-USPS).

In 2011, 71 percent of ARVs funded by PEPFAR were delivered by SCMS (SCMS, 2012). Interviewees from many countries mentioned that SCMS was responsible for procurement of ARVs (240-5-PCGOV; 587-6-CCM; 166-6-USG; 166-8-USG; 461-13-USACA; 461-17-PCNGO; 396-4-PCGOV; 396-41-PCGOV; 934-12-CCM; 934-25-USPS). In several countries PEPFAR was also supporting procurement of other commodities such as diagnostic reagents, condoms (587-8-PCGOV; 196-6-USG; 934-10-PCGOV; 934-25-USPS; 116-19-PCACA; 166-11-USG), and drugs to treat TB and other opportunistic infections (166-6-USG; 396-7-PCGOV; 396-41-PCGOV; 934-12-CCM). In some countries, partner country governments have been unable to demonstrate adequate forecasting or quantification for procurement of drugs (and other supply chain issues) (331, 587, 116, 934, 935), so the Global Fund has refused to release funding (636-3-USG; NCV-11-USG). Interviewees from some countries described PEPFAR as a 'safety net' for the government and gave examples of where PEPFAR has provided buffer stocks or emergency procurement to address shortages or stockouts (331-43-USG; 587-1-USG; 587-22-USG; 166-31-USG; 272-1-USG; 272-5-PCGOV; 272-22-USG; 934-5-USG; 116-2-USG; 935-14-USG). Shortages or stockouts may occur due to partner country government financial crises (934-25-USPS), failure to adequately project needs, plan, or procure (331-43-USG; 587-22-USG); temporary situations when demand exceeds supply (272-1-USG), delays in disbursements from the Global Fund or other donors (196-6-USG; 116-2-USG; 934-5-USG; 587-22-USG), or when support for procurement transitions from one donor to another (934-5-USG). In some countries, PEPFAR/SCMS have set up procurement and supply chain systems outside of partner country systems (166-22-USPS). In one country, interviewees noted that the supply chain for antiretroviral therapy must be separate and parallel to the national system in order for ARVs to reach treatment sites (116-18-PCNGO).

Partner country challenges Across partner countries, interviewees described common challenges with procurement and supply chain management (196-7-PCNGO; 196-26-USG; 331-43-USG; 636-9-USACA; 116-2-USG; 116-16-PCGOV; 166-6-USG; 166-31-USG; 461-17-PCNGO; 461-25-ML; 542-21-USNGO). In several countries, insufficient quantification and forecasting, often due to the unavailability of necessary data, threatened the consistent availability of drugs and commodities and had resulted in stockouts (116-16-PCGOV; 331-12-USG; 331-28-PCGOV; 331-38-USPS; 272-20-PCNGO; 461-14-USG; 542-21-USNGO). Stakeholders in nearly all countries struggled with stockouts, constraining the delivery of treatment for HIV (934-17-PCGOV; 461-7-PCNGO; 461-8-PCGOV; 116-12-PCNGO; 587-1-USG; 587-22-USG; 587-18-PCGOV; 331-43-USG), TB (542-21-USNGO), and opportunistic infections (240-25-PCGOV; 587-18-PCGOV; 196-17-PCGOV; 461-17-PCNGO; 116-12-PCNGO; 166-34-PCGOV); and reducing access to HIV testing (116-12-PCNGO; 934-17-PCGOV; 461-15-USG; 166-5-USG; 166-9-USG/OBL/ML; 166-32-USPS; 240-33-USG). Challenges with procurement at the national level, including corruption (542-2-USG; 542-3-USG; 542-11-PCNGO), also threatened effective supply chain management (542-21-USNGO; 331-30-USPS). In some countries, this was attributed to government regulations or processes that caused delays for timely procurement (331-17-USG; 331-28-PCGOV; 542-21-USNGO; 240-3-USG; 240-8-USG; 240-33-USG; 240-21-PCGOV). Weak capacity for financial management was mentioned as a barrier for every step of the supply chain (331-2-USG; 166-6-USG; 166-31-USG; 116-2-USG). Commodity storage (240-24-USG; 331-38-USPS; 116-2-USG), distribution (331-6-CCM; 331-38-USPS; 166-6-USG; 166-31-

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USG; 542-21-USNGO), and logistics (e.g., tracking inventory) (331-17-USG; 166-11-USG; 166-22-USPS) were also mentioned as challenges. Although national supply chains were often inadequate or overwhelmed, parallel supply chains serving different donors or disease programs were described as inefficient and resulted in coordination challenges among partners and donors (396-18-USG; 396-21-USG; 396-57-USG; 636-9-USACA; 331-12-USG; 331-38-USPS; 542-21-USNGO).

PEPFAR Achievements

Across countries, PEPFAR has improved supply chain management capacity for forecasting, procurement, and distribution (240-2-USG; 240-3-USG; 240-5-PCGOV; 240-12-USG; 331-38-USPS; 587-10-USG; 935-9-USG; 935-14-USG; 272-20-PCNGO; 934-5-USG; 934-25-USPS). PEPFAR's efforts to strengthen partner country supply chains have also had a positive impact on Global Fund programs (240-12-USG; 331-38-USPS; 587-6-CCM). In addition to increasing access to HIV-related commodities (e.g., ARVs, condoms) (272-25-USG; 116-9-PCNGO; 240-2-USG), PEPFAR has also contributed to increased availability of medicines and commodities for other health issues (166-4-USG). When partner countries have faced stockouts due to supply chain constraints or delays in disbursements from the Global Fund and other donors, PEPFAR has often provided buffer stocks of medicines and commodities on an emergency basis to prevent interruption of treatment and ensure continuity of care (935-8-PCGOV; 935-17-USG; 587-1-USG; 461-10-PCNGO; 116-9-PCNGO; 240-7-PCGOV; 331-43-USG). PEPFAR partners have been actively involved in convincing Ministries of Health to use the most effective first-line ARV regimens (196-11-USPS; 272-20-PCNGO).

> **Conclusion:** PEPFAR has improved the capacity of partner country governments to quantify, forecast, procure, store/warehouse, distribute, and track commodities; but challenges to assure consistent and reliable supply chain functioning remain in many countries. These challenges are a common issue across countries and are not PEPFAR-specific. Reliable supply chains will be critical for sustainable and cost-efficient HIV/AIDS responses and avoid disruptions to clinical care and treatment of people living with HIV/AIDS.

Laboratory Infrastructure

Functioning laboratories, with the capacity to run screening, diagnostic, and clinical laboratory tests, are fundamental to the monitoring and management of patients with HIV/AIDS and other diseases (Gershy-Damet et al., 2010). When PEPFAR began, access to and quality of laboratory services was a major challenge in partner countries (Cohen, 2007; Sturchio and Cohen, 2012). Lack of prioritization and leadership (e.g., no national policies or strategic plans), inadequate workforce capacity, and dilapidated infrastructure affected laboratory systems with limited available resources. In many countries, limited laboratory capacity was "a major barrier" or "rate-limiting step" for the scale-up of HIV/AIDS and other health services required to meet the Millennium Development Goals (Birx et al., 2009, p. 849; WHO, 2008, p. 1).

Within the last five years, global stakeholders have declared their commitment to strengthening laboratory systems, particularly in Africa. In January 2008, 33 countries and 3 multilateral organizations signed the Maputo Declaration on Strengthening of Laboratory Systems. The Maputo Declaration called on national governments to prioritize support to laboratory systems through development of a national laboratory policy, a national laboratory strategic plan, and a department of laboratory systems within Ministries of Health to address the

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challenges that limit scale-up of services for tuberculosis, malaria, and HIV diagnosis and care. The Maputo Declaration also called on donors and partners to support these national efforts and coordinate and collaborate with each other to support the strengthening of laboratory systems including efforts to build public-private partnerships (WHO, 2008).

PEPFAR Inputs

Guidance During PEPFAR I, support for laboratory services focused on the provision of basic services needed for HIV diagnosis and care (Justman et al., 2009). PEPFAR's first Five-Year Strategy committed to improving laboratory capacity for HIV testing and treatment monitoring, as well as training laboratory technicians in order to quickly expand HIV/AIDS services (OGAC, 2004). COP guidance through 2009 highlighted a programmatic focus on increasing the availability and quality of laboratory services at various levels of the health system in partner countries through purchase of equipment and commodities, provision of quality assurance, staff training, and technical assistance (OGAC, 2008a). During PEPFAR II, the focus shifted to strengthening of broader laboratory systems and included activities such as "quality management systems, equipment maintenance, training, and infrastructure" (Justman et al., 2009, p. S30). PEPFAR country programs were directed to focus on increasing quality assurance of laboratory services, efforts to achieve accreditation, training for laboratory technicians and management, and the transition of laboratory programs to in-country partners (OGAC, 2011b). The second Five-Year Strategy recognized the potential to leverage increased laboratory capacity for other diseases, such as malaria and TB, and highlighted support for laboratories as one of PEPFAR's contributions to the GHI (OGAC, 2009f).

PEPFAR indicators for laboratory infrastructure During PEPFAR I, laboratory-related indicators were limited to the following output measures:

- Number of laboratories with capacity to perform HIV tests and CD4 tests and/or lymphocyte tests,
- Number of individuals trained in laboratory-related activities, and
- Number of tests performed at USG-supported laboratories in the areas of HIV testing, TB diagnostics, syphilis testing, and HIV disease monitoring (OGAC, 2007b)

In 2009, OGAC released the Next Generation Indicator Guidance, including two slightly modified indicators for laboratory infrastructure to reflect this new focus:

- Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests and
- Percent of testing facilities (laboratories) that are accredited according to national or international standards (OGAC, 2009c).

PEPFAR's reauthorization legislation included a new target for the training of 140,000 health care workers, including laboratory experts (Birx et al., 2009).

Funding OGAC has defined a budget code for laboratory strengthening activities (see Box 9-1). From FY 2005 to FY 2011, PEPFAR provided more than $1 billion for laboratory strengthening (OGAC, 2005a, 2006b, 2007c, 2008b, 2010b, 2011d, 2011e).

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PEPFAR Activities

PEPFAR has supported a wide range of laboratory strengthening activities that have been described in the published literature and by country visit interviewees. In several countries, PEPFAR supported the development of National Laboratory Strategic Plans (240-21-PCGOV; 331-3-USG; 116-19-PCACA; 396-22-USG), as well as guidelines and standard operating procedures (196-10-PCGOV; 116-19-PCACA; 272-13-USG). PEPFAR support for laboratory strengthening has often been aligned to partner country strategic plans and in many countries, PEPFAR partners have assisted countries with the development of laboratory strategic plans (396-22-USG; 396-55-USG; 240-21-PCGOV; 331-17-USG).

Interviewees confirmed PEPFAR support for the construction and refurbishment of partner country laboratories at multiple levels, including national reference labs (587-7-PCGOV; 587-13-USG; 240-2-USG), provincial or regional labs (240-12-USG; 240-21-PCGOV; 166-11-USG; 934-5-USG), and local labs (461-3-USG). For example, in Ethiopia, PEPFAR has supported the National Laboratory Strategic Plan of the Ethiopian Health and Nutrition Research Institute (EHNRI) through renovating and equipping the national reference laboratory, four regional hospitals, and six regional laboratories (Justman et al., 2009). In many countries, PEPFAR has provided lab equipment (240-2-USG; 934-24-PCGOV; 934-28-PCNGO; 396-22-USG; 396-41-PCGOV; 116-19-PCACA; 331-16-USG) and supplies such as reagents, test kits, and consumables (166-11-USG; 240-12-USG; 461-8-PCGOV; 934-2-USG; 934-21-USG; 934-25-USPS; 934-28-PCNGO).

PEPFAR funds several partners to provide TA for laboratory systems across partner countries. Several interviewees described PEPFAR support for laboratory information systems (331-15-USG; 166-11-USG; 396-22-USG) with widespread reports of PEPFAR efforts to establish quality management, quality assurance, and quality-improvement programs (240-19-USACA; 240-21-PCGOV; 166-4-USG; 272-12; 461-19-USG; 396-2-USG; 396-22-USG; 934-5-USG). Interviewees in several countries reported participation in PEPFAR's Strengthening Laboratory Management Towards Accreditation Initiative (SLMTA) and other PEPFAR support for lab accreditation (116-19-PCACA; 166-11-USG; 934-28-PCNGO; 331-15-USG; 461-18-USG; 396-2-USG; 396-22-USG) (see Box 9-6).

PEPFAR has supported human capacity development for laboratory skills through South-to-South workshops in Nigeria and the CDC has opened the African Center for Integrated Laboratory Training in South Africa (Justman et al., 2009). Interviewees from nearly all of the countries that the committee visited described PEPFAR support for strengthening human resources for laboratory systems, including pre-service training (116-7-USG; 116-19-PCACA; 166-6-USG; 166-11-USG; 272-13-USG; 461-18-USG) and in-service training (240-2-USG; 240-15-USG; 240-19-USACA; 331-15-USG; 331-16-USG; 331-28-PCGOV; 116-19-PCACA; 166-11-USG; 272-13-USG; 461-13-USACA; 396-18-USG; 934-28-PCNGO).

Although data were only available for some years of the program, PEPFAR indicators reported to OGAC clearly reflect an increased emphasis on laboratory strengthening. During PEPFAR I, the number of individuals trained in the provision of lab-related activities increased from 3,131 in FY 2004 to 60,037 in FY 2009. In the same time period, the number of testing facilities in partner countries with capacity to perform clinical lab tests increased from 282 to 7,211 (see Figure 9-6).

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BOX 9-6
PEPFAR'S Laboratory Systems Strengthening Initiatives Over Time

In 2007, PEPFAR launched a laboratory systems strengthening initiative to be implemented by a public-private partnership with BD, the CDC, national ministries of health, and national reference laboratories (OGAC, 2007a; Sturchio and Cohen, 2012). This approach to strengthening laboratories includes technical assistance (training and mentorship), process improvement related to quality management and specimen referrals, curriculum and leadership development, and strategic facilitation of planning meetings and project management (Thompson, 2011). As of July 2012, the initiative had been launched in Uganda, Ethiopia, Mozambique, and South Africa, with plans to expand to four more countries (Zeff, 2012).

In 2009, the CDC launched the Strengthening Laboratory Management Toward Accreditation (SLMTA) program, a series of workshops designed to improve laboratory management through a task-based framework and mentoring kit that provides information on the day-to-day tasks necessary for ensuring quality services and achieving accreditation (Yao et al., 2010).

In 2009, PEPFAR partnered with the WHO Regional Office for Africa (WHO/AFRO) to launch a five-step framework to help African laboratories achieve accreditation through a star ranking system (Wenner, 2009). The accreditation process involves assessing laboratories and verifying the implementation of laboratory standards to ensure that services are "accurate, traceable, and reproducible" (Gershy-Damet et al., 2010; Palen et al., 2012; WHO, 2007a).

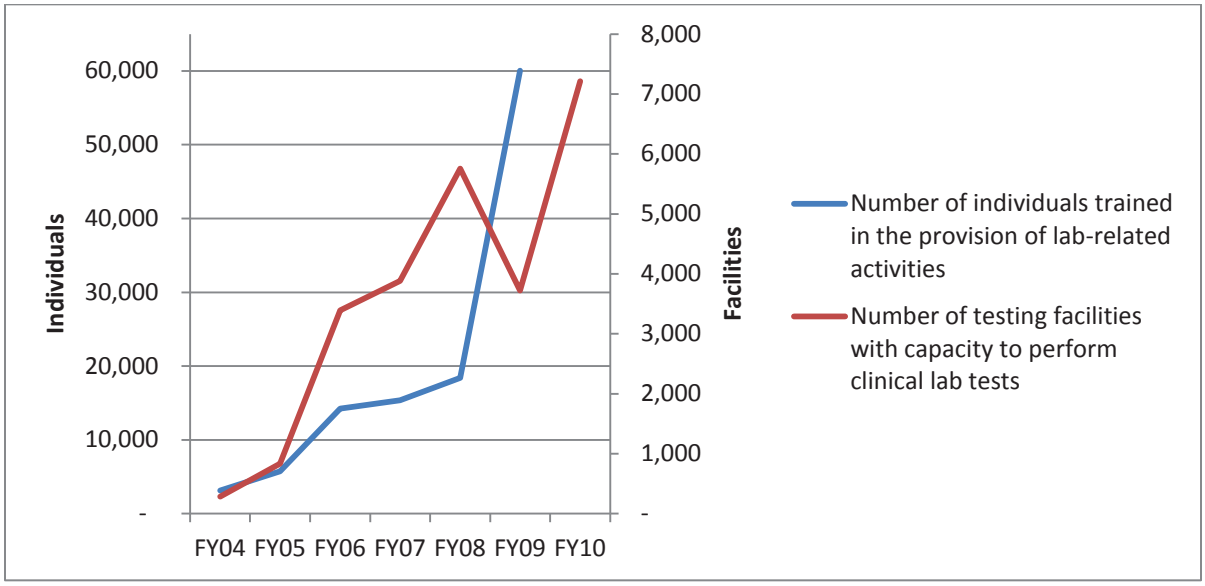

FIGURE 9-6 Select indicators related to PEPFAR's laboratory activities.
NOTE: For "Number of testing facilities […]," FY04-FY09 numbers correspond to Phase 1 indicator 12.1, which has a slightly different definition: Number of laboratories with capacity to perform 1) HIV tests and 2) CD4 tests and/or lymphocyte tests.
SOURCE: Program monitoring indicators provided by OGAC.

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Challenges

Despite PEPFAR's achievements with laboratory strengthening in partner countries, challenges remain. In many countries, capacity is still limited to large labs or urban areas and the process of transporting samples/specimens to labs creates delays between testing and getting results (636-17-PCGOV; 240-24-USG; 272-13-USG; 461-10-PCNGO). Some interviewees described challenges monitoring patient CD4 counts or identifying ARV resistance due to limited capacity (166-11-USG; 166-15-USACA; 461-10-PCNGO; 934-15-PCGOV; 636-17-PCGOV). Across countries, stakeholders expressed the need for more (and newer) laboratory equipment (461-10-PCNGO; 116-12-PCNGO; 116-19-PCACA; 166-15-USACA; 934-34-USNGO) yet also cited equipment maintenance as a challenge (240-8-USG; 240- 21-PCGOV; 331-17-USG; 934-17-PCGOV; 934-28-PCNGO; 396-22-USG). Laboratory networks are also affected by procurement and supply chain challenges (described in the previous section), which can result in stock outs of reagents, test kits, and other laboratory commodities (587-18-PCGOV; 196-10-PCGOV; 116-12-PCNGO; 116-19-PCACA; 166-15-USACA; 934-28-PCNGO). In many countries, shortages of appropriately trained laboratory personal (e.g., lab technicians) are the greatest barriers to expanding access to laboratory services (272-13-USG; 461-13-USACA; 461-18-USG; 934-2-USG; 166-11-USG). Ongoing challenges include adequate pre-service training, lack of management capacity, and site supervision, which are critical for quality services (396-22-USG; 166-12-USG) (Justman et al., 2009).

PEPFAR Achievements

Although challenges remain, the improvement of laboratories under PEPFAR support and guidance has been a signature achievement of the program. There are well-documented examples of how PEPFAR has helped transform labs, such as in the Caribbean where accreditation was attained and quality assurance systems were built, and in Nigeria where lab deficiencies (e.g., failure to monitor ambient temperatures or failure to post HIV rapid-testing algorithms) were reduced from 13 percent to 2 percent (Abimiku et al., 2010; Alemnji et al., 2012). During the committee's country visits, this was a theme emphasized with near universality.

PEPFAR support for labs has increased partner country capacity to provide laboratory services such as HIV testing (331-17-USG; 587-2-USG; 240-2-USG), viral load testing (934-5-USG), and HIV resistance testing (240-2-USG). Interviewees from several countries observed that PEPFAR support for laboratories had spillover effects for entire health system (240-2-USG; 240-19-USACA; 331-17-USG; 331-28-PCGOV; 116-28-USACA; 166-11-USG; 461-18-USG; 396-1-USG; 396-60-USG) They noted increasing capacity for testing of the blood supply (166-11-USG) and the diagnosis and treatment of diseases other than HIV (331-17-USG; 166-4-USG; 166-11-USG), such as tuberculosis (240-2-USG; 331-28-PCGOV), malaria (240-2-USG), and influenza (240-2-USG). In many countries, PEPFAR was the only donor supporting laboratory systems (240-21-PCGOV; 116-4-USG; 166-11-USG).

PEPFAR-supported technical assistance for laboratory information systems has improved the management and sharing of information (166-11-USG). Interviewees reported improved specimen transport and turnaround times for getting lab results as a result of PEPFAR efforts (240-24-USG; 331-38-USPS; 272-13-USG; 934-2-USG; 116-19-PCACA). In some countries, PEPFAR-supported laboratories in partner countries had achieved accreditation (240-33-USG; 396-22-USG).

> **Conclusion:** PEPFAR's laboratory efforts have had a fundamental and substantial impact on laboratory capacity in countries. This laboratory infrastructure and capacity has been, and can continue to be, leveraged to improve the functioning of countries' entire health systems.

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WORKFORCE

Background and Context

The association between an available and competent health workforce and key indicators of morbidity and mortality has long been noted both domestically and internationally (Chen et al., 2004; Speybroeck et al., 2006). The WHO has set a critical threshold of 2.3 doctors, nurses, and midwives per 1,000 population as essential for achieving 80 percent coverage of maternal and child health services within a country. If all countries were able to achieve the WHO's minimal target goal of 2.3 health professionals per 1,000 population, it would not only allow progress toward HIV/AIDS and other global health targets, but it would greatly advance the health status in countries with the highest burdens of disease (DeLuca and Kurth, 2012). In 2006, 57 countries failed to meet this target and were considered to have a severe workforce crisis (Global Health Workforce Alliance, 2010). A full 36 out of these 57 countries are in sub-Saharan Africa, home to two-thirds of all people living with HIV disease globally (and where an estimated 75 percent of adults do not know their status despite scale up of testing programs and campaigns) (Dayrit et al., 2011; Gilliam et al., 2012). The need to expand production and retention of doctors and nurses, as well as other frontline clinical providers such as pharmacists and managers, is critical (King and Fomundam, 2010; Kober and Van Damme, 2006; Scheffler et al., 2008). Given current levels of pre-service training, it has been estimated that even after ignoring most forms of attrition, "it would take 36 years for physicians and 29 years for nurses and midwives to reach WHO's recent target of 2.28 professionals per 1,000 population" in 12 sub-Saharan African workforce crisis countries, with some countries "never" reaching that target (Kinfu et al., 2009, p. 225).

PEPFAR Inputs

Guidance

PEPFAR's authorizing legislation provided increased resources to support training of health care workers, which were needed "particularly at the community and provincial levels, and other community workers and leaders" to address the HIV epidemic.[14] The legislation also recognized the negative impact that emigration was causing on national health workforce capacities in sub-Saharan Africa and called for an analysis of related challenges and strategies for retention for medical and public health personnel.[15] The first Five-Year Strategy identified technical assistance and training of health care professionals, community-based groups, and FBOs as strategies for building local capacity (OGAC, 2004).

In 2009, OGAC elevated the importance of health workforce activities by requiring that PEPFAR mission teams describe these activities in a new section of the COPs: the Human Capacity Development narrative. Previously, this information was captured in the Health Systems Strengthening narrative. A secondary cross-cutting budget attribution was also added

[14] *Supra.*, note 7 at §2(21)(A).
[15] *Supra.*, note 7 at §101(b)(3)(T).

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for Human Capacity Development (OGAC, 2008a).[16] Workforce activities to develop human capacity included

- Human Resources for Health Strategy development/workforce planning,
- Human Resource Information Systems (HRIS),
- Training (pre-service, longer-term, and for task shifting),
- Performance assessment,
- Retention strategies,
- Twinning and volunteers,
- Management and leadership development, and
- Support for salaries (OGAC, 2008a).

PEPFAR II's transition to capacity building and sustainability efforts emphasized the goal of training and retaining "health care workers, managers, administrators, health economists, and other civil service employees critical to all functions of a health system" (OGAC, 2009d, p. 8). PEPFAR's reauthorization legislation expanded the scope of support for health workforce activities and created a new target to train and retain at least 140,000 new health care professionals and paraprofessionals. The target emphasized training for "critically needed doctors and nurses" in order to strengthen partner country capacity to deliver primary health care and help partner countries achieve the WHO-identified critical threshold of 2.3 doctors, nurses, and midwives per 1,000 population.[17] The reauthorization legislation called for the capacity building of partner country institutions in order to promote pre-service training of and postsecondary education for health professionals. OGAC's FY 2010 COP guidance prioritized the development and retention of health care workers in public and nongovernmental settings (OGAC, 2009b). During PEPFAR II workforce efforts focused on pre-service training (or the training of new health care workers), as well as "task-shifting, innovative retention strategies, reemployment, and additional training of health care personnel across the WHO six building blocks of health" (OGAC, 2009f, p. 24).

PEPFAR Funding for Health Care Worker Salaries

Although COP guidance considered salary support to be a component of human capacity development, there are limitations on how PEPFAR funding[18] may be used to support health care worker salaries. Prime partners and sub-partners may use PEPFAR funding "to pay for time-limited contractors to carry out activities essential to HIV/AIDS program goals" and NGOs may hire personnel to work for their organizations, government institutions, or government health facilities (USAID, 2009, p. 32). PEPFAR funding may also be used to provide bonuses or incentives to public or private sector health care workers that achieve certain targets within a performance-based financing scheme. However, PEPFAR funding cannot be

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[16] Secondary cross-cutting budget attributions "are designed to capture all funding associated with a cross-cutting program, regardless of program area" (OGAC, 2008a, p. 69).
[17] *Supra.*, note 2 at §101(a), 22 U.S.C. 7611(a)(4)(J).
[18] These limitations refer to funding from the Global Health and Child Survival appropriations account, which is the largest source of PEPFAR funding (in FY 2010, 86 percent of PEPFAR funding was appropriated through the Global Health and Child Survival account) (OGAC, 2011d). For more information on the PEPFAR funding process, see Chapter 4.

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used to pay for "salaries of permanent civil service employees on public health institution payrolls" or salary supplements, known as "top-ups" to employees of partner country governments (USAID, 2009, p. 32).

PEPFAR Activities

Across countries, PEPFAR has provided support for government leadership related to the health workforce (e.g., planning, monitoring) (240; 934; 587; 116; 166), training and education (240; 636; 934; 587; 461; 331; 196; 116; 166; 272; 396), health worker retention (240; 636; 116; 461, 935), and capacity building of health professional training institutions and universities (240; 587; 116; 166; 461; 934; 396; 331).

Workforce Planning

The Global Health Workforce Alliance/WHO and others have emphasized that countries should have a national plan for workforce development, and for bilateral and multilateral donors to make long-term, dependable investments towards the progress of country-led plans (GHWA, 2011; IOM, 2009). A recent review of WHO's Country Planning Cycle Database however, revealed that only 10 of the 31 PEPFAR countries had national Human Resources for Health Plans (WHO, 2012a).

Interviewees described various aspects of PEPFAR support for planning and management of national health workforces, such as support for national HRH strategies or plans (240-12-USG; 934-38-PCACA); development of an HR unit within the MOH (587-10-USG); human resource information systems (240-12-USG; 116-7-USG; 166-12-USG); and support for workforce licensing, registration, or regulation (240-12-USG; 116-13-PCNGO).

In-Service Training

In the early phase of PEPFAR, most health worker training involved in-service trainings (short-term training for current health workers) related to HIV testing, ARV management, and other focused, protocol-specific approaches needed to allow health systems to rapidly scale up HIV services. PEPFAR II transitioned to a focus on "pre-service" training (or the training of new health care workers), task-shifting [or task-sharing], developing and employing retention strategies, and "reemployment and additional training of health care personnel [including for primary care] across the WHO six building blocks of health" (OGAC, 2009f, p. 24).

Until FY 2010, OGAC indicators related to training captured both new training and retraining of individuals (OGAC, 2005c). These indicators track the number of persons trained in each topic without accounting for duplication across topics or years, so while the committee cannot determine how many unique individuals were trained each year, the data show that PEPFAR supported more than 6 million training experiences in various program areas from FY 2005 to FY 2009 (see Table 9-6). In FY 2010, PEPFAR supported nearly 450,000 in-service trainings (but data were not provided to the committee disaggregated by as many program areas) (see Table 9-7). The committee's interpretation of these output data was limited as there are no data available on the retention of individuals trained within the country, the health sector, or for HIV/AIDS-related service provision.

Despite the renewed focus on pre-service training during PEPFAR II, in-service training is appropriate in some situations. Interviewees from PEPFAR partners described in-service training to disseminate new service delivery guidelines (587-5-PCGOV; 636-17-PCGOV), as well as refresher courses for experienced staff (587-5-PCGOV; 396-56-USNGO; 935-23-PCNGO; 934-22-USNGO; 272-26-

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PCNGO). PEPFAR supports in-service training for multiple cadres of health workers in partner country health systems, including

- Doctors (396-29-PCGOV; 542-8-USNGO; 542-11-PCNGO),
- Nurses (240-5-PCGOV; 331-12-USG; 636-9-USACA; 542-11-PCNGO),
- Volunteers (240-5-PCGOV; 240-7-PCGOV; 272-25-PCNGO),
- Pharmacists (396-29-PCGOV),
- Medics (587-10-USG) and emergency surgical officers (240-12-USG),
- Social workers and counselors (and those working with youth and families) (272-14 -PCNGO; 272-15 -PCNGO; 272-20-PCNGO; 272-21-PCNGO; 166-12-USG; 396-12-USG ; 396-29-PCGOV),
- Laboratory technicians and other personnel (240-2-USG; 240-19-USACA; 116-19-PCACA; 166-11-USG; 272-13-USG; 461-13-USACA; 461-18-USG; 396-22-USG),
- Leaders, program managers, and program supervisors (240-7-PCGOV; 587-10-USG; 587-13-USG; 116-7-USG; 116-11-USG; 272-15-PCNGO; 396-55-USG; 934-38-PCACA),
- Supply chain personnel (240-12-USG; 934-25-USNGO; 461-13-USACA), and
- Data clerks and managers, M&E personnel (196-21-PCGOV; 636-1-USG; 636-18-ONGO; 166-11-USG; 396-29-PCGOV)

In some countries, interviewees expressed the need for continuous in-service training due to frequent turnover of staff and loss of institutional memory (542-11-PCNGO; 587-7-PCGOV; 587-8-PCGOV; 272-6-ML; 272-3235-PCNGO; 331-12-USG; 331-44-USNGO; 240-19-USACA; 934-21-USG; 934-45-USNGO; 396-6-PCGOV; 396-41-PCGOV; 396-56-USNGO; 935-2-USG; 166-6-USG; 166-11-USG).

Pre-Service Training

Only 1 year of data for Next Generation Indicator H2.1.D is available to measure progress toward the PEPFAR II goal of training 140,000 new health workers (see Boxes 9-5 and 9-6 for more information about PEPFAR-supported initiatives to strengthen pre-service training). This indicator reflects the number of clinical (doctors, nurses, midwives, laboratory scientists, pharmacists, social workers, medical technologists, and psychologists) and nonclinical (administrators, managers, monitoring and evaluation advisors, epidemiologists and other professional staff) health workers that graduate from a university-based or affiliated program at least 6 months in duration.

Indicator H2.2.D captures the number of community health or para-social workers (CHSWs) who complete a pre-service training program with PEPFAR support. Although CHSWs do not count towards the legislative target, these jobs are often “the first step in entering the health workforce and they contribute to the pipeline for health workers” (OGAC, 2009c, , 109). In FY 2010, nearly 11,000 doctors, nurses, and midwives graduated from pre-service training institutions, and nearly 138,000 CHSWs completed a pre-service program with PEPFAR support (see Table 9-7).

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TABLE 9-6 PEPFAR Indicators Related to Workforce Training (FY 2004-FY 2009)

	FY04	FY05	FY06	FY07	FY08	FY09
Maximum countries contributing toward results, n	15	15	29	31	31	31
Number of individuals (in thousands) trained:						
In blood safety (3.2)	2.2	7.9	6.6	7.7	9.7	9.6
In injection safety (4.1)	4.4	14.0	55.5	78.1	67.9	75.0
To provide HIV/AIDS prevention programs promoting abstinence and/or being faithful (2.2)	116.6	174.5	346.3	333.7	456.8	567.2
To promote HIV/AIDS prevention through other behavior change beyond abstinence and/or being faithful (5.3)	51.0	92.9	190.6	238.1	207.7	242.5
To provide HIV palliative care (including TB/HIV) (6.3)	27.0	71.2	145.1	129.7	159.6	162.7
To provide treatment for TB to HIV-infected individuals (diagnosed or presumed) (7.3)	10.5	14.9	19.9	28.5	43.3	50.2
In counseling and testing according to national and international standards (9.3)	14.2	22.1	35.5	52.8	54.5	68.9
In HIV-related community mobilization for prevention care and/or treatment (14.6)	--	--	87.8	100.7	95.1	94.6
In the provision of lab-related activities (12.2)	3.1	5.7	14.2	15.4	18.4	60.0
In strategic information (13.2)	9.3	18.0	42.6	38.7	53.0	64.5
In HIV-related policy development (14.3)	24.1[a]	45.9[a]	28.3	26.9	21.1	23.5
In HIV-related institutional capacity building (14.4)			45.4	69.6	83.5	102.6
In HIV-related stigma and discrimination reduction (14.5)	--	--	63.6	186.1	168.0	103.6
Number of health workers (in thousands) trained:						
Or retrained in the provision of PMTCT services (1.4)	24.4	28.5	36.2	31.7	50.8	61.6
To deliver ART services (11.5)	12.3	36.6	59.0	62.6	69.3	84.1
Number of providers/caretakers (in thousands) trained:						
In caring for OVC (8.2)	22.5	74.8	164.4	228.0	255.0	273.1

NOTES: Data are presented in thousands. ART = antiretroviral therapy, OVC = orphans and vulnerable children, PMTCT = prevention of mother-to-child transmission.

[a] In FY 2004 and FY 2005, indicators 14.3 and 14.4 had not yet been separated and were reported as a single result.

SOURCE: Program monitoring indicators provided by OGAC.

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TABLE 9-7 PEPFAR Indicators Related to Workforce Training (FY 2010)

	Result	Target	(%)
Number of new health care workers (in thousands) who graduated from a pre-service training institution within the reporting period (H2.1.D)	10.8	12.4	(87)
Nurses	4.4	0	
Midwives	0.4	0	
Doctors	1.4	0	
Number of community health and para-social workers (in thousands) who successfully completed a pre-service training program (H2.2.D)	136.8	102.6	(133)
Number of health care workers (in thousands) who successfully completed an in-service training program within the reporting period (H2.3.D)	448.1	384.0	(117)
Pediatric treatment	13.4	20.7	(64)
Male circumcision	2.2	4.9	(46)

NOTE: Data are presented in thousands. Indicators H2.1.D includes training for clinical professionals (including doctors, nurses, midwives, laboratory scientists, pharmacists, social workers, medical technologists, and psychologists), other clinical health workers (including but not limited to clinical officers, medical and nursing assistants, lab and pharmacy technicians, auxiliary nurses, auxiliary midwives, Testing &Counseling counselors), and non-clinical health workers (including workers in a health ministry, hospital and facility administrators, managers, monitoring and evaluation advisors, epidemiologists and other professional staff critical to health service delivery and program support) (OGAC, 2009c).
SOURCE: Program monitoring indicators provided by OGAC.

CHSWs—who are the preponderance of trainees—can contribute significantly to the HIV/AIDS response, but only if sufficient training, remuneration, and oversight support systems are provided (Celletti et al., 2010; Jerome and Ivers, 2010). CHSWs may be trained to deliver health services at various levels of complexity, and can "improve access to care and services despite the shortage of higher level healthcare professionals" (Jerome and Ivers, 2010, p. S69). In some partner countries, PEPFAR has supported training for CHSWs, some of which are deployed in rural areas in order to increase access to services (240-12-USG; 331-12-USG; 461-13-USACA; 166-18-USNGO). PEPFAR partners may also provide financial support, mentoring, and/or supervision to community health workers that deliver home-based care (934-29-USNGO; 272-7-USG)

Educational/Training Institutions

PEPFAR and other global health donors have been criticized for supporting in-service training and salary support for existing health workers over pre-service training to expand the health workforce, but since its inception, PEPFAR has supported the production of health workers in partner countries through capacity building of educational institutions (Grépin, 2012b; Vujicic et al., 2012). During its first phase, PEPFAR supported twinning arrangements between U.S.-based and partner country education institutions to build capacity in diverse areas, such as strengthen nursing HIV/AIDS education in Tanzania (OGAC, 2006b). Partner country stakeholders and PEPFAR mission teams described PEPFAR support for academic institutions that offer multiple levels of pre-service training: bachelor's (240-12-USG; 116-7-USG), master's (240-2-USG; 240-12-USG; 38-PCACA), and doctoral programs (240-12-USG; 240-19-PCACA; 331-12-USG). Interviewees in nearly all countries mentioned PEPFAR support for curriculum development (240-2-USG; 240-19-USACA; 587-10-

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USG; 116-13-PCNGO; 166-19-PCGOV; 166-22-USPS; 461-13-USACA; 396-2-USG; 934-21-USG) and faculty educators (240-2-USG; 331-12-USG; 166-11-USG; 166-22-USPS; 934-44-PCACA; 116-7-USG; 396-39-USG) at local institutions.

PEPFAR has also supported the production of health professionals by providing startup costs for Field Epidemiology and Laboratory Training Programs (FELTPs) in six countries (Ethiopia, Mozambique, Nigeria, Rwanda, South Africa, and Tanzania) and continuing financial support to a Field Epidemiology Training Programs (FETP) in Zimbabwe (Nsubuga et al., 2011). The first FETPs were established in Zimbabwe and Uganda in the early 1990s as partnerships between Ministries of Health, universities, and sub-national level of government in partner countries (Mukanga et al., 2010). The first FELTP was established in Kenya in 2004 and added a laboratory component to the FETP curriculum. FELTPs combine didactic classes and fieldwork to build competencies in epidemiology and public health laboratory management. After completing the 2-year program, graduates are usually awarded master's degrees in fields such as public health, applied or field epidemiology, or applied epidemiology and laboratory management (Nsubuga et al., 2011). In 2004, a review of alumni data from the Zimbabwe and Uganda FETPs showed that 85 percent of graduates were still working in their home country three years after completing the program, compared to 40 percent of graduates from medical and other health schools in Africa (Mukanga et al., 2010).

In 2010, recognizing the need to "increase the quantity, quality, and relevance of health care workers" in partner countries, OGAC established the Medical Education Partnership Initiative (MEPI) and the Nursing/ Midwifery Education Partnership Initiative (NEPI) to support medical and nursing education institutions across Africa (Palen et al., 2012, p. S115) (see Boxes 9-7 and 9-8). The MEPI and NEPI initiatives are longer-term investments in African universities to improve the quality of physician and nursing education and increase the quantity of health workers (Mullan et al., 2012; OGAC, 2011f). In the short-term, however, these initiatives with a small amount of funding (about $134 million USD) will not produce large cohorts of frontline clinicians or other health workers to directly staff government or other sector health facilities. Recently, PEPFAR, the Peace Corps, and the Global Health Service Corps launched a public-private partnership to send U.S. medical and nursing professionals to serve as short-term adjunct faculty in overseas medical or nursing schools (Peace Corps, 2012). In 2013, the Global Health Service Partnership will pilot programs in Malawi, Uganda, and Tanzania, supporting 30 volunteers to serve as medical and nursing educators in each country (Global Health Service Corps, 2012). PEPFAR is supporting a similar effort in Rwanda, where the government is partnering directly with 13 U.S.-based universities to strengthen medical and nursing education as part of the country's Human Resources for Health (HRH) Program (Nash, 2012; Rwanda Ministry of Health, 2012). The U.S.-based universities will pay the salaries of full-time medical, nursing, dentistry, and health management faculty serving for one year as educators in Rwandan academic institutions; the Government of Rwanda will provide a housing allowance (Duke University, 2012). The government estimates that after eight years, it will be "positioned to sustain the improved health workforce on its own without foreign aid" (Rwanda Ministry of Health, 2012).

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BOX 9-7
MEPI

The Medical Education Partnership Initiative (MEPI) provides $130 million in direct funding over 5 years to 13 African medical schools for institutional support and management. Each medical school was chosen through a competitive grant process and is partnered with a U.S.-based university. These partnerships have three overarching themes:

1. Increasing capacity through "enhancements in the quantity and quality of medical education in funded schools and in their respective countries. This effort includes increased admissions, curricular innovations, graduate medical education enhancement, and faculty training and support" (Mullan et al., 2012, p. 1564),
2. Retention of "both faculty and graduates to further build the capacity of each school and graduates of the schools in their respective countries" as well as improving geographic distribution of the graduates (Mullan et al., 2012, p. 1564), and
3. Regionally relevant research, which is important for the generation of new knowledge and as an instrument of faculty development and retention.

MEPI is coordinated by The George Washington University School of Public Health and Health Services, in partnership with the African Centre for Global Health and Social Transformation in Kampala, Uganda. The coordinating center is responsible for evaluating each grantee's program and providing technical support. MEPI is funded through OGAC and the National Institutes of Health and receives administrative support from HRSA.

SOURCE: (Mullan et al., 2012).

BOX 9-8
NEPI

Nurses and midwives play an important role in the delivery of health services, particularly in African countries, and PEPFAR has supported capacity building for nurses through various initiatives. In 2006, PEPFAR funded the Global HIV/AIDS Nursing Capacity Building program, implemented by Georgetown University, to build nursing leadership and develop regional networks of nurses to support mentoring (Cavender, 2006). In 2009, Columbia University's International Center for AIDS Care and Treatment Programs (ICAP) was awarded a 5-year grant to continue building capacity for nursing through the ICAP Nurse Capacity Initiative (INCI). INCI is active in seven African countries, where it supports national-level nursing strategies and leadership, as well as pre-service and in-service training of nurses to increase knowledge and skills (Dohrn, n.d.).

In 2010, OGAC launched the Nursing Education Partnership Initiative (NEPI) to build the capacity of nursing and midwifery schools in partner countries. Through NEPI, PEPFAR provides direct funding to national government working groups that choose the education models and interventions and the schools where they will be implemented (Dohrn, n.d.; Palen et al., 2012).

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Retention of Health Workforce

Despite tremendous efforts to train health care workers in partner countries, nearly every country faced workforce shortages that challenged the proper functioning of the health system (396-7-PCGOV; 396-9-PCGOV;240-21-PCGOV; 331-6-CCM; 461-8-PCGOV; 461-8-PCNGO; 587-10-USG; 587-25-ML; 196-16-PCGOV; 636-2-USG; 166-13; 116-23; 272-13-USG; 934-15-PCGOV). In 2010, the Member States of the World Health Assembly adopted the Global Code of Practice on the International Recruitment of Health Personnel, which was developed to provide an ethical framework for international recruitment that attempts to minimize the migration of health workers from countries with severe workforce shortages (WHO, 2010d). However, the principles and practices described in the code are voluntary, and in many countries, external migration is a challenge for many countries (636-2-USG; 636-7-PCNGO; 240-15-USG; 116-7-USG; 272-2-USG; 935-2-USG). Many elements contribute to migration (either internal—to a different provider/organization, or external—to another country) and attrition (the decision to leave the workforce), such as low salaries (331-4-PCGOV; 240-24-USG; 542-11-PCNGO; 935-2-USG), lack of career and professional development opportunities (587-5-PCGOV; 934-17-PCGOV), poor management or supervision (587-5-PCGOV), and poor workplace conditions (636-2-USG; 240-19-USACA) (Willis-Shattuck et al., 2008). Low salaries were a frequently cited cause of attrition, not only for clinicians and laboratory personnel, but also support staff engaged in monitoring and evaluation (396-9-PCGOV; 461-4-USG; 587-9-USG; 934-22-USNGO), supply chain management (331-17-USG), financial management (240-19-USACA; 331-34-USNGO), and other roles. Workplace conditions identified as challenges to health workforce retention include lack of access to basic services such as electricity and running water (636-2-USG; 166-11-USG), lack of internet access (240-19-USACA). In many cases, health care workers are overwhelmed due to understaffing, and attrition and migration increase the burden on those left behind (331-16-USG; 331-44-USNGO; 587-13-USG; 196-16-PCGOV; 636-17-PCGOV; 116-16-PCGOV; 272-13-USG; 272-25-USG; 935-4-PCGOV). A systematic review of 20 retention studies in low-income countries has pointed out that "adequate resources and appropriate infrastructure can improve morale significantly" (Willis-Shattuck et al., 2008). Interviewees agreed with the need to provide an enabling environment with access to appropriate equipment and resource materials in order to retain employees, particularly in rural areas (636-7-PCNGO; 240-19-USACA). Some interviewees felt that opportunities for staff development—'*creating conducive environments for learning and teaching by providing laboratories, reference materials, textbooks, video-conferencing, internet'* (240-19-USACA)—could contribute to greater staff retention, and there were examples of situations in which this strategy was successful: '*Health center does not experience a lot of staff turnover because there is electricity, water, and accommodations are provided for the staff*' (636-22-PCNGO).

Partner country interviewees described PEPFAR support for financial and nonfinancial incentives for retaining health workers, such as provision of health care to health care workers and their families (240-12-USG), opening private wings in public hospitals so that physicians can work in both sectors (240-12-USG; 240-33-USG); ensuring access to necessary medical equipment (116-7-USG; 240-19-USACA), and creating an enabling environment with access to informational resources (240-19-USACA). As described above, PEPFAR funding may not be used to supplement salaries for public sector health workers unless the bonus payments are tied to performance indicators. In at least one country, per diems offered to workers who attended in-service trainings were considered an informal method of increasing salaries (240-12-USG). PEPFAR partners in some countries are providing performance-based top-ups or bonus payments, for example, when employees work overtime (935-13-PCGOV). Interviewees provided examples of successful efforts to retain health workers by increasing salaries, but these were not supported by PEPFAR (934-25; 116-5-PCGOV; 116-7-USG); some interviewees expressed a desire to provide salary top-ups in order to

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motivate staff and attracted well-qualified employees (166-1-USG; 166-6-USG). Sometimes, employees leave the public sector and then PEPFAR seconds them back to government institutions for higher salaries (240-33-USG).

There has been concern that PEPFAR funding may have indirectly contributed to a workforce migration in some countries (in Mozambique more doctors are lost from clinical practice to internal migration, such as to the private sector, rather than external migration), whereby higher pay scales for the HIV programs could induce a siphoning-off of workers from primary care and other general health sectors (Sherr et al., 2012). Interviewees from partner country governments confirmed that private sector (both for-profit and nonprofit) wages often exceed public sector wages, creating a strong "pull factor" away to non-public-sector jobs (331-4-PCGOV; 240-5-PCGOV; 240-19-PCGOV; 587-7-PCGOV; 587-18-PCGOV; 934-17-PCGOV; 116-7-USG; 166-5-USG; 166-9-USG/OBL/ML). In one partner country, increased donor funding for HIV/AIDS had both negative and positive effects; health care workers were recruited away from rural areas to work in the capital or away from primary care to HIV services, but increased funding had also increased job opportunities, which also incentivized formerly emigrated health care workers to return back to the country (935-2-USG). In particular, interviewees attributed some migration of health workers away from the public sector to PEPFAR funding (935-2-USG; 396-55-USG; 587-18-PCGOV; 166-9-USG/OBL/ML; 240-33-USG).

Task Shifting

Given the growing evidence about the trajectory of need for the cascade of services from testing to the provision of ART and patient retention, as well as the benefits of earlier provision of antiretroviral therapy,[19] the need for adequate numbers of providers who can initiate and manage ongoing antiretroviral drug use is critical. This includes doctors (who are extremely scarce in low-income country settings), as well as nurses and other associated clinicians with additional training who are capable of managing HIV including medication dispensing. Task shifting involves the reassignment of clinical tasks to different cadres of workers (Callaghan et al., 2010). One such model at the PEPFAR-funded AMPATH system in western Kenya found that clinician nurse-led monitoring significantly reduced mortality (Braitstein et al., 2012). In South Africa nurse-monitored ART has been found to improve treatment outcomes at an efficient cost (Brennan et al., 2011; Long et al., 2011).

A growing body of literature shows that providers other than physicians (e.g., nurse-practitioners, physician assistants, clinical officers, and other associate clinicians) may provide care that is at least equivalent in quality to that provided by physicians for determining eligibility and deciding to initiate ART, prescribing medication, and managing treatment (Callaghan et al., 2010; Laurant et al., 2005; Mullan and Frehywot, 2007; Sherr et al., 2010; Shumbusho et al., 2009; Veenstra and Whiteside, 2005). In some countries, such as South Africa, use of non-physician providers has single-handedly allowed for ART expansion to over 300,000 new patients, and the task shifting model successful here may be extensible to other health priorities beyond HIV, including non-communicable diseases which are increasingly prevalent in low- and middle-income countries (Dohrn et al., 2009; Lekoubou et al., 2010; Sanne et al., 2010). El-Sadr and colleagues, in a summary of PEPFAR achievements, conclude that "PEPFAR's adoption and

[19] The latest guidance from the U.S. Department of Health and Human Services recommends ART for all HIV-infected individuals (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2012). The latest WHO guidance recommends treatment for "all patients with CD4 counts of ≤350 cells/mm^3 irrespective of the WHO clinical stage" (WHO, 2010a, p. 24).

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support of task-shifting principles has enabled the expansion of HIV treatment in countries with some of the most severe health workforce constraints" (El-Sadr et al., 2012, p. S97).

Task shifting may support efficient models of service delivery that will be increasingly required as a growing number of persons living with HIV are identified and supported for lifetime care (Fulton et al., 2011). Benefits of task shifting—which requires training and support, rather than simply adding more work to different cadres—include increased access to life-saving treatment; improved workforce skills mix, retention, and health-system efficiency; and likely cost advantages (Zachariah et al., 2009). The need to maximize available resources within health systems (including implementation of effective quality-improvement systems) will need to be supported as PEPFAR moves into its next phase of work (Leatherman et al., 2010). It has been observed that these efficiencies are necessary "to achieving the goal of universal access to treatment as well as the sustainability of these programmes" (Grépin, 2012a).

Task shifting or task sharing may occur at all levels of the workforce. For example, initiation of antiretroviral therapy may be reassigned from doctors to nurses or health officers (240-2-USG; 272-20-NGO; 934-10-PCGOV; 636-4-PCGOV; 116-7-USG; 166-6-USG; 461-14-USG); HIV testing may be reassigned from registered nurses to lay counselors or community health workers (272-13-USG; 934-10-PCGOV); and nonclinical health care workers or volunteers may take responsibility for helping newly diagnosed patients navigate the health system, adhere to ARV regimens, or provide psychosocial support, which reduces the burden of clinical health care workers (240-15-USG; 331-19-USNGO; 166-29-PCGOV). Some countries have introduced new cadres of health workers, including associate clinician cadres that require less training than doctors, but more than nurses (240-2-USG; 166-6-USG; 166-23-USG; 116-19-PCACA) and cadres with training in a particular set of tasks (e.g., case management, home-based care) (240-15-USG). Where there are few doctors, these associate clinician cadres are trained to do tasks that are usually done by doctors (166-6-USG), such as diagnosis and treatment of tuberculosis (331-12-USG). PEPFAR has assisted partner country governments to restructure the health workforce and develop strategies for task shifting (272-7-USG; 240-15-USG). In several countries, interviewees described other ways in which PEPFAR partners are supporting task shifting, including TA (272-20-PCNGO), assessments of need for new cadres of workers (116-23-USPS), developing protocols to insure new cadres deliver appropriate services (116-9-PCNGO), mentoring of these new cadres (240-24-USG), evaluating task-shifting efforts (166-1-USG; 461-1-USG), and training for nurse-initiated ART (272-20-PCNGO). PEPFAR has also supported training for new cadres of associate clinician health workers to complement task-shifting efforts, such as "health officers" or "clinical officers" (240-2-USG; 240-3-USG; 240-5-PCGOV; 240-7-PCGOV; 166-6-USG; 166-23-USG; 116-19-PCACA). Some interviewees felt that these new cadres of workers were more likely to stay in the country than doctors or nurses (116-7-USG). In one country where task shifting had not been formalized, PEPFAR was supporting research to provide the government with evidence to contribute to policy development (935-14-USG).

PEPFAR Achievements

PEPFAR has supported millions of training encounters, but without data on the number of health care workers working for PEPFAR programs or supported by PEPFAR funding, it is difficult to determine PEPFAR's impact on the quantity, distribution, productivity, and motivation of health care workers in partner countries (Oomman et al., 2010). In many countries, PEPFAR partners are working on innovative solutions for workforce shortages, such as providing financial and nonfinancial incentives to retain health workers and exploring task shifting strategies.

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Conclusion: PEPFAR's contribution to health workforces in partner countries has over time been more appropriately directed to more pre-service production. Nonetheless, partner countries continue to have considerable need for health workforce development and retention. PEPFAR can contribute to that need by leveraging and maximizing its investments in collaborative efforts to build the capacity of health professional training schools, which would benefit the ability of countries to address not just HIV but the dual burden of infectious and non-communicable diseases that many high-burden countries increasingly face. Adherence by partner countries to the Global Code of Practice on the International Recruitment of Health Personnel and follow-through on commitments to the Abuja Declaration could both support sustainability of their own health workforces and country ownership.

SERVICE DELIVERY

Background and Context

The service delivery building block of health systems includes managing, integrating, and scaling up health services, as well as innovative strategies to deliver and improve services (WHO, 2012d). Service delivery, for prevention as well as treatment and care of disease, is in many ways the *purpose* of a health system, and not simply one of its components. Service delivery stands on a pillar of the other blocks: leadership and governance, financing, health information, access to essential medicines and commodities, and health workforce (see Figure 9-8). Thus, challenges within the other building blocks also affect the delivery of health services. Inadequate levels of human resources (workforce), high costs (financing), and lack of capacity to monitor patients (information) are constraints for expanding and delivering quality services.

Although the most visible aspect of health systems may be government-funded health services, nongovernmental actors from the private sector, civil society, and communities often contribute to the delivery of health services. The private for-profit and nongovernmental sectors play an important role in the delivery of health services (OGAC, 2009a), especially in poor countries where out-of-pocket expenditure for health care needs can be high, and become a large portion of expenditures by the poor (Xu et al., 2007). Although not directly reflected in the six building blocks, the engagement of communities in the health care system is key to the impact of service delivery on population health. During several country visits, interviewees noted the importance of the contributions for service delivery in urban areas from private and civil society sectors, particularly faith communities (240-ES; 331-ES; 636-ES; 116-ES; 166-ES; 272-ES; 935-ES; 461-ES; 934-ES). Each building block of the health system includes private sector actors (USAID, 2010), which is further discussed in Chapter 10.

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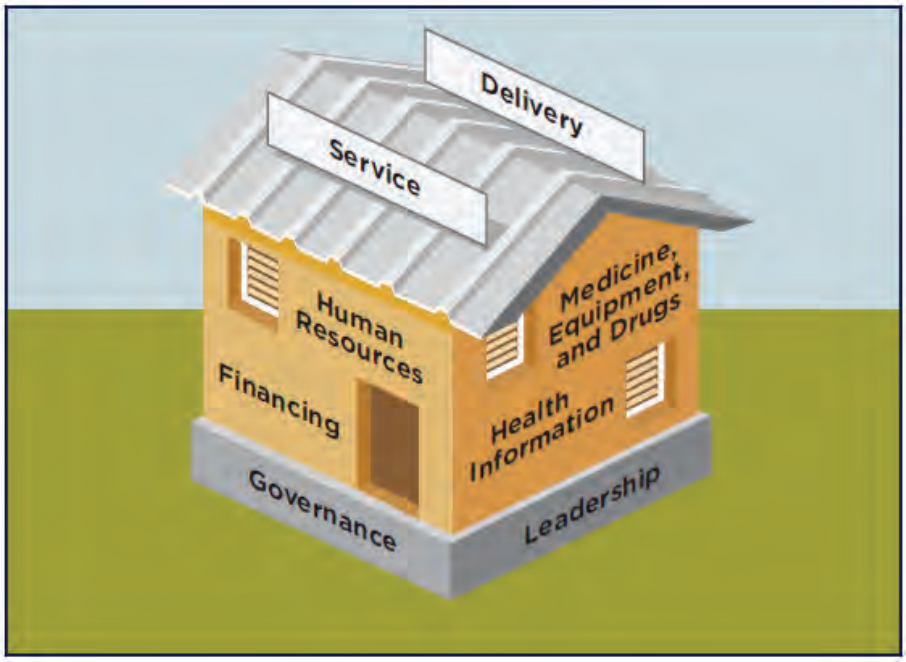

FIGURE 9-8 Health system building blocks represented as a house.
SOURCE: Adapted from (The Lancet, 2009).

Utilization of services, retention in care, and adherence to health worker advice are as important contributions to successful service delivery as other inputs. To make an already complex model more complicated, these system components are interrelated. Clients will respond not only to the cost of services, but also to their quality, including the delivery of services in ways that respect their dignity (Gilson, 2003). While the development of new drug regimens or laboratory tests are clearly technical issues, innovation in health systems approaches lies with developing new service delivery models.

Since its inception, PEPFAR has supported an enormous expansion of service delivery. In many countries, PEPFAR has supported the development of health systems infrastructure through the construction (240-5-PCGOV; 240-7-PCGOV; 240-12-USG; 935-9-PCGOV) and renovation of existing facilities (240-7-PCGOV; 240-9-USG; 240-12-USG; 240-24-USG; 116-12-PCNGO; 116-19-PCACA; 166-11-USG; 166-15-USACA; 272-22-USG; 935-12-USPS; 935-24-USNGO;461-13-USACA; 396-323334-PCGOV) such as health centers, clinics, and hospitals (240-7-PCGOV; 240-12-USG; 240-25-PCGOV; 240-33-USG; 935-12-USPS; 935-24-USNGO); laboratories (240-12-USG; 240-19-USACA; 240-33-USG; 331-17-USG; 587-7-PCGOV; 636-3-USG; 116-19-PCACA; 166-11-USG; 116-15-USACA; 935-9-PCGOV); training centers (240-12-USG) and universities (240-19-USACA); and warehouses for storing commodities (240-12-USG; 587-7-PCGOV; 935-9-USG). Interviewees noted that construction and renovation have sustainable, "horizontal" impacts beyond HIV/AIDS that strengthen the health sector in general and contribute to increasing access to services (240-3-USG; 240-7-PCGOV; 240-19-USACA; 240-25-PCGOV; 240-33-USG; 166-15-USACA). PEPFAR activities and achievements in prevention, care, and treatment services for HIV/AIDS are discussed in Section 2 of this report. The chapters in Section 2 provide a more in-depth look at PEPFAR's efforts to increase access to and availability of HIV/AIDS services. From a systems-level perspective, the committee chose to assess PEPFAR's cross-cutting and capacity building efforts related to service delivery. In particular, the following discussion reflects the committee's efforts to understand PEPFAR's broader contribution to increasing the quality and integration of health services.

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Particularly given the constrained global economic climate and the growing responsibility of lifelong care required for those living with HIV, it is important for PEPFAR and other stakeholders involved in the global HIV/AIDS response to understand how to best identify and propagate efficient models for the continuum of HIV prevention, care, and treatment. The challenge is to lower the unit cost of HIV/AIDS-related health services provided while simultaneously ensuring adequate quality of services to achieve viral suppression for clinical health for those already living with HIV/AIDS, as well as to reduce transmission from this population (Goosby, 2012a). These have been, and continue to be, nearly impossible tasks without addressing the underlying health care and public health systems.

Quality of Service Delivery

PEPFAR Inputs

Guidance Since its inception, PEPFAR has emphasized its goal of providing quality services for HIV/AIDS and recognized the importance of interventions across the health systems' building blocks in order to achieve this goal (OGAC, 2006a). PEPFAR's first Five-Year Strategy committed to developing the infrastructure, staff, and capacity necessary to provide high-quality services through technical assistance for development of appropriate protocols for service delivery and training of health care providers at all levels of the health system (OGAC, 2004). The FY 2009 COP Guidance articulated strengthening quality assurance programs as a key activity for building government and nongovernment capacity (OGAC, 2008a). OGAC guidance on the development of Partnership Frameworks identified the need for building government capacity to regulate services provided in the nongovernmental sector and for capacity building across sectors for the delivery of quality services (OGAC, 2009a). PEPFAR's second Five-Year Strategy noted that "access to quality services for all health conditions remain[ed] problematic in some areas" (OGAC, 2009d, p. 12). One USG official noted that in the beginning, *'it was almost more important that you had clinics for treatment and programs for prevention without looking at quality'* (NCV-3-USG). Although PEPFAR met and exceeded its HIV treatment service delivery targets during the first phase (see Part II of the report), OGAC recognized that "in some countries, this focus did not fully translate to a broader service delivery impact across the health sector" (OGAC, 2009d, p. 12).

PEPFAR Activities

PEPFAR has supported a range of efforts to ensure and improve quality of HIV/AIDS and other health services. Although interviewees described an initially insufficient attention to quality while pursuing scale-up of services to meet PEPFAR's ambitious enrollment targets (272-15-PCNGO; 166-15-USACA; 461-17-PCNGO; 935-2-USG), there has been an increased focus on ensuring quality services in recent years (240-2-USG; 166-15-USACA) and in some countries, new approaches to improving quality of services were mentioned as a primary objective of the PEPFAR program (331-30-USPS; 331-43-USG; 116-1-USG; 396-21-USG).

In nearly all countries, interviewees described interventions with the health workforce as crucial for ensuring the delivery of quality services. PEPFAR supports pre-service (934-5-USG; 331-16-USG; 331-38-USPS; 116-7-USG) and in-service training (934-5-USG; 331-16-USG; 166-15-USACA; 935-13-PCGOV) to build the capacity of health care providers to deliver quality services. PEPFAR partners also use strategies such as supportive supervision (934-22-USNGO; 331-30-USPS; 116-12-PCNGO; 935-22-PCGOV) and mentorship (934-5-USG; 240-2-USG; 240-15-USG; 272-24-USG; 935-23-PCNGO) to improve the ability of health care

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workers to deliver quality services. In countries that are piloting or implementing task sharing models of care and treatment, PEPFAR is supporting in-service training and mentorship programs to ensure quality service delivery (240-2-USG; 240-15-USG). PEPFAR partners are also working to build leadership and management capacity for monitoring of services (331-12-USG; 331-38-USPS; 331-43-USG; 240-12-USG; 240-19-USACA; 636-6-USG; 587-10-USG).

PEPFAR supports quality-assurance (QA) activities (396-12-USG; 934-5-USG; 272-24-USG; 331-12-USG; 587-9-USG; 935-17-USG) and quality-improvement (QI) activities (636-6-USG; 461-8-PCGOV; 331-43-USG; 934-44-PCACA;587-13-USG; 196-1-USG; 272-9-USG; 935-23-PCNGO). Traditionally, QA has referred to retrospective inspections that measure compliance with standards, while QI refers to ongoing approaches to improve processes and systems necessary to deliver high-quality services (Agins, 2007; HRSA, 2013). Often, interviewees used these terms interchangeably, but across countries, the committee heard about processes and tools used by PEPFAR partners to monitor and improve quality, including: the client-oriented provider-efficient (COPE) methodology that was also described as innovative, the continuous quality improvement (CQI) approach, and the HIVQUAL and HEALTHQUAL projects (331-30-USPS; 331-44-USNGO; 587-9-USG; 587-13-USG; 587-18-PCGOV; 396-55-USG; 461-18-USG; 935-23-PCNGO; 166-15-USACA). Although slightly different, these assessments involve examining various steps in the service delivery process, identifying weaknesses or barriers to delivering high-quality services, and developing solutions to improve the quality of service delivery. In particular, PEPFAR supports HIVQUAL and HEALTHQUAL in 14 countries and recent evaluations in Thailand, Uganda, and Mozambique show increased clinical performance in HIV care through the use of this model (HEALTHQUAL International, 2011; Thanprasertsuk et al., 2012).

BOX 9-10
HIVQUAL and HEALTHQUAL

In 1992, the New York State Department of Health AIDS Institute and the Health Resources and Services Administration HIV/AIDS Bureau started the HIVQUAL Project to ensure the quality of HIV/AIDS services. The HIVQUAL method focuses on three areas: performance measurement, quality improvement, and quality management (New York Department of Health AIDS Institute, 2006). While initially a domestic program, HIVQUAL International was extended to PEPFAR focus countries in 2003. In 2010, HIVQUAL International became HEALTHQUAL and adopted a broader approach to public health and expanded its scope beyond HIV/AIDS to include other chronic and infectious diseases (HEALTHQUAL International, 2012). HIVQUAL and HEALTHQUAL International are funded by PEPFAR through the Office of the Global AIDS Coordinator and the CDC Global AIDS Program. Programming is currently in 14 PEPFAR countries: Botswana, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, Swaziland, Thailand, Uganda, Vietnam, Zambia, and Zimbabwe. HEALTHQUAL implementation is established through partnerships between ministries of health and HIVQUAL. Internationally, HEALTHQUAL supports the goals of PEPFAR by promoting sustainability in country health programs (HEALTHQUAL International, 2012). HEALTHQUAL quality-improvement programs have been successful in partner countries. For example, recent HIVQUAL and HEALTHQUAL evaluations in Thailand, Uganda, and Mozambique show increased clinical performance in HIV care through the use of the HIVQUAL model (HEALTHQUAL International, 2011; Thanprasertsuk et al., 2012).

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In many countries, interviewees described the need to develop agreed-upon standards of care before service quality could be assessed against standard processes described above (240-2-USG; 461-18-USG; 166-15-USACA; 331-12-USG; 331-30-USPS; 116-20-USNGO; 542-21-USNGO). Some PEPFAR partners provide TA to support partner countries in the development and implementation of standards of care for services (240-2-USG; 196-11-USNGO; 331-12-USG; 331-16-USG; 461-18-USG; 166-15-USACA; 116-20-USNGO; 272-9-USG).

There was widespread agreement across countries about the importance of collecting and using data to monitor quality of services (240-19-USACA; 272-18-PCNGO; 272-32-PCNGO; 396-55-USG; 461-18-USG; 166-15-USACA; 587-9-USG; 116-9-PCNGO; 934-22-USNGO), including the use of both paper (such as maternal care registries and child health passports) and electronic registries and health records (116-2-USG; 272-20-PCNGO; 587-18-PCGOV; 935-23-PCNGO). To increase the availability of data for monitoring the quality of services, PEPFAR partners have supported the development of electronic patient tracking systems (166-15-USACA; 935-23-PCNGO) and tools for collecting and tracking information (934-45-USNGO; 461-19-USG; 935-23-PCNGO; 331-30-USPS). In Uganda, the PEPFAR program has incorporated quality-specific indicators into the M&E systems of treatment partners, including "the retention of patients on ART and adherence to preventive care guidelines (such as the use of cotrimoxazole)" (OGAC, 2006a, p. 46). More information about PEPFAR support for various activities related to strengthening the generation and use of health data is presented in the Information building block.

PEPFAR Achievements

Interviewees in many countries agreed that PEPFAR partners deliver high-quality HIV/AIDS services (272-15-PCNGO; 196-1-USG; 461-13-USACA; 461-18-USG) and that efforts to improve the quality of HIV/AIDS services have had some success (587-18-PCGOV; 934-15-PCGOV; 461-13-USACA; 461-15-USG; 331-12-USG; 331-30-USPS; 331-44-USNGO; 272-15-PCNGO; 935-23-PCNGO). In some countries, people chose not to seek health care services due to perceptions of poor-quality services, including aspects such as dilapidated facilities, lack of medical supplies and commodities, and unqualified or unmotivated staff (240-22-PCNGO; 240-24-USG). In addition to focused efforts to improve the quality of services, interviewees identified the contribution of PEPFAR activities across the health systems building blocks to improving quality, such as increased availability of medicines and medical supplies (240-24-USG; 934-5-USG; 542-21-USNGO), increased laboratory capacity (934-5-USG; 935-2-USG), and improved infrastructure (196-21-PCGOV; 116-19-PCACA; 396-323334-PCGOV).

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Integration of Services

PEPFAR Inputs

Guidance From the beginning, a fundamental principle of PEPFAR was to integrate prevention, treatment, and care services for HIV/AIDS (OGAC, 2004). The reauthorization legislation called for the integration of services to ensure a continuum of care for those affected by HIV/AIDS.[20] OGAC's guidance for the development of Partnership Frameworks called for the integration of "existing parallel service delivery systems with […] government-coordinated and managed health systems" in order to facilitate government leadership of HIV/AIDS programs (OGAC, 2009a, p. 14). There has also been increasing global recognition of the importance of access to family planning services for HIV-positive women who want to space or limit births and OGAC has articulated the importance of linking HIV/AIDS and family planning programs (OGAC, 2011a).

In 2009, U.S. President Barack Obama proposed the Global Health Initiative (GHI), a 6-year $63 billion effort to develop a comprehensive and highly integrated strategy for all U.S. global health programming (OGAC, 2009f). One of the principles of the GHI is to "increase impact through strategic integration and coordination" through support for "holistic planning and programming among health and development programs," as well as integration, "where effective and efficient" (OGAC, 2009f, p. 7). As the largest component of GHI, PEPFAR support for the delivery of coordinated and integrated services is described in the program's second Five-Year Strategy. Some of the goals during PEPFAR II are to integrate PEPFAR quality interventions with other health and development programs; ensure improved coordination with the partner country governments and between US agencies; and identify and implement efficiencies to maximize the strengths of proven programs to respond not only to HIV care, treatment and prevention, but also to the overall health needs faced by PLHIV, their families, and their communities. The strategy described several areas where PEPFAR could support greater integration such as co-location of HIV/TB services, co-location of HIV and reproductive health services, expanded workforce training to provide health care workers with a strong background in primary care, linking PEPFAR food and nutrition programs with other development initiatives, incorporating HIV prevention messages into educational programs, and expanding economic strengthening and microfinance opportunities for PLHIV (OGAC, 2009f).

PEPFAR Activities

Despite OGAC's early articulation of the principles of integration for HIV/AIDS services, the emergency approach during PEPFAR I coupled with the condition of many country health systems resulted in parallel or vertical systems for the delivery of HIV/AIDS services in some countries, particularly treatment services which had previously been unavailable in the public sector in nearly all countries. In some countries visited, interviewees similarly described HIV care and treatment facilities that were built, staffed, and supplied separate from other government health facilities (451-4-USG; 935-ES; 240-ES; 272-ES; 396-ES; 542-ES). However, interviewees noted a renewed focus on integration during PEPFAR II, including a transition from parallel systems to integration and from projects to programs (587-7-PCGOV; 461-18-USG; 396-18-USG). In particular, the GHI

[20] *Supra.*, note 2 at §101(a), 22 U.S.C. 7611(a)(4)(D).

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offered a fresh opportunity for USG agencies to think about integration (116-2-USG; 331-14-USG; 396-60-USG).

During the committee's country visits, partner country government, multilaterals, and USG participants described integration as an essential part of the HIV/AIDS response (934-12-CCM; 587-10-USG; 166-9-USG/OBL/ML), with efforts to integrate as many services as possible into the overall health system (587-10-USG). In several partner countries, there was strong government support and commitment for integration (166-10-USNGO; 331-2-USG; 240-24-USG; 461-11-PCGOV). Both country partners and the USG shared similar assumptions about the benefits of service integration for the health system in general, such as maximizing the value of human resources (587-5-PCGOV; 587-6-CCM; 396-39-USG; 934-10-PCGOV), preventing stigma (396-23-USG; 331-2-USG), increasing access to services for HIV/AIDS (240-15-USG) and other health needs (934-12-CCM; 934-44-PCACA; 396-60-USG), increasing patient acceptability to use services (331-2-USG), integrating the assistance at the donor partner level to strengthen the health sector overall (166-34-PCGOV), and reducing costs (934-10-PCGOV; 272-20-PCNGO) to create efficiencies for both the health system and its clients. However, service integration should not be assumed to be cost-neutral in initial efforts and for some time after integration (IOM, 2010). Although evidence suggests that some types of HIV/AIDS service integration can be cost effective, more research is necessary to determine the most efficient processes of integration (Sweeney et al., 2012).

PEPFAR Accomplishments at Different Service Levels

Integration of different HIV services and other services PEPFAR has supported many different models for integration of different HIV/AIDS services and other services, particularly through systems of linkages and referrals at the facility and community levels.

Facility level Interviewees felt it was important for sustainability to facilitate linkages between the beneficiaries and local government facilities (331-44-USNGO; 240-29-USNGO; 240-26-PCNGO). Bi-directional linkages were built from outpatient clinics (OPCs) to home based care settings (396-21-USG; 396-44-PCGOV), from OPCs to CSOs especially for PLHIV and their families (196-19-PCNGO; 240-15-USG), and from the community base to the health service provider (396-8-PCNGO; 272-15-PCNGO). PMTCT programs using local facility- and community-based partners simultaneously to facilitate referrals and improve service retention (636- 6-USG). According to interviewees, referral systems attempted to offer comprehensive care to PLHIV (331-44-USNGO). These referral systems were implemented on various levels and communicated to organizations by the MOH and health departments in some cases (396-31-PCGOV). Referrals for VCT to ART and bidirectional referrals for TB patients to HIV testing were offered between health care centers and hospitals (196-21-PCGOV); as well as between facilities and community (240-19-USACA). Simultaneously addressing workforce development, NGOs employed retired nurses to facilitate referrals from the public to community system, especially for children and youth family services including basic cases of pediatric HIV (587-8-PCGO; 587-10-USG; 166-18-USNGO). Sometimes, referrals were from lower-level community clinics to higher government-level clinics (396-13-PCGOV), but this did not always address access challenges including wait-listing patients for services (240-24-USG; 240-25-PCGOV; 934-2-USG). For diagnostic services, a sample referral system and laboratory networks were developed to do CD4s in rural areas (461-18-USG). Provincial and central-level laboratories were connected to provincial and central hospitals for CD4 testing (166-11-USG).

Community level PEPFAR also trained activists to provide home-based care for the very sick to encourage them not to abandon treatment and to provide them with referrals to hospitals

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(166-23-USG; 272-7-USG). CSOs used mobile clinics to identify and refer patients—sometimes targeting sex workers (196-24-PCNGO) —to clinical services. Tracking referrals was done in multiple countries through the provision of an examination card clients presented at clinics (196; 934). Efforts in these countries could be duplicated in other countries to addresses the challenges of being able to track patients (587-13-USG; 587-5-PCGOV). Referral networks for MSMs were developed to ensure their access to counseling and testing, and STI services (396-44-PCGOV). Conducting rapid assessments of organizations and providers to determine the extent of referral facilitation and to identify gaps where capacity building was needed (331-34-USNGO). Teams of health workers deployed to community rural health centers to initiate patients on treatment and make referrals to district hospitals (934-10-PCGOV).

Other examples PEPFAR partners have also provided sub-grants and TA to local NGOs for integration of palliative care (240-29-USNGO) and building the knowledge across the country to integrate care and treatment (587-6-CCM), which was described as a response to the challenge of the inflexibility of the disease-specific focus of PEPFAR funding in some countries (587-3-USG; 396-12-USG). In several countries, HIV prevention education activities were integrated into HIV care to reach different settings and populations, such as communities in general, women, parents, in-school youth, people living with HIV/AIDS, people who inject drugs, and CSO members (331-18-USNGO; 272-12-USNGO; 396-21-USG; 587-6-CCM; 587-10-USG; 196-20-PCNGO; 331-24-PCGOV; 331-44-USNGO; 396-32-PCGOV; 396-33-PCGOV; 396-34-PCGOV; 396-40-PCGOV; 542-11-PCNGO; 542-12-PCGOV;196-21-PCGOV). Interviewees explained PEPFAR-supported education efforts to let the community know about the availability of services (331-18-USNGO) and PLHIV about the quality of services they deserve (331-44-USNGO), and encouraging parents to seek treatment for their children (396-21-USG).

Integrating HIV with other health services Interviewees across countries emphasized PEPFAR's efforts to integrate HIV services with other health services, including maternal and child health (MCH), reproductive health, family planning, and services for tuberculosis (TB/HIV integration is discussed in Chapter 6 and is therefore not discussed here). Interviewees also stated that PEPFAR is supporting innovations to support and integrate medical and psychosocial services to address the needs of PLHIV, women who are survivors of intimate partner violence, sex workers seeking to change their economic generation skills, orphans and other vulnerable children including street children, people who inject drugs, and others with psychosocial needs by using mobile outreach teams; by training of social workers including curriculum development, and by encouraging multisectoral collaboration for the inclusion of social workers in a variety of settings as a needed cadre of workers for health services (396-40-PCGOV; 396-21-USG; 542-11-PCNGO; 542-12-PCGOV; 542-14-PCGOV; 166-27-PCNGO; NCV-10-USG; 587-8-PCGOV; 934-31-PCNGO).

For reproductive health and family planning, interviewees shared some of the positive changes made, such as the government's approach on reproductive health going from a vertical to a comprehensive approach (166-10-USNGO; 116-10-USNGO) with integration of cervical cancer screening (272-21-PCNGO), but other countries described vertically-maintained government systems for health services (542-6-PCGOV; 396-22-USG) including family planning that made integration of these services a challenge 331-16-USG; 396-45-USNGO). Some interviewees felt that integration of family planning with HIV services was a success (240-24-USG; 116-18-PCNGO), while some countries were moving towards integrating HIV care with family planning (331-14-USG; 331-16-USG; 331-44-USNGO; 636-17-PCGOV) and integrating family planning services with MCH services, which increased access to these services for many HIV-positive women (934-17-PCGOV). One program described providing integrated components that included: peer educator outreach to clients, counseling, referrals

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clients to VCT, OPC, STI, TB clinic, ART, and care for other infectious diseases (396-323334-PCGOV).

For nutrition, PEPFAR provided nutrition aid to support moderate to severely malnourished patients on ART (331-16-USG; 396-42-PCGOV), as well as linkages to other nutritional support (240-15-USG) and referrals for food subsidies (especially for children living with elders and those living in child-headed households) (166-8-USG). PEPFAR also contributed to decentralization of food and nutrition services (240-2-USG) and expanded nutrition interventions at the community level to decrease malnutrition (636-6-USG; 116-20-USNGO).

Other service areas for integration were seen in various forms in different countries, including water sanitation and access to potable water via a public-private partnership with a major water corporation in one country (934-14-PCGOV), the provision of malaria bed nets in another country (331-14-USG), and transitioning home-based care services to more integrated services such as chronic disease management in yet another country (587-18-PCGOV). PEPFAR also supported the integration of a new a public health institute that planned to co-locate all of the laboratories and combine funding streams for all diseases (166-11-USG). In one country, PEPFAR also funded a program that integrated multiple services and components such as agriculture, water, family planning, sexual and reproductive health, and MCH (166-9-USG/OBL/ML). Multisectoral efforts were seen with integration of HIV/AIDS into all activities of the Ministry of Labor, including all training related to HIV/AIDS for school youth, job seekers, and for other labor clients (587-14-PCGOV). Additional models and approaches to integrating HIV/AIDS services are presented in Box 9-11.

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Box 9-11
Select Examples of PEPFAR-Supported Models and Approaches to Service Integration

Integration into Primary Care: Efforts by both the government and PEPFAR to integrate HIV/AIDS into primary care while simultaneously strengthening health systems are in progress in many countries (587-13-USG; 396-39-USG; 331-44-USNGO; 934-14-PCGOV; 272-17-USG; 196-7-PCNGO). The committee heard several examples of co-locating services at primary-level clinics, including counseling and testing, treatment of opportunistic infections, ART, PMTCT, nutrition and health promotion. There are also efforts to integrate Integrated Management of Childhood Illness (IMCI) and Early Infant Diagnosis (EID) into primary health care (272-24-USG). In some instances, there was a belief at the national level that HIV care and treatment services were too complex to be delivered at the primary care level (587-13-USG; 934-14-PCGOV). Hospices were also connected to primary facilities through referrals (272-7-USG). Integration of prevention and HIV counseling and testing, with linkages to NGO services were desired as part of integration with primary care (196-11-USNGO).

Integration of HIV/AIDS Within The National Health Care System Or Existing Platforms: Interviewees described integration with existing platforms for service delivery as an opportunity to address other needs besides HIV (934-12-CCM; 934-44-PCACA; 396-60-USG) and reduce costs (934-10-PCGOV; 272-20-PCNGO). Several interviewees considered reducing costs to be critically important due to challenges with funding (934-12-CCM; 196-23-PCNGO; 116-12-PCNGO; 272-20-PCNGO; 587-5-PCGOV; 331-44-USNGO). Other examples included scaling up models of effective intervention within the country to promote integration and sustainability (196-22-PCGOV; 542-11-PCNGO). Integration of care using platforms that PEPFAR had already built such as transportation networks for early infant diagnosis (EID); family planning and MCH resources (116-2-USG); or PMTCT programs into pediatric programs (396-55-USG). Governments also evaluated and used PEPFAR's supported ARV supply system for essential medicines (166-6-USG).

Development of "One Roof" Model: A "one-stop-shop" model was described as the most appropriate way to integrate services. The service delivery levels targeted to offer this approach were the community health centers, while inpatient services were referred to the district hospital (196-17-PCGOV); the clinic level where services such as opportunistic infections, male circumcision, tuberculosis, blood draws, and counseling and testing services were co-located (934-15-PCGOV); the district level with counseling, community support, treatment, prevention, care, and support offered at this level (396-39-USG); and the primary health care level. Interviewees noted this approach was very convenient for patients and was also an opportunity for collaboration among sub-projects (396-44-PCGOV). This type of model may reduce costs by decreasing the number of clinic visits and transportation costs (272-20-PCNGO).

Family-Centered Approach: PMTCT, MCH and family planning services offered together (636-6-USG) with the desire to also streamline budgets for these services (331-2-USG). Having a joint national technical working group to discuss and address PMTCT and Safe Motherhood issues together at the government level (240-24-USG).

Health Information: Improving data systems also contributed to having a stronger referral system. Some countries implemented electronic referral systems where patients were "down-referred" from higher-level to lower-level or smaller clinics for drug management and then "up-referred" when they needed clinicians (587-12-USG; 461-11-PCGOV; 272-20-PCNGO). Several initiatives to improve patient monitoring using electronic data systems and linking maternal and child care databases (116-2-USG), by using child health passports to track babies born to HIV-positive mothers (116-2-USG), and by integrating MCH registers with PMTCT (587-5-PCGOV). These efforts

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were implemented to address the challenge for monitoring HIV patients and to decrease the loss to follow-up in such patients (587-5-PCGOV; 587-13-USG).

Challenges for Service Integration

Despite the explicit goal of integrating prevention, treatment, and care services for HIV/AIDS, as well as integrating HIV/AIDS services with other health services, many interviewees described challenges to achieving integration. Integration initiatives faced challenges despite the integration policy being well accepted (331-16-USG) and the development of guidelines for integration in some countries (240-24-USG). Interviewees described lack of integration at several levels of the delivery of services which was attributed to still treating HIV as a separate entity (240-24-USG; 935-ES; 240-ES; 272-ES; 396-ES; 542-ES). In one country, interviewees described how every region has an HIV clinic but these clinics are not integrated to the country's health system (331-12-USG). Interviewees reported poor linkage for family planning services (240-15-USG), and PMTCT (240-24-USG); lack of a good referral system from VCT to care and treatment (587-12-USG; 240-23-PCGOV); and ART working as a standalone program in some cases (240-19-USACA).

Specific to partner country governments The vertical structure of the country government health care system was reported as a challenge due to the lack of connection between government programs where diseases were managed separately (396-22-USG; 396-45-USNGO; 542-6-ML; 587-3-USG; 272-24-USG). The implementation of integration at the national level was considered a difficult process due to the vertical funding of the national program (331-16-USG). The country government health system's capacity was recognized as fragile which made integration a difficult task. An example was provided regarding integration of PMTC in a country where there was no MCH program (587-2-USG). Capacity at the primary care level was also voiced as a concern when thinking about integration (396-39-USG; 272-20-PCNGO). The decentralization taking place in the health care system of some countries disrupted the flow that was already established among the different service delivery levels (240-15-USG). Finally, political support for integration was not always present, with no government buy-in for integration of services into primary care in one country (587-13-USG).

Partner country governments showed different ranges of financial commitment to the HIV/AIDS response. Interviewees were concerned about the limited funding for integration efforts coming from the government (116-12-PCNGO; 272-20-PCNGO), such as the lack of funding for follow up and care after testing in the transgender community (196-23-PCNGO).

Specific to PEPFAR PEPFAR's initial implementation approach to fold an HIV- focused system into the existing country systems was deemed problematic to current efforts for integration (396-39-USG; 272-7-USG; 461-4-USG). Interviewees also noted that USG agencies in-country worked separately and at different service delivery levels which contributed to broken referrals and linkages (240-15-USG; 461-14-USG). These challenges have been overcome in some countries where stronger coordination has been developed across USG agencies (272; 542; 935) and with the change of the approach described in the second Five-Year Strategy. Interviewees stated that PEPFAR was not clear on their approach for allowing people to access a continuum of care, or the role of civil society and the government (396-45-USNGO). This approach caused uncertainty among stakeholders on how to move forward on integration (116-2-USG; 396-7-PCGOV).

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PEPFAR supported many integration initiatives, some of them as projects or pilots which meant having to stop the funding when the project ended. For example, PEPFAR supported a project on PMTCT services integration by training hospital staff to support pediatric care and link maternal care with pediatric care which was found successful but had to stop (331-44-USNGO). Some interviewees characterized funding coming from PEPFAR as inflexible and with a narrow focus as they mentioned they were not allowed to fund non-HIV activities even when, in their opinion, these would impact HIV (587-3-USG; 396-12-USG). Interviewees expressed partners would usually have a positive view of integration until they were competing for funding (331-16-USG).

Access/capacity challenges One of the main challenges at the community level was the access to facilities for testing, treatment and care that were not close to the patient (461-14-USG). Adding to this, there was a lack of adequate infrastructure (587-3-USG), more specifically a lack of appropriate facilities to which to refer patients (272-15-PCNGO). There were, however, several activities described to improve or build infrastructure to facilitate integration efforts including improvements in the laboratory side (240-19-USACA; 166-10-USNGO; 166-11-USG).

Human resources were presented as critical for the efforts of integration such as the integration of care for children and families through family clinics (116-7-USG). Interviewees shared their experience of having to hire social workers from outside of their networks due to the great workload they faced (272-15-PCNGO). This was one area where many activities were put in place to address the lack of skilled personnel, especially in PMTCT, MCH and family planning services (934-17-PCGOV; 587-5-PCGOV; 166-10-USNGO; 396-21-USG).

Reporting challenges Limitations of reporting systems was often described as one of the challenges to facilitate integration with disconnects between VCT and care and treatment sites because there was no name-based reporting for testing, making it difficult to track patients from testing to care (587-13-USG). In the same way, mobile clinics providing care and treatment to HIV-positive women in remote areas were not sharing data with health care facilities (587-5-PCGOV). In contrast, interviewees also shared several attempts to improve the monitoring of HIV patients by using electronic data systems to monitor linkages with TB and MCH (116-2-USG) and an electronic referral system (272-20-PCNGO).

Stigma Stigma presented a challenge to integration efforts due to loss to follow-up of patients after testing because of denial and lack of acceptance of an HIV-positive status (636-6-USG; 542-16-PCGOV). On the other hand, there was also a concern that integrating services would make it easier to identify patients as being HIV-positive (396-44-PCGOV). PEPFAR funding was used to support implementing partners in the provision of quality services that would ensure the confidentiality of patients (396-44-PCGOV).

Future challenges Interviewees offered some insight on ways to move forward on integration. They expressed the need to take every opportunity to do more strategic planning and support systems (396-55-USG). Interviewees believed partners should support and integrate at facility level in future funding (166-10-USNGO), especially at the provincial level (272-11-PCNGO). According to interviewees, PEPFAR needs to help strengthen linkages to ART, including linkages between HIV diagnosis and ART by involving village health teams (VHTs), associations of people living with HIV, and family care units (461-18-USG). One of the remaining challenges was accessing rural areas for testing which was not considered to be cost-effective unless it was linked to behavior change communication, which was not happening for people outside of schools (240-2-USG). The

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need for a network to respond to the HIV epidemic which should be composed of the health, education, and social welfare systems—and even the church—sharing the same strategy and providing all the available resources was also identified (396-8-PCNGO).

PEPFAR Achievements

Most of the discourse in the literature has focused on the extent to which PEPFAR has resulted in parallel systems for HIV/AIDS services and the consequences to the rest of the health care system, both theoretical (Travis et al., 2004) and empirical (Biesma et al., 2009; Brugha et al., 2010a; Brugha et al., 2010b; Dutta et al., 2012; Grépin, 2012a; Grépin, 2012b; Hanefeld, 2010; Kruk et al., 2012; Shiffman, 2008; Shiffman et al., 2009). During the committee's country visits, however, the renewed emphasis on integration of services in PEPFAR II was considered a successful part of the HIV/AIDS response (934-12-CCM; 587-10-USG; 166-9-USG/OBL/ML). Interviewees stated that progress had been achieved in: integration with continuity of care for HIV patients from point of testing to treatment to follow-up in the community (116-12-PCNGO); coordination for disbursement of drugs among PEPFAR-supported government outpatient clinics (396-29-PCGOV) in order to avoid overlap; and using other USG funding (non-PEPFAR) to build service linkages (934-2-USG). In one country, PEPFAR programs were very well integrated with the government health system and government facilities, as well as other donor activities (636-16-USG).

> **Conclusion:** PEPFAR's impressive achievements in service delivery represent the success of a largely disease-specific approach, which had both positive and negative effects on partner country national health systems. In some countries, an early emphasis in PEPFAR implementation on increasing volume of services to meet targets for service delivery resulted in disease-specific programming, which did not always facilitate service integration. PEPFAR has articulated the goal of increased integration of services and has had some success. Many stakeholders in partner countries have identified an interest and/or need for greater integration of HIV services into the general health system. The best practices for integrating services, such as HIV and TB, reproductive health, and primary care, need to be identified, evaluated, and scaled up.

Other Service Delivery Issues

The evidence on PEPFAR's spillover effects to other health services appears to be mixed; Grepin et al. found that some areas such as overall antepartum care may have improved while others suffered related to PEPFAR funding influence, while Kruk et al. found that the number of patients receiving ART, the availability of support groups for PLHIV, and the availability of advanced HIV infrastructure (e.g., onsite laboratories and electronic databases) were associated with increased volume of facility births by women who were HIV-negative (Grépin, 2012b; Kruk et al., 2012). Data from Zambia showed both positive and negative synergies between HIV and non-HIV services (Brugha et al., 2010b). In Kenya there is some evidence that HIV treatment scale up may have supported health delivery efficiency as measured by costs, rather than becoming a trade-off (Dutta et al., 2012).

In contrast to the attention given to possible parallel systems and the goal of service integration, there is relatively little PEPFAR-wide experience in health system innovations, such as performance based financing (PBF), other incentive programs, or risk pooling. Rwanda

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appears to be an exception, where PEPFAR helped support several innovative strategies, including PBF; the *Mutuelles*, Rwanda's national community insurance system; and an innovative approach to human resources for heath (Logie et al., 2008b; Lu et al., 2012). Rwanda has pioneered performance-based financing in primary health care (Basinga et al., 2011). USAID, with financial support from PEPFAR, has examined the impact of financial incentives for HIV-related treatment performance targets.

Performance-Based Financing

PBF is an innovative funding strategy that rewards "the delivery of specific services to encourage higher coverage, better quality or improved health outcomes" (WHO, 2010e, p. 75). PBF links funding to outputs or outcomes and there is some evidence that PBF can help strengthen health systems and increase quality of service delivery (Holmes et al., 2012; Palen et al., 2012; Samb et al., 2009). OGAC has identified PBF as a innovation for improving efficiencies, health outcomes, and sustainability (OGAC, 2011a, 2011c, 2011d). In some countries, PEPFAR partners are supporting PBF strategies in which the disbursement of funding is dependent on a partner or sub-partner reaching a specific target or result (166-5-USG) (EGPAF, 2012). One PEPFAR-supported partner is piloting PBF with its sub-partners. The organization monitors indicators of performance from district health clinics and roughly 20-25 percent of each grant is dependent on achieving specific targets (166-10-USNGO). One interviewee wanted PEPFAR to engage in more PBF (461-15-USG). Another asserted that PBF by an external partner such as PEPFAR undermines national authority and that poor quality data for monitoring performance makes implementation of PBF a challenge (331-5-ML). In Rwanda and Cote d'Ivoire, PEPFAR is supporting partner country governments to implement PBF (Holmes et al., 2012; Logie et al., 2008b).

SUMMATION

There are a number of ways in which PEPFAR, in both phases of the program, has contributed to strengthening of health systems in high-HIV burden countries in the areas of workforce development, training, and retention; health information tools and systems development; health financing with an emphasis on financial management capacity building; and capacity building and opportunities for practical application for leadership and governance with the Partnership Frameworks and Implementation Plans. PEPFAR has had exemplary achievements in the strengthening of laboratory infrastructure and procurement systems for health commodities and technologies, and has demonstrated positive spillover effects in the areas of blood safety and medical injection safety for overall individual and population health.

Initially, as an emergency response, PEPFAR sometimes developed and supported parallel components of health systems, including the delivery of services outside of partner country health systems; separate processes for procurement and supply chain management; and monitoring, evaluation, and reporting outside of national information systems. In some countries, an early emphasis on increasing service volume to meet service delivery targets did not always facilitate service integration. As PEPFAR is transitioning from an emergency to a sustainable response, increased emphasis has been placed on strengthening and integrating with system components in partner countries. In order to avoid undermining areas of non-HIV-related health care delivery, and to ensure that stretched health systems can deliver care for all populations,

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PEPFAR, in conjunction with partner country governments and other external donors, may be able to synergize even further efforts for overall health system strengthening.

> **Recommendation 9-1: To support the delivery of HIV-related services, make progress toward sustainable management of the HIV response, and contribute to other health needs, PEPFAR should continue to implement and leverage efforts that have had positive effects within partner country health systems. PEPFAR should maintain efforts in all six building blocks but have a concerted focus on areas that will be most critical for sustaining the HIV response, especially workforce, supply chain, and financing.**

Further considerations for implementation of this recommendation:

- An important focus for PEPFAR's future activities and policies should be support for partner country capacity to locally produce and retain clinical, nonclinical, and management professionals whose training and scope of practice are appropriate and optimized for the tasks needed. MEPI and NEPI have provided a starting point for the training of physicians and nurses; however the training of associate clinician providers and other cadres will also be critical to sustainable management of the response. In addition, PEPFAR needs to augment its efforts to build partner country capacity to track the placement of trained workers, to promote retention, and to develop long term human resources plans (see also the discussion and recommendation for capacity building in Chapter 10 on Progress Toward a Sustainable Response).
- Building on the progress made through the public-private partnership with SCMS, PEPFAR should enhance and expand efforts with a greater focus on capacity building for accountable supply chain management in partner countries. The aim of this improved capacity should be to gradually shift to local or regional leadership, coordination, and management to ensure a reliable supply chain for essential medicines and commodities.
- Financing and leadership and governance are particularly critical for sustainable management of the HIV response; this area is addressed in Recommendation 10-1 (see Chapter 10).
- To contribute to the knowledge base for health systems strengthening, PEPFAR should include this area in its research and evaluation agenda and its knowledge dissemination efforts (see also recommendations for PEPFAR's Knowledge Management in Chapter 11).

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PART IV

Future of US Government Involvement in the Global Response to HIV/AIDS

PREPUBLICATION COPY: UNCORRECTED PROOFS

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10

Progress Toward Transitioning to a Sustainable Response in Partner Countries

Main Messages

- PEPFAR is actively engaging in activities and processes to transition to a more sustainable response in partner countries.
- Country Ownership has not always had an agreed-upon definition once it was adopted from the development assistance lexicon and applied to PEPFAR. Recent efforts by OGAC have provided clarity for its definition and how partner countries should assess their achievement of its critical components.
- OGAC sees country ownership as a fundamental element of progress toward more sustainable management of the HIV/AIDS response by partner country governments and other relevant and engaged stakeholders in the country. In the transition to increasing country ownership, by necessity, PEPFAR will gradually cede control as partner countries adopt more dominant roles in setting strategic priorities for investments in their HIV response and in accounting for their results.
- The transition to a more country-led and -sustained response will take time; it cannot be achieved on a proscribed generic timeline for all PEPFAR countries. It will be affected by many criteria and decisions, which will vary by country, including where the country falls in the country ownership spectrum when it is evaluated across all four domains of political ownership and stewardship, institutional and community ownership, capabilities, and mutual accountability including finance. Along the way, major dilemmas, such as differences in how to prioritize services and target populations, will require mutual resolution. Inherent risks during the transition period may be reaching smaller targets, reduced service access, or the diminishing of the quality of services, programs, and data. At the same time, greater embedding of HIV services in national health systems may offer opportunities for better integration of care, greater efficiencies, and broader health benefits.
- PEPFAR has focused efforts on capacity building for all levels of stakeholders and attempts to bring many stakeholders to participate in the planning and oversight processes for the Partnership Framework Implementation Plan for country-led response and leadership but with multsectoral participation. It will be a serious impediment to country ownership if the stakeholders expected to be involved in a country's HIV response do not all build their capacity.

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- The over-reliance on external donor funding in partner countries creates funding fragility and the possibility that the HIV response would be critically disrupted if funding were to be discontinued or severely reduced. It is not realistic to expect that partner countries would be able to independently finance the entirety of HIV programming as it is currently implemented. Yet, this does not abate the importance of partner country governments finding ways to reduce the fragility and dependence of their response by increasing their funding contributions, diversifying the sources of external funding that they receive, and making efficient, albeit difficult, strategic decisions about the use of available resources. Even when countries are not able to substantially increase their own funding for HIV/AIDS or health, it is critically important that they demonstrate the leadership to understand their current and future needs by developing their own resources plan, including the responsibility they will undertake to mobilize the needed resources.

Recommendations Discussed in This Chapter

Recommendation 10-1: To contribute to a country-owned and sustainable HIV response, the Office of the U.S. Global AIDS Coordinator should develop a comprehensive plan for long-term capacity building in partner countries. The plan should target four key areas: service delivery, financial management, program management, and knowledge management.

Further considerations for implementation of this recommendation:

- In all four key areas, OGAC should invest more resources in initiatives for long-term capacity building and infrastructure development such as strengthening in-country academic institutions, degree programs, and long-course trainings, to improve in-country capacity and to accelerate progress toward country ownership and sustainability. These investments should foster the placement and retention of trained personnel in partner countries.
- These initiatives should be monitored routinely at the country level to assess progress and identify necessary modifications. Special periodic multi-country studies could be used to evaluate the outcome and impact of the PEPFAR capacity building initiative. To achieve this, OGAC should, using input from country programs, identify milestones towards achieving specified goals, define core metrics to assess capacity building efforts, encourage innovative approaches through pilot initiatives and develop tools to help country programs monitor and evaluate these efforts, and encourage innovative approaches through pilot initiatives.

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Recommendation 10-2: Building on the Partnership Framework implementation process, PEPFAR should continue to work with partner country governments and other stakeholders to plan for sustainable management of the response to HIV. PEPFAR should support and participate in comprehensive country-specific planning that includes the following:

- **Ascertain the trajectory of the epidemic and the need for prevention, care and treatment, and other services.**
- **Identify gaps, unmet needs, and fragilities in the current response.**
- **Estimate the costs of the current response and project resource needs for different future response scenarios.**
- **Develop plans for resource mobilization to increase and diversify funding, including internal country-level funding sources.**
- **Encourage and participate in country-led, transparent stakeholder coordination and sharing of information related to funding, activities, and data collection and use.**
- **Establish and clearly articulate priorities, goals, and benchmarks for progress.**

Further considerations for implementing this recommendation:

- PEPFAR is not alone in trying to achieve locally-led, sustainable health and development objectives. Contributing stakeholders, including partner countries, will need mutually-agreed, principle-based resource allocation to achieve a strategic and ethical balance among the priorities of maintaining current coverage, expanding to meet existing unmet needs, and increasing coverage eligibility. Having processes in place to support this arduous decision making is a critical part of achieving sustainable HIV programs and sustainable management of the HIV epidemic in partner countries.
- Partners in developing resource mobilization plans and potential sources for more diverse funding and other resources could include national and subnational governments other bilateral donors, multilateral agencies, global and regional development banks, and private sector consultants.
- There may be learning opportunities at both headquarters and country level for PEPFAR and other USG entities involved in development assistance to exchange strategies, best practices, and lessons learned for sustaining development objectives.

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10

Progress Toward Transitioning to a Sustainable Response in Partner Countries

For years, donors have been globally responding to the challenge of HIV/AIDS in many countries by funding efforts to avert new infections, to provide treatment and other clinical and psychosocial support services to people living with and affected by HIV/AIDS, and to assess and strengthen the general societal response, including the health and other sectoral systems. The largest portion of these resources has been provided by the bilateral support of the U.S. government through PEPFAR, as well as by its support to the Global Fund (Kates and Summers, 2004). Given that the burden of the disease has historically been highest in low- and middle-income countries, especially those in sub-Saharan Africa, the focus has been the provision of emergency assistance to countries with many competing development and health needs that were often addressed though fragile and frequently deficient health systems. This type of emergency assistance is akin to global responses to natural disasters, albeit the sheer scope and magnitude of the resources needed to accomplish the current achievements in HIV prevention, treatment, and care is unprecedented for a single-disease focus.

The global landscape is changing. Some countries with high or growing HIV prevalence may still need more urgent and immediate efforts, but in many countries HIV has become more endemic and there has been commensurately growing expectation from the global community about a country's own ability to sustain, and to even expand, its HIV response to meet and manage the trajectory of growing need for prevention and intervention services for its population, as well as to sufficiently address coverage gaps in all services. In addition, the current depressed and tumultuous economies in donor countries is affecting the way in which countries are viewing and in comes cases revamping their development aid strategies.

PEPFAR's progress in transitioning to a more sustainable response in PEPFAR partner countries was not explicitly identified in the legislative mandate as a content area for this evaluation. Nonetheless, given that this was a major goal set forth in the Lantos-Hyde Act of 2008 and the second PEPFAR Five-Year Strategy, in the planning phase for the evaluation it was determined to be an essential element underlying the whole of the requested assessment across specific content areas requested by Congress (IOM and NRC, 2010).

During the timeframe of this evaluation, PEPFAR was early in the implementation of changes to in response to the reauthorization, including efforts to improve sustainability of the response over time, to enhance coordination with partner governments and other global funding

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partners, and to support accountable ownership of HIV program delivery by countries themselves. The timing of this evaluation made it difficult to assess the outcomes or impact of these recently implemented changes, for which the full effect might not be realized for several years or even decades. Therefore, the committee assessed efforts in these areas in order to understand whether PEPFAR is making reasonable progress toward its goals for sustainability

To present that assessment, this chapter begins with some brief background on the evolution of U.S. and global approaches to increasingly focus on sustainability. This is followed by a discussion of country ownership, which the Office of the U.S. Global AIDS Coordinator (OGAC) has identified as one of the most crucial elements that influences sustainability. This is followed by sections on other important elements and efforts related to sustainability and on the most critical barriers to achieving country ownership and sustainability. Finally, the chapter presents the committee's overall conclusions and its recommendations for how PEPFAR efforts can be improved to ensure that the evolving goals for sustainability can be met.

EVOLUTION OF THE U.S. RESPONSE TO GLOBAL HIV

The Emergency Response

The first chapter of this report outlined the origins of the U.S. government's bilateral emergency response to the HIV/AIDS pandemic (PEPFAR I) and the second iteration of the U.S. government's global contribution to the HIV pandemic (PEPFAR II). The authorizing legislation of PEPFAR I emphasized rapid implementation and scale-up of interventions and services and established programmatic goals and objectives for prevention, treatment and care activities as well as fiscal targets for some of these areas. It specifically identified 14 focus countries that received the bulk of the initial, intense PEPFAR investment (a 15th focus country was later identified); these were known as the "focus" countries. It also described the essential elements for program implementation (see Chapter 3 for more information on PEPFAR's organization and implementation). While the focus as an emergency suggested a time-limited response, PEPFAR's authorizing legislation did suggest the need for sustainability of some key interventions and areas to

- "Expand [the] basic interventions to prevent new HIV infections and to bring care and treatment to people living with AIDS, such as voluntary counseling and testing and mother-to-child transmission programs, [that] are achieving meaningful results and are cost-effective, from a pilot program basis to a national basis, in a coherent sustainable manner."[1]
- A sustainable supply of quality "HIV/AIDS pharmaceuticals, antiretroviral therapies, and other appropriate medicines."[2]
- "Promote sustainability for medical and support services to HIV positive parents and their children identified through existing programs to prevent mother-to-child transmission" that were established though a pilot program authorized by the President.[3]

1 United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Public Law 108-25, 108th Cong.,1st Sess. (May 27, 2003) §2(16).
2 *Ibid*. §301(a), 22 U.S.C. 2151 §104A(d)(5)(C).
3 *Ibid*. §315(a).

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While there was limited direction mention of sustainability beyond the larger emergency response, these examples do indicate that Congress intended at the beginning of the program that some activities would not only continue into the future, but would also be expanded to national-level programs in a coherent manner.

Toward a Sustainable Response

The Lantos-Hyde Act of 2008 reauthorized PEPFAR and it differs significantly from the emphasis of PEPFAR I by specifically focusing on a transition to activities and goals intended to contribute to a more sustainable HIV response in and by partner countries.[4] Even after the Lantos-Hyde Act, the Center for Strategic and International Studies' Commission on Smart Global Health Policy report in 2010 continued to call for "maintaining the USG commitment to fight HIV/AIDS, malaria, and tuberculosis on a consistent trajectory" as part of a smart, long-term global health policy that would also see an "ushering in of a new era where partner countries take ownership of goals and programs" (Fallon and Gayle, 2010, p. 9) and would use the leverage of existing disease-focused investments to build longer-lasting health systems and partner country capacity solutions to address health needs.

The previous Institute of Medicine (IOM) evaluation of PEPFAR recommended that "the U.S. Global AIDS Coordinator should continue to focus on planning for the next decade of the U.S. Global AIDS Initiative, taking full advantage of the knowledge gained from the early years of PEPFAR about the focus countries' epidemics and how best to address them. The next strategy should squarely address the needs and challenges involved in supporting sustainable country HIV/AIDS programs, thereby transitioning from a focus on emergency relief" (IOM, 2007 p.6). There has been clear uptake of these recommendations in the reauthorization legislation that calls for "a longer-term estimate of the projected resource needs, progress toward greater sustainability and country ownership of HIV/AIDS programs, and the anticipated role of the United States in the global effort to combat HIV/AIDS during the 10-year period beginning on October 1, 2013."[5] Additionally, the Lantos-Hyde Act called for a USG commitment to "help partner countries to develop independent, sustainable HIV/AIDS programs."[6] Various other sections of the reauthorization legislation promote the idea of sustainable approaches for programs, activities, and initiatives, including the statement that the USG should "help countries to assume leadership of sustainable campaigns to combat their local epidemics [that] should place high priority on

> (A) the prevention of the transmission of HIV;
> (B) moving toward universal access to HIV/AIDS prevention counseling and services;
> (C) the inclusion of cost sharing assurances that meet the requirements under section 110; and

[4] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Public Law 110-293, 110th Cong., 2nd sess. (July 30, 2008).
[5] *Ibid*, §101, 22 U.S.C. 7611(a), (a)(29).
[6] *Ibid* §301(a)(2), 22 U.S.C. 2151b-2(a), §104A(b)(1)(D).

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(D) the inclusion of transition strategies to ensure sustainability of such programs and activities, including health care systems, under other international donor support, or budget support by respective foreign governments."[7]

The Lantos-Hyde Act also identified compacts and framework agreements (also discussed in Chapter 9 on Health Systems Strengthening) that would be important tools to assist in the transition towards sustainability. The purpose of such compacts and agreements are aligned with the type of assistance provided by the USG (direct services or limited technical assistance connected to services in countries or regions—both of which are discussed in subsequent sections of this chapter). The reauthorization legislation also identified the need for an updated, comprehensive, 5-year global strategy that called for maintaining gains to date in the respective technical areas. Specific strategic components for sustainability were also identified in the reauthorization legislation including:

- Requirements supporting "descriptions of criteria for selection, objectives, methodology, and structure of these frameworks with countries or regional organizations including the role of civil society, the degree of transparency, the benchmarks for success, and the relationship between such agreements and the national HIV/AIDS and public health strategies and commitment of partner countries"[8]
- Approaches to address investments in health by external donors and increased national funding for HV/AIDS with "descriptions of capacity-building efforts undertaken by countries themselves that included assessments of the impact of IMF macroeconomic and fiscal policies on national and donor investments in health."[9]

Definition of Sustainability

Neither the authorizing legislation nor the subsequent PEPFAR strategies or annexes formally define sustainability. For the purposes of this evaluation, the definition proposed by the Development Assistance Committee of the Organisation for Economic Cooperation and Development (OECD-DAC) is used. It defines sustainability as "the continuation of benefits from a development intervention after major development assistance has been completed" (Development Assistance Committee, 2002).[10] Given the focus of programmatic efforts that are funded by many external donors, development assistance should be viewed not strictly as financial, but should also be thought of as technical and managerial assistance (Merson et al., 2012). While the continuation of benefits into the future is the ultimate goal, PEPFAR's strategies and the Paris Declaration on Aid Effectiveness suggest a number of intermediate outputs or outcomes posited to improve sustainability:

- Affordability, which is the extent to which countries can bear the cost of programs,

[7] *Supra.*, note 4 at §301(a)(2), 22 U.S.C. 2151b–2(a) , §104A(b)(3)(a-d).
[8] *Ibid.* §101, 22 U.S.C. 7611(b), §101(b)(2)(S)(i-iv).
[9] *Ibid.* §101, 22 U.S.C. 7611(b), §101(b)(2)(Q).
[10] Two alternate definitions are also offered but are not being used by the IOM evaluation committee: (a) "the probability of continued long-term benefits"; and (b) "the resilience to risk of the net benefit flows over time."

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- Efficiency/cost-effectiveness as a measure of how economic resources or inputs such as funding, expertise, and time are converted to results (Development Assistance Committee, 2002),
- Country capacity, which is the ability of the government, the private sector, and civil society to "plan, manage, implement, and account for results of policies and programs" (OECD, 2005, 2008),[11] and
- Coordination and harmonization with donors and governments to "implement common arrangements at country level for planning, funding, disbursement, monitoring, evaluating and reporting to government on donor activities and aid flows" (OECD, 2005, 2008).[12,13] It is also important that this harmonization, reporting, and accountability be multidirectional, flowing between and among donors and partner country governments, to demonstrate transparency as part of their communication, coordination, and collaboration.

These outputs and outcomes are resonant with the new PEPFAR emphasis on sustainability for HIV/AIDS responses: they must be "country-owned" and "country-driven;" "address HIV/AIDS within a broader health and development context," and "build upon strengths and increase efficiencies" (IOM and NRC, 2010).

Global Accords That Influence Sustainability

PEPFAR's new 5-year strategy also stated that management of the response to HIV and its effects must not only be increasingly planned and led by countries, with support from bilateral or multilateral partners and national funding, but also increasingly owned with processes of monitoring, evaluating and responding to the unique characteristics of the epidemic in their countries (OGAC, 2009a). These objectives are aligned with the principles of country ownership, leadership and governance, harmonization of donor and partner county government priorities and activities, and national responsibility for a country's social and economic development articulated in several global accords that are framing OGAC's strategies and activities that support sustainability of responses. A number of select global accords, summarized in Box 10-1, influence PEPFAR's efforts and goals for transitioning to sustainable HIV responses. Box 10-2 lists indicators to measure progress and achievements of the Paris Declaration in the areas of ownership, alignment, harmonization, measuring for results, and mutual accountability—principles that are discussed in PEPFAR's concepts of country ownership and in the Partnership Frameworks and Partnership Framework Implementation Plans, which are all discussed in subsequent sections of this chapter.

[11]The Paris Declaration does not specify whose capacity within countries this defines, but it is assumed to be the government's capacity. Thus, this proposed definition is somewhat broader.
[12] Harmonization is explained as the "donor countries coordinate, simplify procedures, and share information to avoid duplication."
[13] As the extent to which PEPFAR has contributed to harmonization has been evaluated by the U.S. Government Accountability Office, it will not be explicitly addressed in the present evaluation.

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BOX 10-1
Select Global Accords That Influence Sustainability of HIV/AIDS Responses

Abuja Declaration (2001)

In 2001, African heads of state gathered at a special summit in Abuja, Nigeria, focused on HIV/AIDS, tuberculosis, and other related infectious diseases. They undertook an assessment and critical review of the consequences of these diseases in Africa. The importance of other agreements and action plans for HIV/AIDS from African development forums was also acknowledged. These leaders made several pledges, including to increase spending on health to at least 15 percent of government spending in what became known as the Abuja Declaration on HIV/AIDS, Tuberculosis, and Other Related Infectious Diseases.

The Monterrey Consensus on Financing for Development (2002)

The United Nations' International Conference on Financing for Development held in Monterrey, Mexico, in 2002 resulted in a consensus that has since been adopted as a major reference for what constitutes good international aid cooperation. Attendees at the conference committed to "address the challenge of financing for development around the world, particularly in developing countries . . . [with the goal] to eradicate poverty, achieve sustained economic growth, and promote sustainable development" (United Nations, 2003). It emphasizes six key areas of financing for development including but not limited to mobilizing domestic and international financial resources for development; external debt; and addressing systemic issues to enhance coherence and consistency in using international monetary, financial, and trading systems to aid in development. It also emphasized the primary responsibility each country has for its economic and social development, further highlighting the importance of external donors committing to the use of development frameworks that embody poverty reduction strategies and that are "owned and driven by developing countries" (United Nations, 2003).

The Paris Declaration on Aid Effectiveness (2005)

This declaration, in which signatories from the governments of more than 90 donor and developing countries, as well as multilateral development organizations, development banks, and other international agencies resolved to "take far-reaching and monitorable actions to reform the ways we deliver and manage aid," represented a new paradigm with broad international consensus on how to make aid more effective (OECD, 2005). The concept of country ownership is at the heart of the Paris Declaration and is a key guiding document for OGAC's newly articulated definition and strategy for country ownership. With the five fundamental principles of ownership, alignment, harmonization, managing for results, and mutual accountability, the Paris Declaration emphasizes the importance of strengthening the national systems in low- and middle-income countries by building measurable development capacity to strengthen public financial management capacity and national procurement systems in countries. The Declaration also has a monitoring and evaluation component to promote the concept of mutual accountability with diagnostic reviews and performance assessments by outlining 12 indicators for national measurement and international monitoring progress on the five principles with defined targets for 11 of their proposed indicators (see Box 10-2).

Accra Agenda for Action (2008)

Signed at the Third High Level Forum on Aid Effectiveness in Accra, Ghana by Ministers of low- and middle-income and high income countries, as well as heads of multilateral and bilateral development institutions, the Accra Agenda for Action recognized that the international community had made progress on the implementation of the Paris Declaration, but that more needed to be done and at a faster pace to meet targets as set and measured by the Declaration. The Accra Agenda highlighted three focus areas for more intense and faster-paced action: (1) strengthening country ownership over development by having countries strengthen their capacity to lead and manage development,(2) building more effective and inclusive partnerships for development by harnessing the energy, skills, and abilities or all stakeholders including external donors, civil society, and the private sector; and (3) delivering and accounting for development results by focusing on greater transparency and increasing the medium-term predictability of aid (OECD, 2008).

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BOX 10-2
Indicators to Measure Progress and Achievements of the Paris Declaration

Ownership: Percentage of partner countries have operational development strategies, including Poverty Reduction Strategies, that have clear strategic priorities linked to medium-term expenditure frameworks and are reflected in annual budgets.

Alignment: Reliable country systems—number of partner countries that have procurement and public financial management systems that either (a) adhere to broadly accepted good practices or (b) have a reform program in place to achieve these. Aid flows are aligned on national priorities – Percent of aid flows to the government sector that is reported on partners' national budgets. Strengthen capacity by coordinated support – Percent of donor capacity-development support provided through coordinated programs consistent with partners' national development strategies. Use of country public financial management systems – Percent of donors and of aid flows that use public financial management systems in partner countries, which either (a) adhere to broadly accepted good practices or (b) have a reform program in place to achieve these. Use of country procurement systems – Percent of donors and of aid flows that use partner country procurement systems which either (a) adhere to broadly accepted good practices or (b) have a reform program in place to achieve these. Strengthen capacity by avoiding parallel implementation structures – Number of parallel project implementation units (PIUs) per country. Percent of aid disbursements released according to agreed schedules in annual or multi-year frameworks and Percent of bilateral aid that is untied.

Harmonization: Use of common arrangements or procedures – Percent of aid provided as program-based approaches and encouragement of shared analysis – Percent of (a) field missions and/or (b) country analytic work, including diagnostic reviews that are jointly performed.

Managing for results: A Results-oriented frameworks – Identity the number of countries with transparent and performance assessment frameworks that could be monitored to assess progress against the national development strategies and sector programs.

Mutual accountability: Number of partner countries that undertake mutual assessments of progress in implementing agreed commitments on aid effectiveness including those in this Declaration.

SOURCE: (OECD, 2005)

The Role of Health Diplomacy

According to Katz et al. (2011), global health diplomacy has several different meanings, but it is a term regularly used by policymakers and academics as the utilization of "new mechanisms to implement ambitious global health initiatives while at the same time securing favorable perceptions in a changing diplomatic space . . . with activities ranging from formal negotiations to a vast array of partnerships and interactions between governmental and nongovernmental actors" (Katz et al., 2011). By early design, high-level embassy staff, specifically country Ambassadors and Deputy Chiefs of Mission (DCMs), have been actively engaged in PEPFAR implementation and oversight. According to Collins et.al (2012) health diplomacy has in some cases, also been a strong tool for the USG to promote the connection between human rights and health by encouraging partner governments to weigh the scientific evidence and the possible consequences for the country's epidemic when determining whether national policies would jeopardize the country's HIV/AID response by marginalizing or excluding key vulnerable populations from access to HIV/AIDS services.

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The use of health diplomacy was also a theme that resonated in the committee's interview data (331-14-USG, 331-44-USNGO, NCV-11-USG, NCV-24-USNGO; NCV-22-USNGO). [14,15] An overarching description of the value of health diplomacy from USG interviewees aligns with the concept of securing favorable perceptions in the changing diplomatic space:

> *"The value of health diplomacy cannot be underestimated. This is a precious asset that PEPFAR brings, that needs to be highly valued and cared for in terms of the goodwill it gains"* (NVC-12-USG).

In addition to providing leadership for PEPFAR mission teams, (240-33-USG, 331-3-USG, 166-3-USG; 542-2-USG), senior diplomatic staff have played a key role in engaging with partner country governments and other donors in their response to the HIV (116-2-USG; 166-23-USG); this engagement is a critical part of the principles laid out for transitioning to sustainability. Since Ambassadors were described as already having a strong background for how to discuss things with governments, an important goal for Ambassadors to achieve was to not only understand the larger country context but also how to place HIV/AIDS within that context. Over time the role of senior leadership expanded beyond the Chief of Mission; in the beginning missions *"did not systematically utilize the Deputy Chiefs of Mission, they are now seen as an important part of the program for health diplomacy"* (NCV-11-USG). During country visit interviews, the committee also heard about the use of formal and informal health diplomacy in many areas, including not only the highest levels for engagement of country government counterparts but also at other technical levels to achieve PEPFAR goals including planning and execution of Partnership Frameworks, Strategic Plans, and Partnership Framework Implementation Plans (272-ES, 116-ES; 542-6-ML; 542-13-USG).

> *"[This] is[a] very top heavy country. Lots of things (and an astounding level of detail) go through the Prime Minister's box so requires high level of US involvement and involves the Embassy automatically. So here, the team needs Ambassador engagement on more issues."* (166-3-USG)

> *"The government of […] is hierarchical and to move things forward, often the Ambassador has to get involved as with the Partnership Agreement Framework – it would not have happened without the Ambassador."* (542-2-USG)

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[14]Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Noncountry Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG**=US Government; **USNGO**=US Non-Governmental Organization; **USPS**=US Private Sector; **USACA**=US Academia; **Partner Country**: **PCGOV**=Partner Country Government; **PCNGO**=Partner Country NGO; **PCPS**=Partner Country Private Sector; **PCACA**=Partner Country Academia; **Other: CCM**=Country Coordinating Mechanism; **ML**=Multilateral Organization; **OBL**=Other (non-US and non-Partner Country) Bilateral; **OGOV**=Other Government**; ONGO**=Other Country NGO

[15] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

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In addition to engagement with partner country counterparts and other stakeholders, beginning in FY 2005, program funds administered under the direct leadership of the Chiefs of Mission were made available for all PEPFAR countries and regional programs that followed specific criteria and reporting requirements to support the development of small, local partners (OGAC, 2009c). These funds were part of the Ambassador's Self-Help Funds program for activities addressing HIV/AIDS. The total dollar amount of PEPFAR funds that could be dedicated to this program was to not exceed $300,000 or 5 percent of the country allocation, whichever is the lower amount (OGAC, 2009c) and the individual grants in the country were usually much smaller in amounts awarded. This discretionary fund has enabled the U.S. Ambassadors in several countries to use PEPFAR small grants for capacity building of small, grassroots organization for program and budget management (331-47-USG, 636-16-USG, 461-19-USG, 166-15-USACA, 166-23-USG). The currently available funding, now known as the PEPFAR Small Grants Program, is often administered by the Mission's Public Affairs Office (166-23-USG) which also works on publicizing PEPFAR's activities in-country (934-2-USG) as part of the expression of good will described in the reauthorization legislation, which called for messaging that demonstrated that PEPFAR is a "commitment by the citizens of the United States to the global fights against HIV/AIDS, tuberculosis, and malaria and enhance awareness by program recipients that the program in an effort on behalf of the citizens of the United States."[16].

Overall, the role of PEPFAR as a tool for diplomacy in the field and globally has grown over time and is largely seen as one of the successes of the program (NCV-16-USACA; NCV-12-USG, NCV-11-USG; NCV-14-ML; NCV-25-USNGO; 542-ES). The role of U.S. Ambassadors in addressing the HIV/AIDS pandemic was described admiringly by a multilateral partner:

> *"What I was impressed with also very often is that most American Ambassadors today, they can have a very serious conversation about AIDS. And that's, I think another credit to PEPFAR, because the early decision was to put the Ambassador in the country basically in charge of the program. Which meant, then, that they went through a fast learning curve. And I think that was, I always hoped that other nations would then, their ambassadors would get to the same level, which is actually only rarely the case."* (NCV-14-ML)

COUNTRY OWNERSHIP: A FUNDAMENTAL ELEMENT OF PROGRESS TOWARD SUSTAINABILITY

The Paris Declaration and other global accords described previously identified "country ownership" as an important element that influences sustainability. For PEPFAR, the Lantos-Hyde Act of 2008 explicitly referenced the principles of the Three Ones, the Abuja Declaration (discussed in Chapter 9), and the need to develop frameworks for program expansion or creation of new programs that emphasize increased country ownership and the promotion of sustainability of countries' responses to their epidemics.[17] The following paragraphs will discuss the concept of and perceptions about country

[16] *Supra*., note 4 at §101, 22 U.S.C. 7611(a), (h)(1-2)
[17] *Supra*., note 4 at §2, 22 U.S.C. 7601(40).

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ownership and efforts of the Office of the Global AIDS Coordinator to accelerate an alignment of its definition of country ownership with stakeholders in partner countries.

Definitions of Country Ownership

Country "ownership" has not been well defined in the past, but commonly included phrases such as 'effective leadership, planning, and oversight', 'country-led or country-driven', or identified activities or outcomes that would be expected with some kind of rating of country ownership. In recent years, OGAC has worked determinedly to articulate what country ownership is or what it entails since OGAC considers the concept as a critical tool to achieve sustainability (NCV-9-USG; NCV-20-USG; NCV-30-USG; NCV-12-USG). In 2010, OGAC engaged the consulting firm McKinsey & Company, with support from the Bill & Melinda Gates Foundation, to conduct a year-long review of PEPFAR's country ownership strategy and "engage and align key domestic and international stakeholders on an action plan to accelerate country ownership of the HIV AIDS response."[18] As a part of this review, McKinsey & Company conducted interviews with high level stakeholders in Washington, DC, including OGAC staff, as well as in-country stakeholders in two pilot countries, Botswana and South Africa. Based on these interviews and consultations, McKinsey & Company also worked with OGAC to do a facilitated self-assessment of PEPFAR's country ownership strategy, articulate a clear definition for country ownership, develop a roadmap to roll out the implementation of the new PEFPAR country ownership strategy, and create a toolkit to facilitate the implementation and measure progress of the new strategy. OGAC then piloted the rollout of the new strategy and toolkit in Botswana and South Africa.

Table 10-1 shows the culmination of their discussions to visually represent a multi-dimensional definition of country ownership and forms the foundation of the Country Ownership Assessment Tool (COAT), which would be used by the U.S. Mission Teams and national stakeholders in a participatory process "to assess a baseline of country ownership and use its finding to develop a thematic road map for country ownership . . . [and] develop an action plan and determine a path for monitoring and reporting, and evaluating impact" (USG, 2012).

[18] McKinsey & Company/OGAC (Unpublished). "Accelerating HIV/AIDS Country Ownership: PEPFAR Roadmap" Presentation to OGAC, July 8, 2011, slide 1. Used with Permission.

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Table 10-1 OGAC-Identified Dimensions and Operational definitions for Country Ownership

OWNERSHIP DIMENSIONS	GENERAL CHARACTERISTICS
Political ownership and stewardship	▪ Host Government has a clear aspiration for what should be accomplished in each stage of program development, implementation and monitoring, generated with input from their own cities and rural areas, civil society, NGOs, and private sector, as well as their own citizens ▪ National plans are aligned to national priorities to achieve planned targets and results, with full costing estimates and plans incorporated ▪ Host country (public and private sectors) is the architect that fully implements and provides oversight of national plan to achieve results and applies and scales-up evidence-based best practices; this includes specific activities conducted by stakeholders in each stage from design to delivery of programs
Institutional and community ownership	▪ Host country institutions (inclusive of government, NGOs, civil society, and the private sector) constitute the primary vehicles through which health programs are delivered and take responsibility for each program ▪ Host country institutions adopt and implement transparent, evidence-based policies/regulations for priority areas that align with national plans ▪ Host country institutions manage funds
Capabilities	▪ Host country has effective workforce, organizations and systems at all levels able to perform activities and carry out responsibilities that achieve priority health outcomes ▪ National coordinating bodies and local institutions have the ability to gather and analyze epidemiological and program data to plan and measure program progress and results ▪ Host country institutions have the capabilities required to perform or oversee activities for programs ▪ Host country institutions have the ability to dynamically modify programs based on evidence and feedback from monitoring processes
Mutual accountability, including finance	▪ Host country is responsible to country citizens and international stakeholders for achieving planned results ▪ Host government is responsible for financing and financial stewardship over health ▪ Explicit roles and responsibilities are described with appropriate management of performance in place ▪ Measures are robust ▪ Information and processes are transparent and there are mechanisms for input and feedback from civil society, the private sector and donors

SOURCE: McKinsey & Company/OGAC (Unpublished). "Accelerating HIV/AIDS Country Ownership: PEPFAR Roadmap" Presentation to OGAC, July 8, 2011, slide 3. Used with permission.

A definition of country ownership and its policy implications was further articulated in the most definitive public statement by the USG-authored paper on the topic:

> "Countries that effectively manage their public health response demonstrate leadership over their health budgets, policies and strategies, and coordinate public health actions, including the contributions of the private sector, donors and civil society. Country ownership involves shared responsibility and mutual accountability with donors and other partners, particularly when outside financial and technical resources are needed to fully respond to the health sector needs of host countries. The USG fosters country ownership by investing in high impact and evidence-based country-led priorities, plans and systems. The USG also encourages country ownership when it promotes direct financing by

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> recipient countries for priority interventions such as malaria and family planning commodities. Ultimately, a well-coordinated, country-led health response enhances efficient use of resources and contributes to long-term sustainability of global heath programming" (USG, 2012).

U.S. Secretary of State Hillary Clinton also clarified the USG definition and position on country ownership at the Global Health Summit in Oslo Norway in June 2012:

> " . . .[It is] not just a matter of semantics, because if we are not clear about what country ownership means, we cannot know whether we are making progress toward achieving it. To us, country ownership in health is the end state where a nation's efforts are led, implemented, and eventually paid for by its government, communities, civil society and private sector. To get there, a country's political leaders must set priorities and develop national plans to accomplish them in concert with their citizens . . . And these plans must be effectively carried out primarily by the country's own institutions, and then these groups must be able to hold each other accountable . . . So while nations must ultimately be able to fund more of their own needs, country ownership is about far more than funding. It is principally about building capacity to set priorities, manage resources, develop plans, and carry them out. We are well aware that moving to full country ownership will take considerable time, patience, investment, and persistence. But I think there are grounds for optimism" (Clinton, 2012).

While OGAC may have had an evolving vision for country ownership, and even based some of its policy and diplomatic decisions and programmatic activities on the principles of the global accords, it has had difficulty in articulating its definitions and expectations, how it would measure when or whether a partner country government had achieved country ownership, and thus make determinations about the country's ability to sustain its current national HIV/AIDS responses, as well as plan for the future needs of their responses including gaps in services and populations who need to access them. Table 10-2 gives a summary of some of the high-level, but critical insights from PEPFAR's self assessment and study of country ownership.

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Table 10-2 PEPFAR-identified Insights from an Internal Study Commissioned by OGAC on the Principles of Country Ownership

OWNERSHIP DIMENSIONS	HOW PEPFAR CONTRIBUTES TODAY
Political ownership/stewardship	• While agencies feel they have cultures compatible with country ownership, there is a lack of shared vision across the program • PEPFAR financial and reporting processes are seen as inconsistent with ownership and poorly understood by country stakeholders
Institutional ownership	• Real strength in civil society engagement, but with CSOs more as implementers than as patient advocates • While PEPFAR readily engages in dialogue when there is disagreement, teams say they would benefit from clearer dispute resolution mechanisms, talking points and proactive early engagement
Capabilities	• While there are many examples of capability activites, these are typically not part of an overall PEPFAR strategy, opportunity to take the best ideas and scale them more systematically • PEPFAR's organization structure, professional incentives, and skill sets at HQ and in country remain oriented toward PEPFAR I and are not set up to support country ownership
Mutual accountability	• Stakeholders do not understand some PEPFAR processes such as the COP and desire more transparency • PEPFAR does not require accountability for country program performance

SOURCE: McKinsey & Company/OGAC (Unpublished). "Accelerating HIV/AIDS Country Ownership: PEPFAR Roadmap" Presentation to OGAC, July 8, 2011, slide 6.

Perceptions of Country Ownership in Partner Countries

The perceptions of Mission Teams, partner country governments, and implementing partners from the interview data collected by this IOM committee showed a range of comprehension and alignment, compared to OGAC's perceptions and understanding, for not only the meaning of country ownership, but also of how the country should be assessed or measured for achievement. The most aligned of the field and OGAC HQ perspectives indicated that PEPFAR has been a country driven process from the beginning:

> *"What has been remarkable has been the partnership. The interest on ground in solving a problem and working hand in hand as a partner has been amazing. Everyone feels this is a huge challenge, there is a level of respect that is unique, and everyone is considered a colleague—with the local partners as well . . . 'we are all in it together we are going to innovate together. There is a misconception about PEPFAR that there is someone in DC turning the screw. That is not my experience you walk in country and see USAID, CDC, and country sitting together solving problems. It has been a country driven process from the beginning.' [I] think PEPFAR has been country owned all along."* *(NCV-5-USACA)*

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Others suggested that, in some cases, partner country stakeholders perceived that ownership was already attained: *"is here"* or *"we own it," "the government takes it seriously and tries to get whatever they are responsible for right"*, but some perceived that ownership was more about owning HIV as a serious health problem rather than the actual HIV response (166-ES, 240-ES, 587-ES, 934-ES; 636-ES). By contrast, several partner country governments or national coordinating entities clearly stated their responsibility for the HIV/AIDS response (542-ES, 240-ES; 331-ES; 272-ES):

> *"I accept this idea [of country ownership]. The government of each country should be responsible for the needs of the people. Donors should fill the gap, not replace government activities. The government should own/lead planning, implementation, and M&E—otherwise the program cannot be scaled up and sustained. Donor funding should slowly decrease and the country should use more of its own resources. The country should work with partners for how donor contribution can be replaced by the government gradually using an exit strategy"* (240-7-PCGOV).

> *"[The] country has the "liberty" to prioritize what the money is for rather than have it be for pre-determined agenda in relation to what donors have money for . . . having [its] own group of national experts to manage and plan the response—in-country expertise . . . Having a system for assessing/evaluating programs, demonstration of national commitment to meeting costs . . .and no one stakeholder takes more ownership than any other including the government. We are in our country, we know our problem, we know what to do to stop our problem . . . they should listen to us too"* (331-6-CCM).

> *"It means that the country should finally start addressing the problem instead of relying on an outside agency addressing it. It's like they have just taken a step back and let USAID and PEPFAR address it"* (272-15-PCNGO).

Some interviewees saw country ownership as *"a catch phrase where the country owns the issues and the fix, but is driving with donor money"* (587-3-USG); '*necessarily requiring a lot of time for coordination and meetings, but not having a lot of resources dedicated to its achievement'* (116-26-USG); or '*feared it an "exit strategy" to abandon countries'* (116; NCV-16-USG; NCV-12-USG; NCV-30-USG).

IOM Country Visit Teams also heard various elements of country ownership (see Box 10-3) linked with country capacity (587-ES) including the existence of a national infrastructure (331-ES) to support the response, and country government-perceived responsibility for and commitment to leading, managing, and financing all aspects of the HIV/AIDS response (166, 272, 396, 461).

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BOX 10-3
Elements of Country Ownership from Interview Data

- Country capacity (587-ES)
- Government/country perceived ownership of (or desire to own) the response (166-ES, 587-ES, 934-ES)
- Government committed to (166-ES) and responsible for response (166-ES)
- Government -led (331-ES, 461-ES), controlled (240-ES), funded (272-ES), planned (461-ES), set policy for (461-ES), managed (166-ES), and was accountable (396-ES) for the response (240-ES).

Government/national actions:

- Reduced donor dependency (272-ES)
- Government funding of part (461) or all of the response (331-ES)
- Government-donor jointly developed donor exit strategy (240-ES)
- Government control of funding (331-ES, 396-ES)
- Existence of a national infrastructure (331-ES)
- Strong national plan (587-ES)
- Government-led response planning and prioritization (240-ES) of needs
- Strong local organizations (461-ES)
- CCM plays major role (331-ES)
- Stakeholders coordinated (331-ES)

Donor actions:

- Donor funding reduced (272-ES) or eliminated (240-ES)
- PEPFAR support of country priorities (240-ES); provision of direct funding to government (166-ES)
- Track 1 Partners transition to local NGOs (166-ES)
- Activities aligned with National Strategic Plan (934-ES)
- OGAC leadership needed (272-ES)

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Interviewees also identified the need for both partner country governments and donors to facilitate country ownership and the transitioning from a donor-led emergency response to a more sustained country-led response. Reduced donor dependency (272) in concert with increased government leadership and commitment of resources ultimately contributed to country ownership. Additional potential contributors to country ownership included civil society, local organizations, other stakeholders, and the CCM. Some examples given of country-owned capacity for various parts of the HIV/AIDS response included fully and nationally-managed procurement systems (587-11-PCGOV; 587-15-PCGOV/ML/USPS) to majority or increased funding for the procurement of ARVs by partner country governments (542-9-PCGOV; 272-2-USG.)

Two challenges to country ownership were uniquely identified by USG interviewees. The first was the USG organizational culture and mindset of some of the USG staff and implementing partners' roles in facilitating both the cultural change and country ownership. Concerns of financial stewardship of U.S. taxpayer dollars and quality of services provided to beneficiaries by implementing partners, coupled with a strong sense of ownership of the program by USG staff and implementing partners, may have contributed to the perception that country counterparts might not approach the stewardship the same way, with the same intensity, or with the same results for quality of services (NCV-9-USG; NCV-30-USG)

> *"And there's no way around it because the culture and structure of our institutions are actually not built for that true transfer. That is not the culture or structure of our multilateral or bilateral institutions. We talk about it all the time and everyone talks about it but structurally we are actually not, or culturally we are not built for that. The culture of our institutions is still we are in control, we are the donors, as much as we try to say we're not, that's not the culture and it's not the structure. The Global Fund is the only institution in a multilateral sense that was created to respond to those principles of fully country-owned. No other institution was, and the Global Fund hasn't succeeded at it. PEPFAR was created as a bilateral but it's really hard as a bilateral to force that. MCC [The Millennium Challenge Corporation] was created that way as a bilateral but it's really hard"* (NCV-16-USG.)

> *"And it's like oh no, no, no, my sense of ownership you don't understand this program is successful because of my blood and sweat. And I think we have to be very respectful of that, sensitive to that, because this change is not going to happen in Washington. So our chiefs of mission, our leadership is a good place to start because they can model the type of behavior, and it's like no, that's the kind of engagement [that we want]"* (NCV-9-USG).

It was perceived by some interviewees that even PEPFAR's operation through implementing partners itself could have created layers of distance that did not facilitate opportunities for oversight staff to be more directly engaged in the field with all of the

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stakeholders and leaders among whom partnerships and communication are needed for country ownership (NCV-9-USG; NCV-30-USG). Interviewees representing implementing partners and oversight staff in U.S. Missions generally offered a variety of reasons for their inability to engage partners and subpartners as often as they would have liked, primarily the time-intensive activities needed for program implementation including COP planning and programmatic reporting requirements (542-23-USG, 166-26-USG; 636-23-USG).

> *"In the midst of all of these conversations we also know that your ability to move forward in this dialogue is as good as the partner who is across the table from you and sometimes you know we can blame our teams but sometimes there are legitimate barriers of just basically not having across the table a partner who wants to engage . . . especially when we're getting to hear from the other side just what it's really like for them sometimes in country and how really you know "yeah you can say that I wasn't, I didn't produce a lead for the ART program but I don't recall anytime your people coming to ask us and things like that". So you know it's not that easy to sometimes know what the reasons are. And so that all comes to play when you started to say okay let them decide"* (NCV-9-USG).

Another challenge identified by USG stakeholders was the way in which technical assistance is delivered by the USG for capacity building. In their piloted activities to better understand the facilitators and barriers to country ownership during the McKinsey consultation, OGAC learned that they were more often providing technical assistance to USG staff in the field rather than the local partners for whom they needed to build in-country capacity. It was stated that change was needed for these challenges at both the headquarters and field levels to become more facilitative of country ownership and build in-country capacity for a sustainable response (NVC-9-USG).

IOM team members identified impediments to country ownership that interviewees shared during the country visits where partner country entities, PEPFAR, or both contributed to what the committee characterized as impediments during analysis of interview data (see Box 10-4).

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BOX 10-4
IOM Committee-Recognized Impediments to Country Ownership From Interview Data Analysis

Partner Country-Related

- Lack of capacity and resources to adequately and independently support the response. Country ownership may be unrealistic given country lack of capacity and resources(116-ES)
- Lack of partner country or government commitment, responsibility for, or investment in the response.
- Unpredictable partner country/government leadership and partners (166-ES)
- Fragmentation of the response (166-ES)
- Misaligned partner-country and PEPFAR priorities (240-ES, 331-ES)
- Unclear role or recognition of civil society in country ownership (166-ES)

PEPFAR-Related

- A failure by OGAC to clearly define the concept, "country ownership," (396-ES) presented issues because the concept then meant different things in different countries (272-ES)
- OGAC's efforts to "roll out" concepts such as country ownership occurred with no input or guidance from the field (396-ES).
- Belief that OGAC should play a greater leadership role in country ownership efforts (272-ES)
- Lack of measures to demonstrate the progress or measure the impact of country ownership efforts (461-ES).
- simultaneously addressing capacity building leading to ownership and also achieving PEPFAR annual targets was viewed as difficult to impossible to do—they are opposing tasks (166-ES).
- Misalignment of PEPFAR and partner-country priorities (331-ES)
- Inadequate terminology, as the potential existed for partner countries to view the term, "country ownership," as offensive or paternalistic (396-ES). Alternative terms for consideration might have included, country "leadership" or "stewardship" (396-ES)
- OGAC ignoring stakeholder-identified priorities (331-ES)
- Increasingly detailed directives from OGAC (331-ES)
- PEPFAR or implementing partner branding (396-ES)

Efforts to Accelerate Country Ownership

From its consultation with McKinsey & Company, OGAC has developed insights into the differences between the perceptions and understandings country ownership that it held compared to those by partner country stakeholders, as well as PEPFAR Mission Team members. As a result, OGAC has identified several important areas and strategies for accelerating the alignment of its definition in partner countries. For nearly each issue identified across the four domains of country ownership described in Table 10-2, OGAC identified a number of 'priority themes for change' with 14 initiatives to address them (see Box 10-5).

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BOX 10-5
OGAC's 14 Initiatives to Address Priority Themes to Accelerate Country Ownership

1. Definition and second phase of PEPFAR change story: Align on a shared definition of country ownership and PEPFAR's future vision, how the organization will achieve this vision, and communicate throughout all levels and agencies
2. Shared vision with development partners and multilaterals: Convene donors and international development partners to create a shared global vision for HIV/AIDS programs under full ownership, and roadmap for achieving it (including, e.g., roles of each stakeholder). Also align on international standards, such as harmonizing reporting requirements
3. Reform roles, responsibilities, and staffing processes: Institute a strategic staffing and role realignment process that ramps up staffing for results; identify, address, and track skill gaps in-country and at HQ by developing slate of required technical and managerial skills in management, negotiation, and dispute resolution for advancing ownership and avoiding duplication between agencies; meaningfully enhance country coordinator role including formal training and mentoring, establishing SOPs, clear reporting lines to OGAC and decision rights in country; and require countries to assign relationship leads within partner country MoH, MoF, NACAs
4. SOPs for PEPFAR engagement and interactions in countries: Develop SOPs for country teams on interactions with stakeholders in-country, including flexibility of indicators/reporting schedule for teams to align with country response, talking points for USG team for negotiations with partner country government and clarifying USG policy (e.g., funding only evidence-based approaches). The SOP should address differing perspectives on funding priorities during COP development between agencies, country teams and governments, with transparent publication of points of disagreement and rationale for ultimate decisions. Develop guidance for and leverage embassy support in appropriate countries for ensuring CSOs have a meaningful "seat at the table" in country planning processes at NACAs and PFIP drafting. Develop SOP on best practices in-country to promote efficiency and effectiveness
5. Communication platform for sharing best practices: Create a collaborative Web-based communication platform for rapidly and regularly sharing best practices amongst country teams including civil CSO success stories and managerial innovations
6. Workshops and trainings for countries: Develop and deliver new workshops and trainings for countries on reviewing most recent epidemiological data on high impact interventions to align on priorities, PEPFAR processes and reasoning for allocation decisions with local stakeholders, and exchanging views on priorities between governments, NACs, and country teams
7. Efficiency and effectiveness benchmarking: Advance efficiency and effectiveness in countries by conducting annual cross-country cost benchmarking by leveraging existing tools, investing in new data management and tracking systems (as needed), and clarifying data quality requirements for reporting. Benchmark cost effectiveness data across PEPFAR countries and provide benchmarking data and additional capacity (staff and/or training) to pilot in-country performance management analysis and propose solutions for country teams
8. Transparent HQ data presentation: Create new read-outs of plans/allocations in COPs and PFIPs (e.g., in a user-friendly interactive website) outlining program priorities, financial decisions, and links to funded programs
9. Country segmentation and country ownership guidance by segment: Provide guidance tailored to countries ownership situation segmenting countries according to their position on the ownership continuum, set in each segment performance milestones for second phase of PEPFAR and a view on long-term graduation. Issue clear guidelines for funding in each segment and earmark a percentage of total country funds to be spend on capacity building with a focus on governance and advocacy. Develop exit plans from funds for CSOs to encourage their sustainability post-PEPFAR. Renew contracts to encourage transition from international partners to coalitions/local partners in mature programs, setting target percentages of funds to transition to local partners or coalitions. Pilot performance based funding in two to three countries in the first year.

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10. COP reform: Revise COP templates and processes to include adding ownership actions into four TANs, requiring teams to present a separate document on ownership during COP review. Meet with country stakeholders (including CSOs) during development and include country leadership in COP review presentation. Pilot full ownership metrics / assessment in this COP cycle with 5 countries. Move point of approval for high-level country program budget allocations earlier in COP review process to minimize later reworking of funding priorities
11. Metrics: Develop a country ownership index supported by objectively verifiable metrics to measure change and progress over time across each dimension and in the aggregate
12. Individual performance reviews: Create country ownership objectives for agencies to add to individual performance reviews so that success on advancing initiatives can be acknowledged and rewarded
13. Strategy reviews in-country: Pilot in-country cross-agency strategy reviews, to include defined agency roles and competencies. Joint identification of areas or overlap and gaps between coverage and country team develops future state vision/plan and roadmap to address gaps
14. Revision of technical assistance model: Revise guidance so that all forms of technical assistance are shaped to advance ownership, e.g., consolidate guidance for all TWGs to create and monitor policy including standardized documents/reports which incorporate ownership principles

SOURCE: McKinsey & Company/OGAC (Unpublished). "Accelerating HIV/AIDS Country Ownership: PEPFAR Roadmap" Presentation to OGAC, July 8, 2011, slides 37-43.

Transitioning to Country-Led Responses

From interview data, some interviewees associated a planned or actual transition in leading, managing, and financing from donors to partner country as progress toward ownership. The pace of transition and the point at which countries were located in the transition to ownership varied among countries. As PEPFAR and other donors facilitate country ownership, they will need recommendations from partner country entities on how to best to shift direct funding to the government, decrease donor support (240-ES); align all activities with country priorities (240-ES) and national plans (166-ES, 934-ES); and shift implementation leadership and activities from donors to governments/ministries and local NGOs (166-ES). In addition, some interviewees believed that *"OGAC should play a greater leadership role in [facilitating] country ownership efforts"* (272-ES).

> *"I think that as country ownership becomes more of an explicit goal they[PEPFAR] could do more to guide international processes and national processes to sort of make sure that those things will continue to happen when they're gone"* (NCV-24-ONGO).

PEPFAR's shift from a USG-led and USG-funded program to their vision of a more country-led program has been an intentional and deliberate process over several years (NCV-9-USG).

> The transition process is intended to facilitate a smooth transfer of the program's management, implementation, and ownership to the intended host country recipient. . . It focuses primarily on technical, managerial, and financial aspects of the program. The ultimate intention of a transition is a changed relationship, one of a mutually beneficial technical partnership between USG and the partner country. It is fully acknowledged that

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> country progress may occur at different rates depending upon individual country circumstances. . . For example, a financial transition is more likely to occur with a faster pace in upper middle-income countries, later in lower middle-income countries and later still in low-income countries. (USG, 2012)

USG Precedents in Transitioning Health Programs

Transitioning to a more country-led initiative with either reduced or no USG direct funding, as well as programmatic responsibility and oversight is not without precedent in USG development assistance. Although not of the same scale and scope as PEPFAR, these precedents offer salient lessons. Family planning has been an area of long-standing support by USAID—in some developing countries for decades. When USAID's family planning portfolio was evaluated by the Office of Management and Budget (OMB) in 2002 with the Program Assessment Rating Tool (PART),[19] it was determined that USAID did not allocate these resources to the countries in greatest need. In response, USAID developed need-based assessment tools that also considered other criteria that affect budgeting including "absorptive capacity, country stability, country commitment, and other donor contributions." They used these tools to develop strategies that would enable USAID to gradually decrease funding in select, long-standing countries after it was determined by several measures that these countries could provide the service without USG assistance. This allowed for a strategic reallocation of funds to countries in greatest need. These transitions became gradual and were undertaken over a period of years to avoid abrupt termination of funding to countries (Bertrand, 2011). In 2006, USAID's working group for this issue recommended that all USAID assistance programs in developing countries be designed and implemented "with the expectation that the host country program will no longer eventually require or receive direct support from USAID or other donors" (Bertrand, 2011).

A domestic example of health systems planning, ownership, and management may also be informative to PEPFAR's transitional efforts in partner countries. Prior to 1968 all health care for Alaskan natives was provided by the USG. With the advocacy of the Alaska Native Health Board (ANHB), the Alaska Native Tribal Health Consortium (ANTHC) was formed in 1997. While operational funding is still received from the U.S. government, the Consortium has increasingly assumed ownership and control from the U.S. government for all statewide health programs that serve the more than 200 federally-recognized, sovereign tribes in Alaska. With this transference of ownership and control, all Alaska Natives are not only owners, but also customers of this consortium (ANTHC, 2008). The Consortium's Executive Leadership Team comprised of the CEO and 12 senior leaders were responsible for assessing their organization and identifying the improvements needed in the system with the use of benchmarking and the Baldrige Criteria for Performance Excellence to assess their organizational performance and quality assurance needs (ANTHC, 2007).

The Alaska Tribal Health Compact, established through the USG Indian Health Service, is the umbrella agreement that outlines the tribal government–to–U.S.-government terms, as well as the conditions of the comprehensive health system; authorizing tribes and Native health

[19] This tool was developed by the OMB to "assess and drive the improved performance of U.S. government programs by examining factors that affect and reflect program performance, such as program purpose and design, performance measurement, evaluations, strategic planning, program management, and results" (IOM, 2007).

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organizations to operate health programs.[20] The compact also stated that each tribe retains autonomy over its respective health priorities, services and policies in its specific geographic area (Indian Health Service, 2012). The Alaskan natives are responsible for comprehensive services across the entire continuum of care (ANTHC, 2008) which includes but is not limited to: managed hospitals, health centers, substance abuse treatment centers, specialty care, and health promotion/disease prevention programs (Indian Health Service, 2012). In fact, this model informed the early conceptual development of PEPFAR, especially in terms of approaches to local ownership by sovereign entities (NCV-16-USG).

The Consortium emphasizes working with partners to develop and enhance collaboration with health and funding agencies; promoting the use of the consortium services by Native beneficiaries and building capacity for Native health professional development; unifying and strengthening the health system; and creating the highest-quality health services by improving clinical outcomes and reducing rates of preventable disease and illness. The consortium identifies many successes that include the recognition of cultural competency of all ANTHC; their growing reputation; low to no cost services for beneficiaries; the provision of lifelong care; and community involvement. The main challenges that the association currently faces are the current competition of federally run hospitals within Alaska, "Alaska Native health status, budget/reimbursement, access to care, workforce development and management, relationship management and infrastructure improvement" (ANTHC, 2007).

Metrics for Progress Toward Country Ownership

Although OGAC may have had an evolving vision for country ownership, and even based some of its policy and diplomatic decisions and programmatic activities on the principles of the global accords, it has had difficulty in articulating its definitions and expectations and how it would measure when or whether a partner country government had achieved country ownership. It has thus been a challenge for OGAC to make determinations about a country's ability to sustain its current national HIV/AIDS responses, as well the country's ability to plan for the future needs of its response including how to fill gaps in services and improve access to them.

PEPFAR has often identified outcomes of country ownership, such as sustainable procurement, improvement of supply chain systems, and strengthened capacity in local institutions; however, metrics and indicators for progress toward country ownership, especially in the four domains identified by OGAC, is very newly published. Mapping and using national indicators as metrics for progress towards country ownership, rather than relying only on the amount of money the government contributes as evidence of commitment are possible measures (NCV-9-USG; NCV-30-USG). Illustrative examples of other metrics from the USG Interagency Paper on Country Ownership include domestic health and HIV/AIDS spending; expenditure reports; indigenous prime partners; and transitioned management of USG programs. Box 10-6 provides other USG-identified examples of potential measures of success for country ownership. The use of these measures to assess the transition to country ownership could address concerns identified

[20] Tribes and Tribal Organizations operate under the authority of Indian Self-Determination and Education Assistance Act, Public Law 93-638.

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by interviewees in order for all to know where a country stood in each of the OGAC-identified domains for country ownership (396-ES; 461-ES; NCV-2-USG; NCV-30-USG).

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BOX 10-6
USG-identified Potential Measures of Success for Country Ownership

USG country teams interaction with host country partners:

- USG COP alignment with government plans
- USG engagement as a key stakeholder as part of the national strategic planning process
- USG transparency in sharing its total funding for programs in country and making the information available to partner governments in an understandable manner
- USG engagement with partner government in resource allocation discussions and decision for prioritized programs

Promoting and Engaging In-Country Partners – Governments:

- Increased domestic government health spending over time
- Increased number of programs of proven efficacy taken to scale by local entities
- A shift and/or expansion of direct funding to government institutions
- A shift and/or expansion of direct funding to non-governmental local institutions
- Use of government planning and management systems
- Demand created at the community level which enhances accountability for government and/or local service delivery

Promoting and Engaging In-Country Partners – Civil Society:

- Increased percentage of USG funding that is awarded to local partners through contracts, cooperative agreements and grants
- Number of new prime partners in fiscal year who were sub-awardees in the past
- Number of effective civil society organizations with mechanisms in place for citizens to express views to government bodies (social responsiveness and accountability)
- Average % change in organizational capacity amongst USG direct local NGO implementing partners as measured by a defined organizational capacity assessment tool (e.g. (e.g. Organizational Capacity Assessment (OCA), Organizational Capacity Assessment Tool (OCAT), Institutional Development framework (IDF), Discussion Oriented Organizational Self Assessment (DOSA))
- Representation of community members and active participation of communities in governance structures

Promoting and Engaging In-Country Partners – Private Sector:

- Increased number of trainings in financial management convened by the private sector for the public health sector
- Joint financing agreement is developed with the private sector and government
- Increased number of private health facilities certified by the government
- Increases in the percentage of Total Health Expenditure (THE) attributed to the private sector
- Increases in the percent of out-of-pocket expenditure for health attributed to the private sector

Promoting and Engaging In-Country Partners – Bilateral/Multilateral Organizations and Regional Bodies:

- Government reveals a costed health strategy budget that is inclusive of Global Fund, USG, and other donor annual contributions
- The government annual work plan includes the activities being conducted by all stakeholders

Promoting and Engaging In-Country Partners – Academia:

- Increased number of health-related research projects conducted and disseminated by host country academic institutions
- Increased number of research conferences convened by host country academic institutions
- Increased number of local academic institutions engaged in health surveillance, research and evaluation

SOURCE: (USG 2012)

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OTHER KEY ELEMENTS FOR ACHIEVING SUSTAINABILITY

Different Models of USG Assistance

The U.S. government has described different models of support to countries along a continuum varying by the degree of direct assistance for service delivery versus technical assistance for collaboration. The model to offer for each partner county is dependent upon the progress towards country ownership and sustainability. In countries with high HIV burden and U.S. geopolitical interest, other factors including unmet need, high resource needs, Global Fund financing availability, and capacity gaps, might warrant a long-term engagement strategy for service delivery through mechanisms that allow PEPFAR to fund implementing partners in a country—from national government to local non-governmental organizations. This would be the case for countries like Haiti and Sudan that are experiencing setbacks in their HIV/AIDS response due to external shocks like natural disasters or post-internal conflict efforts (USG, 2012). Countries with high poverty and development needs might also qualify for this type of long-term engagement. The next model is described as a blend of technical assistance for priority areas or key populations with some funding for capacity building for direct service delivery for this targeted population. Countries in the Caribbean region were identified as recipients of this type of assistance. Another model is focused on technical collaboration for continued in-country capacity building as countries have demonstrated management, technical, and financial capacities, as well as an increased ability to wholly or co-finance the response. This co-financing expectation is based on a targeted range of annual economic growth and South Africa, Botswana, and Namibia were provided as examples of these countries. The last model was described as a sole technical collaboration for innovation and joint research between or among countries themselves that have advanced country ownership, implementation, and management of their HIV/AIDS responses. The countries highlighted for this model included Brazil, India, and Mexico (USG, 2012) (NCV-9-USG, NCV-12-USG, NCV-30-USG). It was stated that OGAC could learn from these advanced countries in terms of best practices and forming partnerships in the private sector that could contribute to sustainable responses to apply to other countries including nascent or continued emergency responses in countries (NCV-12-USG).

The committee learned that PEPFAR assistance in a country may start with a technical assistance model only, but that does not necessarily mean that the country might not also receive assistance for direct service provision if the HIV burden is high. Complexities in the interaction of the dimensions of country ownership may produce the need for flexibility in the type of assistance that PEPFAR provides without strict demarcations. For example, the USG may not have a strong relationship with the political leadership of a country with high burden, but PEPFAR may provide services through nongovernmental organizations as implementing partners (NCV-12-USG, NCV-9-USG, NCV-30-USG).

OGAC described sustainability as a partner country being able to assume greater to complete responsibility to plan, cost, oversee or manage, monitor, and evaluate its current HIV/AIDS response. While this was not limited to a country being able to pay for the entirety of its response, it did include co-financing and increasing financial contributions by the national government to meet the Abuja targets for national financing for health and HIV/AIDS, as well as efficient and maximal mobilization and use of all of its diverse resources for fiscal management and oversight of the response including addressing gaps in services for improved access and coverage. The planning of the response should not only use available epidemiologic,

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programmatic, financial, clinical, surveillance, and special survey data for identification of current needs and gaps, but also project and anticipate the trajectory of need and correspondingly plan for implementation and management of their response. These data should also be used to determine the costs of their national strategic plans and services, and maintain gains in the current response.

Even if a country cannot increase its own funding contribution, it is the critical responsibility of the partner country government to ensure and oversee the development of a resource mobilization and diversification plan specific to that country that reflects its understanding of the financial need to pay for its response and their responsibility to help find the resources instead of the heavy reliance in many countries for PEPFAR or other donors to project the costing and pay for the response. Finally, the USG and its partner countries need to use benchmarks or metrics to measure success and progress toward sustainability (NCV-30-USG).

As seen in Box 10-6, one of the measures of country ownership is USG transparency of its funding with the partner country government in an understandable way. While PEPFAR ranked 29th out of 72 donors in the 2012 Aid Transparency Index published by Publish What You Fund,[21] there were variable perceptions among interviewees regarding the extent of PEPFAR's transparency on the amount of funding that would be allocated to partner countries (116-ES, 166-ES). Some interviewees perceived that PEPFAR is more transparent than other external donors (NCV-9-USG; 116-5-PCGOV; 116-16-PCGOV), while others suggested that PEPFAR continues to need improvement in transparency (934-ES; 331-ES; 636-ES;116-ES; 166-ES). PEPFAR is currently working on increasing transparency to country governments about the funding provided by external donors, even if the funds were not placed into common-fund mechanisms that would allow the country direct access and complete control of the disbursements (331-ES; 461-ES).

Partnership Frameworks and Partnership Framework Implementation Plans

In addition to the Country Ownership Assessment Tool described previously, OGAC has identified other tools to shepherd increased country ownership and the promotion of sustainable responses—the Partnerships Frameworks (PFs) identified in the reauthorization legislation. OGAC reports that during the last 2 years, PFs have been established with all funded countries. This Partnership Framework model has been developed to "strengthen country capacity, ownership, and leadership" (OGAC, 2009b) and increase partner country government autonomy in decision making by promoting harmonization with national AIDS plans. Furthermore, the reauthorization process required that all frameworks "shall include provisions to promote local and national efforts to reduce stigma associated with HIV/AIDS and work with and promote the role of civil society in combating HIV/AIDS."[22]

Partnership Frameworks were described as a product of OGAC functioning as a learning organization. The development of the PFs was based on the understanding of the principles of the Paris Declaration, the achievements and challenges of PEPFAR implementation, and other goals and considerations of USG bilateral development assistance. OGAC strived to use policy principles of country ownership and strong leadership and governance to progressively build in-

[21] Publish What You Fund is the global campaign for aid transparency. They work to make comprehensive, timely and comparable information about foreign aid available and accessible. The Campaign seeks to empower civil society advocates, parliamentarians and officials with information, both in aid dependent countries and the donor countries assisting them. They receive financial support from the William and Flora Hewlett Foundation, Christian Aid, Development Initiatives, ONE, Tiri, Water Aid and World Vision. (Publish What You Fund, 2012)

[22] *Supra*., note 4 at §301(a)(2), 22 U.S.C. 2151b-2(a), §104A (e)(2)(C)(i-ii)

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country capacity for an HIV response that would be sustainably managed by partner countries (NVC-16-USG).

> *"Partnership Frameworks were one of the most significant policy shifts [for PEPFAR] "under the leadership of Ambassador Mark Dybul, and Ambassador Goosby has continued it full force with the umbrella of country ownership as the route and path to sustainability."* (NCV-11-USG)

> *"[I] must commend the efforts that PEPFAR has made in recent years." PEPFAR has tried as much as possible to harmonize and align with country priorities, for example, through the Partnership Framework. This has been advocated at the highest level. This is a strong achievement."* (116-16-PCGOV)

While the Partnership Frameworks were intended to articulate goals, activities, and accountabilities for the USG and the partner country governments, the Partnership Framework Implementation Plans (PFIP) are to include specific actions to be taken by specific stakeholders and metrics for documenting progress towards accelerating country ownership. PFIPs would then represent the primary considerations for countries to increasingly manage and ultimately sustain their responses (see also Chapter 9 on Health Systems Strengthening). However, at the time this report was written, there were 14 countries and two regions that had completed PFIPs, and four countries and 2 regions had signed PFIPs. Several years may be needed for countries or regions to have both a Partnership Framework and a Partnership Framework Implementation Plan. This delay may be due in part to the length of time that it takes to reach an agreement on the content between USG and the partner country government (including multisectoral input), as well as the time it might take to obtain the high-level signatures required from the U.S. Mission Senior Leadership and the partner country government's senior leadership. Partnership Frameworks have been developed in many PEPFAR countries and in several regions, with the first being signed in Malawi in 2009. Partnership Framework Implementation Plans have been developed in more than a dozen countries and would presumably document the differences among the countries epidemics, their commensurate responses, and their variant PEPFAR experiences in terms of implementation, achievements, and challenges for sustainability. The focus of this section will be the PFIP between Government of the Republic of South Africa and the Government of the United States of America, even though the committee understands that PEPFAR is conducting very similar activities to promote sustainable responses across many countries.

The South Africa Example

South Africa it is one of the largest PEPFAR countries, was a focus country with substantial initial and ongoing PEPFAR investments, and its PFIP was one of two that were publicly available (the other being Swaziland). Therefore, the committee focused on the PFIP between the Government of the Republic of South Africa and the Government of the United States of America that covers the period from 2012/13 – 2016/17 for its examination of OGAC and partner country government process and activities, resonance of stakeholder roles and accountability resonance with articulated principles, and identification of benchmarks. South

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Africa was also identified by the USG as one of the countries furthest along the pathway in terms of transitioning to a more country-led and country-financed response and with more elements of sustainability than many other PEPFAR countries (USG, 2012) The governments' representatives signed the document on August 8, 2012; the copy available to the committee was a duplicate that had been translated into English. It was not possible for the committee to assess the implementation of the PFIP, since it would occur primarily after the committee's data collection period had ended, making this examination more descriptive than interpretive. Even though PFIPs have been developed in other countries, examples of the application of the PF and PFIP guidance outside of South Africa will be limited in this section.

Overall, the PFIP commits the two country governments, with signatures from the U.S. Ambassador to and the Minster of Health of the Republic of South Africa, to the principles of "South African leadership; alignment; sustainability; innovation and responsiveness to the epidemic; mutual accountability; multi-sectoral engagement and participation; gender sensitivity; financial commitments and transparency; and finally, fostering a collaborative and not contractual partnership." The roadmap for the PFIP is reportedly South Africa's National Strategic Plan (NSP) for HIV, STIs, and TB—described "as a multisectoral plan that lies at the heart of the development agenda of the South African government" (SAG and USG, 2012) and also spans the same five-year time frame as the PFIP. Eight other intermediate and long-term social, health, economic, and health financing, and education development plans were identified as influencing the activities of the two governments outlined in the PFIP.

Other important framing for the PFIP included a mutual intergovernmental decision that PEPFAR's investments in South Africa will gradually transition from support of direct clinical care treatment towards support for health and social systems strengthening. The strengthening of these systems aimed to increase the efficiency of implementation of the national response, which includes activities related to "integration of HIV services, referrals systems, training, mentorship, supervision, quality improvement, health planning/budgeting, human resource management, supply chain management, information management, and monitoring and evaluation" (SAG and USG, 2012). The PFIP also calls for a strategic focus on HIV and TB prevention among key populations. PEPFAR will support the SAG's combination HIV prevention efforts focusing on key populations as part of comprehensive prevention interventions for people living with HIV and those affected by it. These key populations include orphans and vulnerable children, migrant and mobile populations, people living in informal settlements, and in-and-out-of school youth (p. 19) and "populations that are most at-risk of acquiring new infections, and populations where new infection rates are high" (SAG and USG, 2012, 18). It was also noted that several PEPFAR-supported care and treatment implementing partners tailor services to "special populations including very remote populations, men who have sex with men, undocumented foreigners, and other marginalized and key population groups." In addition, the PFIP identified the "need for proper assessment and planning to continue treatment and leverage added value for services to these "most vulnerable populations" (SAG and USG, 2012, 22).

The South African Government (SAG) is to increase the number of patients on treatment through its public health system, prioritize the prevention of new HIV infections, and have a more integrated response to the country's HIV and TB epidemics. PEPFAR has supported several models for ART provision: (1) the General Practitioner (GP) model which capitalizes on South Africa's extensive capacity in the private sector (this model was expected to be fully phased out by the end of 2012); (2) capacity-building in non-public facilities with engagement of a number of NGOs, many of which were faith-based organizations with existing health

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infrastructure (hospitals, clinics, programs), especially in rural areas; and (3) capacity-building in the public sector, largely focused on strengthening public sector facilities to increase access to ART. The PFIP reports that, "the majority of PEPFAR support (>97%) is in the public sector to support the South African government's efforts to increase access to ART" (SAG and USG 2012, 20). As public health clinics are capacitated, PEPFAR and the SAG intend to ensure patients currently treated in NGO sites under PEPFAR funding are transitioned to other non-PEPFAR models of support (whether nearby public health facilities or NGO facilities with other sources of funding) (SAG and USG, 2012). "Since 2010 there has been an extensive effort to ensure that PEPFAR-support (through all models of care) was provided in a more synergistic manner by working closely with province, district and sub-district management to direct support to areas of greatest need. To reduce duplication and improve efficiencies, one PEPFAR partner was designated to work in a district or sub-district, covering all 52 districts" (SAG and USG, 2012, 20).

The aforementioned goals track with the metrics identified in Box 10-6 for systems strengthening and in-country capacity building by PEPFAR engaging the host country in allocation decisions, and the South African Government increasing its domestic spending on health over time (SAG and USG, 2012). The PFIP described the mutual recognition that there is need to strengthen capacity at provincial and district level for financial management to increase efficiency and effectiveness of resources in response to increasing SAG expenditure to scale up much needed HIV and TB services, especially since provincial and district leadership will be increasing responsibility for the provincial and district leadership as they seek to further integrate a multisectoral HIV and TB response more broadly. The PEPFAR Expenditure Analysis Initiative (described previously in chapter 4) should help facilitate transparency of the PEPFAR budget and joint planning of future activities by identifying PEPFAR financial inputs by program and geographic area; as well as provide the necessary information per district for the National AIDS Spending Assessment. All of these data can contribute to the country's ability to develop costed national strategic HIV/AIDS plans.

Management Structure

The PFIP described an established management structure for leadership of South Africa's development assistance for health that is spearheaded by South Africa's National Department of Health which is "taking ownership of strategies, action plans, and review mechanisms. In collaboration with development partners, the NDOH focuses on results, links activities to outputs, ensures clear and unambiguous expectations, and facilitates the process of alignment and coordination. This framework ensures that development partner resources are used more efficiently and effectively, fulfilling resource gaps" (SAG and USG, 2012). The South African National AIDS Council (SANAC), which oversees the implementation of the NSP, has national and subnational representatives, as well as from civil society and various government sectors.

There is also a Steering Committee scheduled to meet twice a year to provide strategic oversight and direction for the PFIP. The PFIP suggested that it be co-chaired by the U.S. Ambassador to South Africa and the South African Minister of Health. Proposed membership included USG implementing partner directors, senior members of various Ministries of the South African government, a representative from the Deputy President's office, and delegates for each province, and the Executive Officer of the SANAC. The timing of the meeting was to coincide with periods that are more aligned with the planning and budgeting processes of the South African Government, which would then feed into annual USG COP planning for the COP to be reviewed by this same steering committee before it is submitted to OGAC (SAG and USG,

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2012). These efforts track with several of the metrics to engage partner country government for improved communication and coordination and the USG involvement in the host country planning process, as well as improving transparency and contributing to a culture of mutual accountability and show considerable improvement from earlier PEPFAR planning and coordination with the partner country.

A management committee, with a subset of members from the Steering Committee structure, was tasked to carry out the objectives of the Steering Committee. It had four deliverables which specifically included active discussion of national priorities and needs during the COP process including a review of targets and geographical coverage; review of PFIP progress for all parties including the transition of PEPFAR-supported activities outlined in the PFIP M & E framework; review and potentially recommend new funding opportunities for PEPFAR funds while adhering to necessary confidentiality agreements for that process. There were also plans to confirm that the SAG's basic accounting system could generate timely reports on government spending for HIV and TB at the national and provincial levels and that the PEPFAR Expenditure Analysis could do the same for USG expenditures. These expenditure data could be used to inform the SAG's budgeting process, as well as to enhance PEPFAR coordination at the provincial level since provinces would be expected to play a critical role for PEPFAR implementation at these levels for PFIP (SAG and USG, 2012).

> *"PEPFAR is supporting a Results for Development consultancy to identify countries' spending on health, in South Africa, Nigeria, and 13 other countries. They are trying to develop a practical set of tools as a fair method to identify what the country is investing on health in order to help PEPFAR to be fair and put them in the right trajectory."* (NCV-12-USG)

There was also a Transitional Task Team for Clinical Service, which was intended to engage with PEPFAR implementing partners to better understand the realities and challenges to implementation, to address issues as they arise, and to highlight successes of the transition. Initially established to address the immediate issue of ensuring continuum of care with new implementing partner agreements and those agreement that are ending, it would oversee the broader transition of clinical services including provision of strategic direction to the transition of direct service delivery to health systems strengthening, and monitoring government's efforts to assume direct service delivery currently provided by PEPFAR. "The transition of the PEPFAR program within the broader development agenda of the SAG is expected to need support from both the USG and SAG to ensure that the South African system is adequately prepared to absorb the programmatic elements that PEPFAR built up over the years, particularly the clinical services, without compromising patient access to care and treatment, quality of services and continuum of care. In addition, PEPFAR is to maintain its strategic focus on prevention to address critical areas of intervention. It is critical therefore that the strategic focus is built around the themes of the NSP, which are embedded in the development agenda of government" (SAG and USG, 2012,17).

For multisectoral engagement including the role of civil society, "PEPFAR enhances the multi-sectoral response of SAG by working with key departments at the national level and in all provinces. These include the Departments of Health; Social Development; Basic Education; Higher Education and Training; Correctional Services; Defense; Public Service and

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Administration; Women, Children and People with Disabilities; National Prosecuting Authority; National Treasury, and the South African Police Service. In addition, PEPFAR engages with SANAC and the private sector. PEPFAR has direct funding agreements with more than 120 prime implementing partners, including SAG, parastatals, non-governmental organizations, unions, private entities, and universities. Approximately 10% of PEPFAR's budget directly funds and provides technical assistance to several national departments and parastatals" (SAG and USG, 2012).

System Strengthening Activities and Capacity Building

Shortages of critical human resources, especially doctors and pharmacists, has led the adoption of a nurse-based model of treatment, care by the South African Government and support that incorporated community-based services to ensure equitable access of quality HIV and TB services. Coordination, leadership, and management skills are needed to mobilize all sectors around a common vision that takes into account the nature of the epidemics in their locality. For community systems strengthening, PEPFAR was responsible for building capacity of community structures and leadership to coordinate with relevant SAG departments to improve and sustain the HIV/TB response by actively linking the community to HIV/TB services and addressing social, cultural, and gender norms that underpin the epidemic As the PEPFAR program transition from direct service provision, the focus would be on strengthening the capacity at provincial and district level along the WHO six building blocks.

Select activities highlighted for building block foci include the development of several health information systems to track health outcomes for people on ART, a TB surveillance system, supporting the country's information system that provides information on OVC service delivery, and support the SAG's development of a Monitoring and Evaluation (M&E) framework to track the implementation of the NSP and progress towards achieving national HIV, STI and TB targets. The PFIP is expected to also promote an environment of data transparency and sharing between PEPFAR and SAG in order to maximize data use and streamline reporting, including the development of a joint data sharing agreement. In collaboration with SAG and other in-country partners, PEPFAR is expected to contribute to monitoring of national targets for impact and outcome indicators. A final technical assistance and capacity building monitoring system is expected to be developed by PEPFAR in consultation with SAG and partners, which should leverage in-country and headquarters PEPFAR support and be completed by the end of 2012. This system is expected to enable PEPFAR to quantify its contribution to NSP targets through technical assistance activities (SAG and USG, 2012). Impact monitoring goals in the SAPFIP include: Reduce new HIV infections by at least 50 percent using combination prevention approaches; Initiate at least 80 percent of eligible patients on ART, with 70 percent alive and on treatment 5 years after initiation; Reduce the number of new TB infections, as well as the number of TB deaths by 50 percent; and Reduce reported stigma and discrimination related to HIV and TB by 50 percent.

The multisectoral response also included strategies and prioritized activities for the Department of Basic Education and the Department of Social Development. While the USG is identified as being responsible for services for OVC, the SAG is identified as strengthening interventions for childhood morbidity and mortality, The SAG was expected to add a focus beyond the Life Skills program for 15- to 19-year-olds to more comprehensively respond to the epidemic and to improve physical and psychological safety in all schools with an increase in education to reduce HIV incidence among 15- to 19-year-olds, while also improving the sexual and reproductive health knowledge of students, staff, and other school officials. The Department

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of Social Development was to also "ensure provision of comprehensive social services which are designed to protect the poor and vulnerable within the South African Constitution and other legislation in the country"; as well as create an enabling environment for sustainable development; and deliver integrated, sustainable, and quality services in partnership with all those committed to building a caring society. Specifically, the PFIP aims to reduce new HIV and AIDS infections through social and behavioral change; mitigate the psychosocial and economic impact of HIV and AIDS as well as TB and other chronic illnesses; and strengthen community capacity and systems" (SAG and USG, 2012, p. 10).

Improving the health of all South Africans was identified as the fifth strategic priority in the PFIP. This included phasing in a national health insurance system and increasing institutional capacity to deliver health system functions. It also included initiating major structural reforms to improve health services management that not only emphasized the treatment of drug-resistant TB, but also enhanced public health services to respond to a range of chronic diseases, injuries, and trauma. Lastly, it included the introduction of new child vaccines to reduce significant causes of childhood morbidity and mortality.

Other key foci of the SA PFIP included facility, district, and provincial level capacity building for supply chain management for pharmaceuticals and commodities to ensure continuous supply of medicines such as ARVs, OI medicines, TB prophylaxis and treatment, and commodities such as condoms and test kits. Health service delivery innovation was described as needing continued support to create service delivery models and new prevention and treatment guidelines. Country-specific research, innovation, surveillance, and program evaluations were reported as needs to improve health outcomes including HIV and TB outcomes and to prevent new infections; as well as an outcomes-based planning model to make progress in curbing the epidemic (SAG and USG, 2012).

PEPFAR-Wide Multisectoral Capacity Building and System Strengthening

PEPFAR has supported partner countries to build capacity in multiple sectors and support policy-enabling environments that would assist a partner country government in planning, executing, and overseeing a multisectoral HIV/AIDS response. These efforts were broadly across sectors for HIV/AIDS inclusion in their sector programming to more narrow specific activities within sectors. For example, to address the combination of needs and interventions for the prevention and intervention of gender-based violence (240-24-USG) and the risks of HIV transmission, training or co-location of law enforcement officers in clinics created multiple entry points for service access that could provide timely post-exposure prophylaxis, reporting and processing of the criminal behavior by the perpetrator, and awareness of the various providers to the needs of these survivors. This also created support for the enforcement of existing policies and laws in countries to protect women and children or the opportunity to develop them (NCV-10-USG). Capacity building and partnerships with Ministries of Education were often cited in countries with the inclusion of HIV/AIDS, health, and nutrition, into school curricula (587-8-PCGOV), the training of teachers, the work force development for social workers and para-social workers with pre- and in-service training and salary support for their hiring, and increased services for out-of-school youth were also highlighted (542-14-PCGOV). PEPFAR supported the U.S. Department of Defense in its efforts for HIV prevention and HIV counseling and testing activities for military forces in partner countries (196-2-USG; 331-17-USG; 934-ES) and also included laboratory infrastructure improvements and functioning (331-17-USG). Lastly, PEPFAR supported,

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either Ministries of Labor efforts in partner countries for the development of workforce programs for HIV prevention programs, HIV testing, care and treatment, as well as training and information systems development to track participants in the Ministry's programs (587-14-PCGOV; 587-17-PCNGO; 396-50-PCGOV).

From the Lantos-Hyde Act of 2008, Congress stated:

> The Secretary of the Treasury, acting through the head of the Office of Technical Assistance, is authorized to provide assistance for advisors and partner country finance, health, and other relevant ministries to improve the effectiveness of public finance management systems in partner countries to enable such countries to receive funding to carry out programs to combat HIV/AIDS, tuberculosis, and malaria and to manage such programs.[23]

Local Capacity for Program and Fiscal Management of the HIV Response

Though country ownership may be starting point for sustainability in OGAC's view, there has also been an historical focus in PEPFAR on building local capacity in partner countries, from the national to the civil society levels for HIV/AIDS planning, policy, implementation, and accountability to move towards a goal of shared responsibility and accountability. During country visits, the greatest challenge and need that interviewees widely identified was a deficit of trained and skilled personnel in all sectors of the response, including health care, and the retention of such personnel once trained (They noted the existence of sometimes severely limited human resource capacity in health including a deficit of management knowledge and skills in a diversity of sectors, including technical, program, commodities, financial, and personnel management (166-ES; 461-ES; 542-ES; 587-ES; 240-ES; 934-ES; 116-ES). Of the primary USG implementing partners, USAID had focused more resources on building capacity of local nongovernmental organizations to play various roles in the response—from advocacy to service provision.

Conversely, a different experience was described as awkward between the sectors since PFPAR directly funded NGOs and provided technical assistance including program and fiscal management, monitoring and evaluation, and resource diversification using grantwriting. The *"partner country government saw the NGOs as competition for external resources,"* yet the NGOs felt that *"they were providing invaluable services to people affected by HIV/AIDS and that their communities looked to them for services that were not accessible or available elsewhere"* (587-21-PCNGO; 461-10-PCNGO). In many cases, the NGOs were long-standing agencies in the country that once respected, were sought after by the county government for active partnerships in HIV/AIDS planning and implementation from developing training materials and curricula for use in government facilities to serving on national-level technical working groups that also made recommendations for policy making relate to HIV/AIDS (240-ES; 542-ES, 166-ES; 116-ES). OGAC financially incentivized broader efforts for local capacity building for NGOs by awarding points that would result in increased funding for prime partners that used umbrella grant mechanisms for capacity building (NCV-16-USG). Civil society was also described as a "watchdog for governmental accountability" for service provision and efforts for supply to keep pace with demand for quality services (542-ES; 166-ES;116-ES; 331-ES; 587-ES). In nearly every

[23] *Supra*., note 4 at §204, 22 U.S.C. 7621, §204(b)(1).

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country visited, there was a description of individual and institutional local capacity building efforts for the maintenance and sustainability of the HIV/AIDS response in nearly every area (monitoring and evaluation and research are further discussed in chapter 11 on Knowledge Management). PEPFAR annual reports, from the very beginning, have also reported on efforts to "build capacity for partner countries to sustain their programs for the long term" (OGAC, 2005).

Track 1.0 partners deserve credit and acknowledgment for much of the capacity building for the provision of prevention, care, and treatment services for adults and children, including training of health personnel, as well as rapid scale-up in the early days of PEPFAR (OGAC, 2005) and continuing through the transition of their programs to local entities within the countries they have worked. The USG has consistently emphasized scaling up of services using core competencies of USG agencies (and their partners) across sectors (Goosby et al., 2012a). While capacity building for workforce efforts are largely described in the chapter on health systems strengthening, it should be noted that the reauthorization legislation highlighted the need for local capacity "foreign service nationals provide critically important services in the design and implementation of United States country-level HIV/AIDS programs and their skills and experience as public health professionals should be recognized within hiring and compensation practices."[24]

New Partners Initiative

In PEPFAR I, USAID was the lead agency for the New Partners Initiative (NPI), which was started in 2005 and aimed towards improving local capacity and increasing the number of local partners A director for NPI was situated at OGAC headquarters. Early in the program, NPI offered nearly $200 million USD to new community-based organizations through cooperative grants in the 15 focus countries. These organizations may have had experience providing prevention, treatment, and care services, but little experience working with the U.S. government (USAID OIG, 2007).

"Under PEPFAR, NPI was created to build the capacity of organizations at the community level to achieve local ownership and enhance the long-term support and viability of HIV/AIDS responses. Specifically, NPI's goals are to (1) increase PEPFAR's ability to reach people with needed services by identifying potential new PEPFAR partner organizations, (2) increase the total number of partner organizations and their capacity to provide prevention and care services, and (3) build capacity in host nations by developing indigenous capacity to address HIV/AIDS to promote the sustainability of host nations' efforts" (USAID OIG, 2007). USAID's Office of the Inspector General had several audit findings. First, Mission Teams reported an increase in their workloads, including for their technical officers due to the new initiative and uncertainty about the future residence of the partners had a negative effects on USAID interaction with these partners. Secondly, these partners did not have the capacity to comply with USAID administrative requirements tested though partner improvements in some of those areas were identified during the audit. Specifically, "weaknesses in program and financial reporting, accounting practices, and work plan requirements" were cited in the audit (USAID OIG, 2007) and USAID OIG made recommendations of the Office of HIV/AIDS for corrective action to address these deficiencies. Despite the weaknesses in the organizational assessments, USAID's OIG recognized that many of the deficiencies were being addressed.

[24] *Supra*., note at §103, 22 U.S.C. 7612 (d)(2)

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During the country visits, the committee heard from the NGOs, partner country government, and USG representatives that local capacity building was having a net positive effect. In other examples, early introductions were as critical to develop or build relationships.

> *"Another area not appreciated enough is the effort getting PEPFAR programs going on the ground, building the partnerships and ownership with the people running the programs. Getting the buy-in of the people living in the community working in the facilities. Also training peer workers, supporting networks of people to start groups. Building a supportive community and engaging community partners has been a process and a huge effort."* (NCV-5-USACA)

Transitioning of Programs to Local Prime Partners

The first phase of transitioning programs began with the PEPFAR original Track 1.0 partners, which were all required to complete transitioning of their programs and services to local entities in the partner countries in which they operated by February 2012 (NCV-9-USG, NCV-12-USG, NCV-30-USG, NCV-11-USG). Some of the entities are partner country government at the national and subnational levels and their implementing partners, while others are local nongovernmental organizations (NCV-5-USACA, 166-33-PCGOV, 636-9-USACA, 636-19-USNGO, 166-10-USNGO). Reportedly, entity readiness for accepting management of programs was based on formal and informal assessments of local partners including Ministries of Health, health facilities, district government entities, and nongovernmental organizations before receiving direct USG funding to serve as prime partners (NCV-4-USACA, NCV-5-USACA, NCV-6-USNGO). Some assessment tools were developed by USG partners, including USG agencies, but they vary in complexity in terms of what they measure and their ease of use. The Track 1.0 partners' transition is offered as an example of what the USG would like to achieve across similar health programs (USG, 2012).

> *"The transition has to occur with trust, they shouldn't be afraid to let go but at the same time they need to have systems in place to make sure the quality of the care provided is ensured. There is anxiety about readiness, for example with the Track 1.0 transitions. It's time to change the relationship with the countries, changing the role of PEPFAR staff from the person who manages the program to the person who is with the person who manages the program."* (NCV-12-USG)

For some long-term partners, *'the transfer of money was not the sole issue or concern. Performance was identified as equally important—the transfer of the work once the money is transferred.'* Once programs and services have been transferred, other practical considerations were raised: *"What are the parameters to monitor and who is responsible for it? How do you see the effect beyond the actual transition of the money?"* The measure itself might also determine whether there is success:

> *" If competitive awards for money to local groups were the measure, then we would say it's successful because the local*

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> *groups and government could actually win the funds. Most of these efforts are just being started, we will have to see over time how implementation goes."* (NCV-5-USACA)

Private Sector Capacity Building and Involvement

In its eighth annual report to Congress in 2012, OGAC identified public-private partnerships as a tool to enhance country health system strengthening and to leverage PEPFAR resources and complementary technical focus. The report further stipulates that the business sector has other specific skills and technical expertise, such as marketing, distribution networks, and laboratory and information capacity and PEPFAR is working to establish more linkages and partnerships to contribute to a collective effort towards sustainability (OGAC, 2012b).

Public-private partnerships (PPPs) were also important for health workforce development and health system strengthening, themes that were described in every single country the IOM committee visited as tremendous challenges. PPPs had similar roles for health and other workforce development, national policy development including clinical guidelines, and provision of services for both adult and especially pediatric care and treatment services, including the establishment of Centers for Excellence for training and capacity building (Damonti et al., 2012). Salient examples of other critical roles for PPPs in the HIV/AIDS response include: Becton, Dickinson, and Company's expertise to improve laboratory infrastructure, quality, and operation; the Partnership for Supply Chain Management strengthened supply chains; Together for Girls addressed prevention and reduction of sexual violence; and Voxiva's role in supplying information technologies to deliver interactive mobile health services (Sturchio and Cohen, 2012). In September 2011, the Pink Ribbon Red Ribbon initiative was launched by PEPFAR, along with the public-private partnership among The George W. Bush Institute, Susan G. Komen for the Cure, and UNAIDS. This innovative partnership leveraged public and private investments targeting breast and cervical cancer, which are described as two of the leading cancer causes of death for women in low and middle income countries (OGAC, 2012b). This initiative is also discussed in the services integration section of the health systems strengthening chapter.

Increased partnerships with the private sector were identified for untapped potential and innovation for "*system-strengthening efforts*" including "*forecasting and distribution, mobile services, worker outreach through their extensive networks*, and *use and development of different technologies for point of care diagnostics for structural system changes for service delivery, communication systems, and community education in rural areas through mobile technology such as mHealth*" (NVC-12-USG).

> *"The system could be planned around the assets they bring and they could be embraced more within the system. Not all the activities have to be done by the government. 50-55% of the health care delivered in [a PEPFAR country] is done through the private sector. Therefore, there are lots of opportunities in the private sector that should be considered such as help with supply and distribution challenges. This would also get more than just the government invested in success. Looking at the program with*

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> *private sector eyes, including different financing options, provides a different and possibly very beneficial insight. This is not PEPFAR's area of expertise but others can bring this."* (NVC-12-USG)

> *"The government also needs to not leave it to others; partners are putting in a big contribution. Supply management, prevention, ARVs. When you have a donor that is bringing in a lot of money and technical resources, and you know that this is what they are going to help you with, it's easy to say "okay, that is covered," but sometimes isn't good enough. It is not just capacity building. It's a sense of ownership of what needs to be done. The partners have ideas and money, but when the government lets go, is it really something you're leaving behind. There is something there that needs to change."* (166-9-USG/OBL/ML)

There is eager interest from partner country stakeholders to not only explore increasing financial resources from the private sector to diversify HIV/AIDS responses, but to also have the sectors learn from each other in terms of best practices that can be applied for sustainability of country responses to HIV/AIDS and other health issues (NCV-30-USG, NCV-12-USG).

Greater Focus on Prevention

There is some global enthusiasm that OGAC quickly moved forward to respond to emerging scientific evidence from the results of recent biomedical interventions showing an impact on ART on HIV transmission to determine how best to incorporate them into the PEPFAR portfolio for prevention. OGAC "convened a consultation "on unresolved issues in HIV prevention in generalized epidemics" to inform this discussion" (Ryan et al., 2012). This consultation reportedly focused on the current types of evidence and their weighting to determine a mix and prioritization of prevention activities they termed "core interventions." The consultation also "acknowledged that treatment would play a critical role in reducing new infections and that behavioral interventions to support these core interventions and reduce risk are critical (Ryan et al., 2012). Even though the Five-Year strategy for the reauthorization legislation emphasized prevention as a high priority towards sustainability, as discussed in Chapter 5 of this report there is still a concern about the focus and prioritization of behavioral interventions for their singular as well as combinative contribution to prevention of sexual transmission, as well as the funding that is allocated programmatically and the way in which these interventions are studied and measured, despite this scientific advancement. Palen et al. (2012) stated that "if low-income countries do not do better with prevention, all "efficiencies" achieved within their delivery systems are simply more efficient ways to commit ever-expanding resources to an interminable pandemic." Interviewees also voiced a similar concern that behavioral and structural prevention has been largely ignored compared to scaling up of care and treatment (636-ES; 953-ES). Chapter 5 on Prevention and Chapter 6 on Care and Treatment also discuss the role ART can have on prevention of HIV transmission.

The committee heard specific concerns from country visit interviewees about the link between prevention and sustainability. Participants in nearly all countries visited associated prevention with the concept of sustainability and several participants noted that their country would be unable to maintain all of its current activities, including prevention activities, if

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PEPFAR funding were withdrawn. Some interviewees in national planning positions stated that their national attention to HIV prevention had waned and prevention as a stronger part of the national response needed re-emphasis (166-7-PCGOV; 636-4-PCGOV; 240-ES) to yield a longer return investment to reduce incidence, which in turn makes sustainability more likely (934-12-CCM). A mix of USG and partner country interviewees identified a shift to prevention activities as a step on the path to sustainability (240-2-USG; 331-43-USG; 587-1-USG; 116-23-USPS; 461-10-PCNGO; 934-12-CCM). There was more concern among participants in different countries about the reach of prevention messaging and the differential coverage for funding allocated to support population-based prevention messages compared to the coverage and reach for the amount of funding supporting individual treatment activities:

> *"So we would rather have, it's more sustainable to have prevention than treatment. And prevention is cheaper. Prevention is much, much cheaper than treatment. You talk about messages on TV, messages on radio. . . . But you do that one message for eight thousand dollars, you reach the 7 million, 15 million people, I mean, 13 million people in [this country] by one message, for a thousand dollars. But you procure ARVs for a thousand dollars that don't reach that number of people. And they need such procurements every other time. So prevention to sustain this one is a key issue."* (934-12-CCM)

The most frequently repeated concern, across most countries by all types of stakeholders and across multiple interviews in a country, was how inadequate supply chain management could have crippling effects on prevention programs without continued a supply of condoms, test kits, reagents, and circumcision kits (636-16-USG; 636-19-USNGO ;166-5-USG; 166-13-PCGOV; 396-12-USG; 934-45-USNGO; 934-18-PCGOV; 934-39-PCGOV; 116-18-PCNGO; 542-8-USNGO):

> *"There are [national] condom manufacturers and with donors leaving, having a huge number of free condoms or even socially marketed condoms is just completely unsustainable. So we're really working now towards trying to stimulate [this country's] condom market to get them to be a lot more engaged. It turns out that there . . . I know there's about 300 different brands of condoms. A lot of them—even within the price range of the socially marketed condoms available*" (396-12-USG).

At the 14th International AIDS Conference, Ambassador Eric Goosby publicly reinforced his concerns when he expressed that he is humbled by the fact that all of the programmatic and collective progress in the individual and population cascade from prevention to treatment can be seriously affected, if not completely disrupted, due to inadequate supply chain management issues in a country.

The Integration of PEPFAR and other U.S. Programs

Though the committee was not tasked with evaluating the Global Health Initiative (GHI), it is at least important to acknowledge that this initiative, which was launched by President

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Obama in May 2009, PEPFAR is reported to serve as a central part of GHI as the largest U.S bilateral health program, affording a "forum for interface between PEPFAR and other U.S. programs in strengthening health systems, improving monitoring and evaluation, adopting a woman and girl-centered approach to health and gender equity, and integrating across health and development programs" (Goosby et al., 2012a).

> *"[OGAC] is responsible for the policy priorities of this program, but OGAC does not work in isolation and you know there's a deputy principles group within OGAC that basically provide a lot of recommendations to Ambassador Goosby that he then makes on behalf of the program. But because our health programs are so integrated in many countries we realize that we all need to go hand in hand, so we can't have a country ownership agenda for PEPFAR that USAID's maternal health program isn't also considering. So we all came together, we actually came together not just as PEPFAR, our dialogue has included MCC as well who have a lot of good practices in country ownership, and tried to have a common message that we could present to partner governments around country ownership and what it is U.S. government means."* (NCV-9-USG)

Technical Assistance and Longer-Term Capacity Building for the Global Fund

Despite the continuum of rate-limiters for capacity building efforts at any level, PEPFAR's alternate method for technical assistance could engage multiple stakeholders and country leadership at different levels with its larger and longer-term capacity building for and technical assistance to the Global Fund. As discussed in the Funding chapter, there is collaboration and cooperation between the Global Fund and PEPFAR. Given that they are the two largest sources of external funding in nearly every county, their existence and collaborative relationship affect the performance of each. They have been described as having different and complementary models of assistance from their very beginnings. With country leadership, the new paradigm for the future response entails more joint planning, cognizance of their shared responsibility to people who need their services, to donor countries, and to the U.S. taxpayers to be assured of effective and efficient use of their resources (Goosby et al., 2012b). The U.S. Congress permits the U.S. GAC "to withhold up to five percent of the Foreign Operations appropriation for the U.S. contribution to the Global Fund to provide technical assistance (TA) to improve grant implementation and build capacity. From FY 2005 through FY 2010, the Coordinator has made over $160 million available for centrally-funded TA activities for Global Fund grants" (USG, 2011a). As previously discussed in the chapter on Health Systems Strengthening, there are 19 USG-supported Global Fund Liaisons, requested by the Mission Teams, placed into key bilateral and regional missions as part of the longer-term capacity building and technical support for the Global Fund during the last 2 years. These Liaisons "support Global Fund grant implementation and oversight including improving coordination between USG bilateral programs and Global Fund-financed disease programs" (USG, 2011a), can provide broad assistance for areas mentioned above or narrower technical assistance, such as with Global Fund's financed laboratory program, and they communicate monthly with OGAC about issues in their respective countries (NCV-20-USG).

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The USG-supported Grants Management Solutions (GMS) project was used to provide shorter-term or more urgent technical assistance and grant management support to primarily the Country Coordinating Mechanisms (CCMs) and the Principal Recipients in countries with current Global Fund grants.[25] The purpose of this urgent attention was to "unblock bottlenecks and resolve systemic problems that hinder the response to AIDS, tuberculosis, and malaria GMS provides this support in four technical areas: Organizational development including leadership and governance; Program and Financial Management; Procurement and Supply Management; and Monitoring and Evaluation" (USG, 2011b). This headquarters-funded technical assistance can augment rather than duplicate support already provided by USG teams through the USG bilateral programs for the three focal diseases of the Global Fund, which can include development of future Global Fund proposals as well as overall longer-term systems strengthening and capacity building (OGAC, 2012a). The GMS program is coming to an end and is being replaced with another iteration that will continue to focus on addressing these issues (NCV-20-USG).

OGAC senior leadership recognizes the importance of the Global Fund as a large-scale financing mechanism for the three diseases, especially where large-scale bilateral assistance is not available in countries. However, the United States is leveraging its contributions to the Global Fund from other donors to "multiply the impact beyond what U.S. dollars could do alone" and for the two initiatives to discover new and complementary ways of doing business (Goosby et al., 2012b). Within the last few years, OGAC developed a more strategic approach to the use of PEPFAR-funded support for technical assistance to maximize the performance of the Global Fund overall. Other PEPFR-supported efforts include improving their collaboration and communication includes an appointed HQ-level liaison from OGAC to Global Fund headquarters in Geneva beginning in 2011; the use of PEPFAR technical working groups and field expertise to provide effectiveness and efficiency considerations for renewal of grants; participating as a permanent member of the Global Fund Board; and review of Global Fund issues during OGAC headquarters COP reviews (NCV-20-USG).

> *"Ambassador Goosby [wanted] . . . some kind of strategy, some kind of approach that took this TA money, expended it in a way that could show measureable results, and have a clear sense of why it was expended in a certain way. . . So there's a really very active participation and really concern and desire for this administration to see this Global Fund work in the best way possible, in a way that's the most efficient, the most effective, and really to have an impact on what it is that we're trying to do in these countries, which is save lives."* (NCV-20-USG)

[25] There are some exceptions to the eligibility for technical support for focus countries under PEPFAR I in which PEPFAR team are instructed to address their technical support needs though their Country Operational Plans or for countries that are listed by the U.S. State Department as sponsors of terrorism.

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KEY BARRIERS TO ACHIEVING COUNTRY OWNERSHIP AND SUSTAINABILITY

Financial Responsibility with High Numbers of External Donors and Large Magnitude of External Assistance

Country contributions to their own HIV responses varied widely. Contrast, for example, a contribution of 10 percent to the HIV response budget provided by one country—*"This is quite worrisome for the sustainability of the program"* (166-16-PCGOV), with 70 percent of the budget allocated by another country (272-ES). Of all donors, the USG provided the majority of funds in support of the HIV response in countries visited (461-ES). In some cases, governments could partially support their response (587-ES; 542-ES, 240-ES; 116-ES; 636-ES), but clearly not at the level afforded by the support of PEPFAR and other donors. The likelihood of a country to sustain its own HIV response without external funding (166-ES) and support was interrelated to issues that included prevailing economic conditions (240-ES), political will (396-ES); prioritization of the response by the government; deflection of attention to competing government priorities (166-ES), including other prevalent and serious health problems (587-ES); level of donor contribution (461-ES), and capacity to manage the response (166-ES) financially and in other ways. According to some interviewees, the presence of so many donors and so much funding in a country may present a deterrent to country acceptance of responsibility, including financial responsibility, for its HIV response (461-ES) with some suggesting inviting contributions from the private sector (166-ES; 331-40-PCPS), shifting treatment costs to the government (461-ES, 542-13-USG; 636-4-PCGOV), exploring innovative financing such as social insurance schemes or performance-based financing (461-ES; 116-23-USPS) or requiring matching funds between donors and the government (461-ES). Interviewees noted that the consequences of generous donor funding and support of the HIV response led to reliance on donors. Donor support could precipitate reduced or absent government urgency to allocate funding earmarked for HIV/AIDS (461-ES) or use such funds as they were intended (272-ES). Willing and generous donor support thus provided opportunities for governments to address other pressing health issues (461-ES) or de-prioritize health in general (272-ES). In contrast, anticipation of withdrawal of donor funding can serve as a trigger to leverage multiple funding sources for national level HIV-related planning and budgeting and the country's response (587-ES).

Timeline for Transitioning and Quality of Services

A recurring refrain by interviewees was the *"need [for] time to plan"* (587-ES, NCV-5-USACA) for sustainability. Interviewees observed that sustainability cannot be undertaken in *"fast forward,"* (396; NCV-9-USG, NCV-16-USG) but instead should be viewed as a gradual process (240-ES; 272-ES). Above all, interviewees across stakeholders were concerned about achieving the transition effectively and about finding efficiencies, such as task-shifting to nurse-provided ART and reducing duplication among implementers, without having to sacrifice quality (272-ES, 240-ES, 587-ES, 116-ES NCV-24-USNGO). Interviews recognized that the process entails making arduous choices and being selective about the best programs to offer.

Furthermore, interviewees observed that many countries were not yet ready yet to shoulder complete responsibly (272-ES; 934-ES; 166-ES; 116-ES; 331-ES; 587-ES; 636-ES; 935-ES; 461-ES; 542-ES) for their response given major gaps in resources, deficits in realistic planning (240-ES), and other issues. One interviewee observed that *"As an emergency response, PEPFAR was not designed to be sustainable*" (331-43-USG). For these countries, interviewees perceived the timing of the transition to a country-led response to be critical (272-ES). In addition to a financial commitment

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(461-ES), critical improvements were potentially needed in overall economic conditions (240-ES) as well as capacity and accountability. Government commitment to service delivery might require both program improvement and scale up (272-ES). In order to achieve sustainability, governments must be organized, have a plan, and demonstrate capacity at the highest levels (272-ES). Even within countries, some regions had greater capacity and potential to transition to sustainability more than others.

There is concern from vested stakeholders that the move to country-ownership and financial responsibility not transfer prematurely in PEPFAR, or occur in such a way that PEPFAR's clear progress with country partners to date, the 'foreign policy dividends', or its 'diplomatic leverage' to influence global HIV and health policy are undermined (Collins et al., 2012). This was a repeated and frequent theme in the IOM interviews across the types of interviewees including USG, partner country government, local NGOs, INGOs, global stakeholders, the global policy community, and implementing partners.

> *"I think everybody understands we need to be moving towards country ownership. I'm really worried this is happening on much too accelerated basis and we're looking at real divestment in terms of resources from PEPFAR going to countries all over Africa, all over Asia before those countries are willing to or are able really to, willing and able to devote more [resources] to their epidemics."* (NCV-22-INGO).

> *"It's going to take a lot of time, and too fast of a push is actually counterproductive—not only are people going to suffer because things aren't going, you're not going to have continuity of services, but you're also going to reflexively have people say that doesn't work so let's go back to the old way of doing it. And this has happened in the past where people have pushed too hard to have partners, local partners take on stuff and 6 months later it was a disaster and had to go back and then take it over again. So what's going to be the instinct the next time you try that? We tried that it doesn't work. So pushing too hard on this stuff is actually counterproductive and we haven't actually taken the time to learn, no one has actually studied Track 1 to say what are, this massive transition of hundreds of millions of dollars a year and hundreds of thousands of people in chronic care, we haven't actually sat down to look at that and say what's worked, what hasn't worked, what lessons are in here for the bigger, if that works or doesn't work and we learn from that, that's what we can actually begin to do globally and you learn what the right pacing is and you learn what the benchmarks are, and you learn how to do this well. The biggest challenge is moving too quickly to implement stuff that isn't ready to be implemented and that's true globally as well as on the ground. The capacity challenges are enormous. Now what we've also learned is those capacity challenges everyone throws up is not a reason to do something, cause everyone said ten years*

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> *ago that you couldn't possibly get 2 million, let alone 6 million people in Africa on treatment."* (NCV-16-USG)

SUMMATION

The committee concluded that many PEPFAR-supported activities and policy initiatives are contributing toward partner country stakeholder capacity building, particularly for partner country governments through national HIV planning, service provision, quality-assurance initiatives, and health systems strengthening that are needed to sustain an effective HIV response. Gains made in partner countries in terms of provision of services and management of the response are a critical focus of sustainability; it will be a serious impediment to country ownership if the stakeholders expected to be involved in a country's HIV response do not all build their capacity. There has been improvement from PEPFAR I to PEPFAR II in communication, coordination, and transparency for more joint strategic planning between PEPFAR and the partner countries on HIV responses that are led by partner country priorities.

Recommendation 10-1: To contribute to a country-owned and sustainable HIV response, the Office of the U.S. Global AIDS Coordinator should develop a comprehensive plan for long-term capacity building in partner countries. The plan should target four key areas: service delivery, financial management, program management, and knowledge management.

Further considerations for implementation of this recommendation:

- In all four key areas, OGAC should invest more resources in initiatives for long-term capacity building and infrastructure development such as strengthening in-country academic institutions, degree programs, and long-course trainings, to improve in-country capacity and to accelerate progress toward country ownership and sustainability. These investments should foster the placement and retention of trained personnel in partner countries.
- These initiatives should be monitored routinely at the country level to assess progress and identify necessary modifications. Special periodic multi-country studies could be used to evaluate the outcome and impact of the PEPFAR capacity building initiative. To achieve this, OGAC should, using input from country programs, identify milestones towards achieving specified goals, define core metrics to assess capacity building efforts, encourage innovative approaches through pilot initiatives and develop tools to help country programs monitor and evaluate these efforts, and encourage innovative approaches through pilot initiatives.

Overall, the committee concluded that the fact that PEPFAR and the Global Fund are the primary donors in most countries creates a potentially vulnerable situation for partner countries. While PEPFAR's efforts to assure maximal performance of the Global Fund in many countries is critical for the future, it is even more critical for countries to not only increase their own funding for health, but to also diversify their sources of funding and reduce their overreliance on external funding. Even when countries are not able to substantially increase their own funding for

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HIV/AIDS or health, it is critically important that they demonstrate the leadership to understand their current and future needs by developing their own resource plans that will transparently inform everyone, including external donors, of the funding that is needed and the responsibility that the countries will undertake to mobilize the needed resources.

Recommendation 10-2: Building on the Partnership Framework implementation process, PEPFAR should continue to work with partner country governments and other stakeholders to plan for sustainable management of the response to HIV. PEPFAR should support and participate in comprehensive country-specific planning that includes the following:

- **Ascertain the trajectory of the epidemic and the need for prevention, care and treatment, and other services.**
- **Identify gaps, unmet needs, and fragilities in the current response.**
- **Estimate the costs of the current response and project resource needs for different future response scenarios.**
- **Develop plans for resource mobilization to increase and diversify funding, including internal country-level funding sources.**
- **Encourage and participate in country-led, transparent stakeholder coordination and sharing of information related to funding, activities, and data collection and use.**
- **Establish and clearly articulate priorities, goals, and benchmarks for progress.**

Further considerations for implementing this recommendation:

- PEPFAR is not alone in trying to achieve locally-led, sustainable health and development objectives. Contributing stakeholders, including partner countries, will need mutually-agreed, principle-based resource allocation to achieve a strategic and ethical balance among the priorities of maintaining current coverage, expanding to meet existing unmet needs, and increasing coverage eligibility. Having processes in place to support this arduous decision making is a critical part of achieving sustainable HIV programs and sustainable management of the HIV epidemic in partner countries.
- Partners in developing resource mobilization plans and potential sources for more diverse funding and other resources could include national and subnational governments other bilateral donors, multilateral agencies, global and regional development banks, and private sector consultants.
- There may be learning opportunities at both headquarters and country level for PEPFAR and other USG entities involved in development assistance to exchange strategies, best practices, and lessons learned for sustaining development objectives.

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OGAC has recently articulated PEPFAR's understanding of country ownership and provided clarity about ways to mutually assess progress towards sustainability of a more country-led response. This transition to sustainability will be affected by many criteria and decisions, most of which will vary by country. Transitioning will take time; it cannot be achieved on a prescribed generic timeline across PEPFAR. Along the way, major dilemmas, such as differences in how to prioritize services and target populations, will require mutual resolution. In addition, transitioning to new models of PEPFAR support, including less direct support for service delivery and more technical assistance and systems strengthening, is part of a reasonable strategy for achieving sustainable management, but it also carries the inherent risks that in the transition period the same level of targets and access to services will not be achievable and that the quality of services, programs, and data may diminish. At the same time, greater embedding of HIV services in national health systems may offer opportunities for better integration of care, greater efficiencies, and broader health benefits. The U.S. government, like all donors, has its own considerations and requirements for funding decisions, but PEPFAR has made progress in making its considerations a part of joint planning processes rather than a displacement of country priorities. This joint planning includes both local processes for national plans as well as PEPFAR-specific processes, especially Partnership Frameworks. By necessity, PEPFAR will gradually cede control as partner countries adopt more dominant roles in setting strategic priorities for investments in their HIV response and in accounting for their results.

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11
PEPFAR's Knowledge Management
Main Messages

Informing Priorities for PEPFAR-Supported Programs

- Despite some exceptions, PEPFAR has implemented evidence-informed programs that have been modified as new knowledge and scientific evidence emerged. Target setting has been used to focus PEPFAR activities, program planning, and accountability. PEPFAR has utilized epidemiological and intervention effectiveness data to drive program activities.
- PEPFAR has provided financial and technical support for collecting epidemiological information in partner countries. This was widely seen as a positive contribution to inform decisions and priorities in planning the HIV/AIDS response and implementing HIV programs, encouraging and facilitating responsiveness to the epidemic and the needs in partner countries.

Program Monitoring Data

- PEPFAR's program monitoring indicator system has faced technological challenges limiting the ability of both PEPFAR and external stakeholders to utilize and access both current and historical trend data; resolving these challenges is critical for successful program monitoring.
- PEPFAR's program monitoring has evolved over time: the number of centrally reported indicators was reduced, indicators to monitor new program activities were introduced, and indicators identified as problematic, removed. PEPFAR needs a program monitoring strategy which can adapt over time to respond to feedback, reflect emerging program priorities, and accurately capture program activities and outcomes. However, this needs to be balanced with the reality that changes in indicators place a burden on partner country programs and limit comparability of data, hampering the ability to monitor trends.
- PEPFAR's current indicators do not capture sufficient information on its stated prioritized goals and activities and are focused primarily on input and outputs. As a result, the program monitoring system has limited utility for determining the effectiveness of PEPFAR's efforts.
- The need to quickly measure results at the onset of PEPFAR contributed to the development of PEPFAR-specific data collection systems, which has limited harmonization with partner countries and the global HIV/AIDS community. More recently, OGAC has worked with other global actors to harmonize indicators and validate reporting. OGAC has modified the PEPFAR monitoring system to reduce reporting burden and improve alignment with partner country programs, however, further modifications could be made by eliminating PEPFAR-specific language in the indicator guidance; further reducing the reporting burden; improving indicator harmonization with global indicators; and advancing alignment with partner country data collection at the program level.
- There are some good examples of PEPFAR data use at the implementing partner, Mission Team, and headquarters levels but, the preponderance of data collected does not seem to be routinely utilized. PEPFAR's requirement for collection and reporting of a large amount of program monitoring data places a large burden on implementing partners and Mission Teams that has limited the ability to analyze and use data.
- PEPFAR has invested in building the capacity of partner countries to plan for, collect, manage and use HIV data, which has implications for the larger health system. As a result, PEPFAR has contributed to fostering a culture of evidence among partner countries.

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PEPFAR Supported Evaluation and Research

- The manner in which PEPFAR initially approached research activities was a missed opportunity to establish, from its inception, mechanisms to evaluate programs, assess impact, contribute to the global knowledge base, and develop in-country research capacity.
- PEPFAR has made progress in carrying out evaluation and research activities over time: moving from an early proscription against research, to using TEs and PHEs to work within research restrictions, to the recent creation of what holds promise as a more useful processes for establishing priorities, managing activities, documenting "what works," expanding PEPFAR's technical leadership, disseminating findings, and continually improving the effectiveness and impact of PEPFAR. Defining appropriate and allowable research activities within PEPFAR, however, was and remains a challenge; specifically clarity around the activities and aims for evaluation and research within PEPFAR.

Knowledge Transfer and Learning within PEPFAR

- PEPFAR has successfully established and used a variety of mechanisms to transfer knowledge throughout PEPFAR; however, more progress is needed to address limitations in current systems and to establish formal mechanisms to systematically transfer experiences across countries, implementing partners, and sites. Without this, there will be missed opportunities to capitalize on best practices and internal lessons learned.

Knowledge Dissemination External to PEPFAR

- OGAC would benefit from developing a formal system to track and manage PEPFAR-funded dissemination products (publications, reports, abstracts, guidelines and tools) from which to measure contribution to the global knowledge base, and the global HIV/AIDS community would benefit from a publically available central repository of these products from which to share, collaborate, and accelerate knowledge creation.
- PEPFAR has had some success in external dissemination of PEPFAR knowledge including: establishing formal and informal mechanisms share knowledge externally and contributing vast amounts of evidence and publications to the Global Knowledge Base. Despite this, more progress is needed to: develop routine formal mechanisms for knowledge exchange with partner country governments and other partners, increase the amount PEPFAR data that is publically available for use by researchers and evaluators, and track and measure PEPFAR's contribution to the global knowledge base.

Overall Conclusion

- PEPFAR has made progress in managing knowledge by developing systems for data creation and collection, streamlining program monitoring data, advancing PEPFAR's role and approach to evaluation and research, and utilizing a wide variety of mechanisms to transfer knowledge. Yet, like other entities involved in the global HIV/AIDS response, it struggles with creating, acquiring and transferring the right knowledge, at the appropriate scale, and in a manner that facilitates use. PEPFAR has the potential to lead the global HIV/AIDS community in knowledge management by adopting a conceptual framework that articulates the vision, purposes, intended audiences, and goals of knowledge; how knowledge will be acquired, created, transferred, used, and disseminated to achieve these goals; and the complementary roles of program monitoring, evaluation, and research. PEPFAR has the opportunity to optimize program efficiency and effectiveness through an improved strategy that 1) streamlines and focuses knowledge creation within PEPFAR; 2) increases acquisition of knowledge external to PEPFAR; 3) improves the efficiency and effectiveness of knowledge transfer within and external to PEPFAR; and 4) institutionalizes the use of knowledge to improve the way work is accomplished.

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Recommendations Presented in this Chapter

Recommendation 11-1: OGAC should develop a comprehensive knowledge management framework, including a program monitoring and evaluation strategy, a prioritized and targeted research portfolio, and systems for knowledge dissemination. This framework should adapt to emerging needs to assess PEPFAR's models of implementation and contribution to sustainable management of the HIV response in partner countries. This knowledge management framework will require that PEPFAR implement and strategically allocate resources for the following :

A. **To better document PEPFAR's progress and effectiveness, OGAC should refine its program monitoring & evaluation strategy to streamline reporting and to strategically coordinate a complementary portfolio of evaluation activities to assess outcomes and effects that are not captured well by program monitoring indicators. Efforts should support innovation in methodologies and measures where needed. Both monitoring and evaluation should be specifically matched to clearly articulated data sources, methods, and uses at each level of PEPFAR's implementation and oversight.**

B. **To contribute to filling critical knowledge gaps that impede effective and sustainable HIV programs, OGAC should continue to redefine permitted research within PEPFAR by developing a prioritized portfolio with articulated activities and methods. The planning and implementation process at the country and program level should inform and be informed by the research portfolio, which should focus on research that will optimize the effectiveness, quality, and efficiency of PEPFAR-supported activities and will also contribute to the global knowledge base on implementation of HIV/AIDS programs.**

C. **To maximize the use of knowledge created within PEPFAR, OGAC should develop systems and processes for routine, active transfer and dissemination of knowledge both within and external to PEPFAR. As one component, OGAC should institute a data sharing policy, developed through a consultative process. The policy should identify the data to be included and ensure that these stipulated data and results generated by PEPFAR or through PEPFAR-supported activities are made available in a timely manner to PEPFAR stakeholders, external evaluators, the research community, and other interested parties.**

<u>Further considerations for implementation of Recommendation 11-1A: Program monitoring and evaluation</u>

- OGAC's current tiered program monitoring indicator reporting structure (illustrated in Figure 11-10) should be further streamlined to report upward only those indicators essential at each PEPFAR level:
  - Tier 1: A small set of core indicators, fewer than the current 25, to be reported to central HQ level. These data should be used to monitor performance across PEPFAR as a whole, for congressional reporting, and to document trends; as such these indicators should remain consistent over time. Whenever possible and appropriate, these indicators should be harmonized with existing global indicators and/or national indicators; therefore some centrally reported indicators will reflect PEPFAR's contribution rather than aiming to measure direct attribution.
  - Tier 2: A larger menu of indicators defined in OGAC guidance, from which a subset are selected for their applicability to country programs to be reported by implementing partners to the U.S. mission teams but not routinely reported to

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HQ. These data should be used to monitor the effectiveness of the in-country response and support mutual accountability with partner countries and their citizens. These data could be considered for occasional centralized use to inform special studies or respond to congressional requests but aggregation and comparability across countries may be limited in this tier as all mission teams may not collect the same data.

- Tier 3: Indicators selected by implementing partners to monitor and manage program implementation and effectiveness that are not routinely reported to mission teams. Implementing partners should select appropriate indicators defined in OGAC guidance and augment this with other indicators as needed for their programs. Implementing partners should work with mission teams in developing their program monitoring plans with selected indicators. Mission teams should provide oversight and technical assistance to ensure implementation of these plans and to promote local quality data collection, use, and mutual accountability. Although not routinely reported, some of these data could be considered for occasional country-level and centralized use.
- OGAC should create mechanisms for implementing partners, mission teams, and agency headquarters to mutually contribute to a periodic review across all tiers of indicator development, applicability, and utility and to make modifications if necessary.
- Tier 1 indicators should be harmonized whenever possible and appropriate with existing global indicators and/or national indicators. For indicators that are not routinely reported centrally (Tiers 2 and 3), country program planning should facilitate alignment of indicator selection and data collection with partner country HIV monitoring and health information systems.

- OGAC should complement program monitoring with a unified evaluation portfolio that includes periodic program evaluation at the PEPFAR country program and implementing partner levels to assess process, progress, and outcomes as well as periodic impact evaluations at the country, multi-country, and headquarters levels.
  - OGAC evaluation guidance should provide information about prioritizing areas for evaluation, the types of evaluation questions; methodologies guidance, potential study designs, template evaluation plans, examples of key outcomes, and how evaluation results should be used and disseminated. PEPFAR should support a range of appropriate methodologies for program evaluation, including mixed qualitative and quantitative methods, and should shift emphasis from probability designs to plausibility designs that provide valid evidence of impact.
    - To allow for some comparability across countries and programs, OGAC and HQ technical working groups should, with input from country teams, strategically plan and coordinate a subset of evaluations within programmatic areas that include (but are not limited to) a minimum of centrally identified and defined outcome measures and methodologies.
    - Within PEPFAR-supported evaluation activities there should be an emphasis on the use of in-country local expertise to enhance capacity building for program evaluation and contribute to country ownership.
- For both program monitoring and evaluation OGAC should continue its work on defining and developing measures to assess progress in the currently under-measured areas of country ownership, sustainability, gender, policy, capacity building and technical assistance.

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Further considerations for implementation of Recommendation 11-1B: Research

- OGAC should clearly define what activities and methodologies will be included under the umbrella of PEPFAR-supported research, as distinguished from program evaluation.
- OGAC should draw on input from implementing agencies, mission teams, partner countries, implementing partners, the Scientific Advisory Board, and other expert consultations to identify and articulate research priorities and appropriate research methodologies. The research proposals and funding mechanisms should be designed to ensure that these priorities are met and methodologies are applied through RFAs and other investigator-driven research proposals as well as through targeted solicitations of research in gap areas not met through open requests.
- Given PEPFAR's legislative and programmatic objectives to support research that assesses program quality, effectiveness, and population-based impact; optimizes service delivery; and contributes to the global evidence base on HIV/AIDS interventions and program implementation, at the time of this evaluation the committee identified the following gaps in PEPFAR's research activities:
    - Behavioral and structural interventions, especially in areas such as prevention, gender, nonclinical and OVC care and support, and treatment retention and adherence. These research activities should employ appropriate methodologies and study designs, without being unduly limited to random assignment designs.
    - Costs, benefits, and feasibility of integrating gender-focused programs with clinical and community-based activities.
    - Health systems strengthening interventions across the WHO building blocks, with a prioritized goal of determining setting- and system-specific feasibility, effectiveness, quality of services, and costs for innovative models.
- To contribute to country ownership, PEPFAR should facilitate in-country local participation and research capacity building through simplified, streamlined, and transparent application and review processes that encourage submissions from country-based implementing partners and researchers.

Further considerations for implementation of recommendation 11-1C: Knowledge transfer and dissemination

- The knowledge created within PEPFAR that should be more widely documented and disseminated includes program monitoring data, financial data, research results, evaluation outcomes, best practices, and informal knowledge such as implementation experience, lessons learned, and other information.
- To institutionalize internal and external knowledge transfer and learning, PEPFAR should develop appropriate systems and processes for the most needed types and scale of knowledge transfer. To achieve this, PEPFAR should draw on broad stakeholder input to assess the strengths and weaknesses in current processes and to identify needs and opportunities for improved knowledge transfer.
- PEPFAR should invest in innovative mechanisms and technology to facilitate knowledge transfer across partner countries and implementing partners. Mechanisms currently used successfully on a small scale and an ad hoc basis could be more formally scaled up across PEPFAR. OGAC should also look to other organizations with wide geographic reach and organizational complexity, such as multi-country PEPFAR implementing partners, other large global health initiatives, and global corporations, for models of successful knowledge transfer systems.
- OGAC should develop a policy for data sharing and transparency that facilitates timely access to PEPFAR-created knowledge for analysis and evaluation. The

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purpose of this policy would be to ensure that, within a purposefully and reasonably defined scope, specified program monitoring data and financial data, evaluation outcomes, and research data and results generated with PEPFAR support by contractors, grantees, mission teams, and USG agencies be made available to the public, research community, and other external stakeholders. OGAC and the PEPFAR implementing agencies should consult with both internal and external parties who would be affected by this policy to help identify the data that are most critical for external access and that can be reasonably subject to data sharing requirements, as well as to help develop feasible mechanisms to implement a data sharing policy.

- For routinely collected financial and program monitoring data, a limited set of essential data should be identified and made available for external use in a timely way.
- Evaluation and research reports and publications using data collected through PEPFAR-supported programs should be tracked and made available in a publically accessible central repository. U.S. government agencies with similar repositories can be considered as models.
- For research data and other information that is expressly generated for new knowledge, the policy should respect time-bound exclusivity for the right to engage in the publication process, yet also ensure the timely availability of data, regardless of publication, for access and use by external evaluators and researchers. OGAC should look to U.S. government agencies with similar research data policies as models.
- In developing the policy and specifying the scope of data to be included, several key factors and potential constraints that can affect the implementation of the policy will need to be addressed. In particular, these include patient and client information confidentiality; the financial resources, personnel, and time needed to make data available; and issues of data ownership, especially in the context of increasing responsibility in partner countries and provision of PEPFAR support through country systems or through activities and programs supported by multiple funding streams.

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11

PEPFAR's Knowledge Management

INTRODUCTION

Knowledge is generated across all levels of PEPFAR from implementing partners, partner country mission teams, PEPFAR implementing agencies, and OGAC headquarters. This knowledge, if appropriately synthesized, transferred, disseminated, shared, and used, has the potential not only to contribute to program improvement and sustainability of PEPFAR's efforts, but also to help the global community in its response to the HIV/AIDS epidemic. As the largest donor currently addressing the global HIV/AIDS epidemic, PEPFAR has both the ability and the responsibility to play a significant leadership role in this realm.

Knowledge management has been defined by Swan as, "any process or practice of creating, acquiring, capturing, sharing and using knowledge wherever it resides, to enhance learning and performance in organizations" (Swan, Scarbrough, & Preston, 1999). Knowledge management is a strategy used by many organizations to harness and respond to both existing and created knowledge and has been adopted by organizations such as The World Bank and the World Health Organization (Loermans, 2002; The World Bank, 2003; WHO, 2005).

An organization that is skilled in knowledge management is able to efficiently and effectively manage knowledge that has been created (Loermans, 2002). Examples of the types of knowledge PEPFAR has created and utilized include developing a system for collecting extensive program monitoring data, supporting epidemiologic and surveillance activities in partner countries, strengthening partner country health information systems, implementing various program evaluation approaches, supporting research, and the creation of both tacit and experiential knowledge as a result of program implementation.

Evaluating PEPFAR's knowledge management was not an explicit part of the committee's congressional mandate, but because availability and access to information was key to every aspect of this evaluation, the committee felt strongly that to help guide PEPFAR's future efforts, examining and making recommendations regarding PEPFAR's knowledge management approach was critical. PEPFAR has made strong efforts in generating knowledge, often at a level not seen in other development programs. Yet, as reflected in prior chapters of this report, there are key areas where the information needed to assess efforts and guide future activities are unavailable or insufficient. Significant gaps remain in PEPFAR's knowledge management approach, especially in the realms of knowledge creation, dissemination, and utilization, and to date, OGAC has not articulated a clear and comprehensive strategy for managing knowledge to optimize PEPFAR's performance and effectiveness.

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This chapter shifts its focus away from assessing and addressing the limitations in the available information that affected the committee's ability to respond to the specific charge mandated by Congress; these were discussed in Chapter 2. Rather, the aim of this chapter is to offer an assessment to guide PEPFAR to more strategically and efficiently meet its information needs going forward. This chapter will review and assess PEPFAR's current approach to knowledge management, culminating with recommendations from the committee for future directions to address current gaps and to strengthen PEPFAR's ability to generate, share, and utilize knowledge more effectively.

Strategic Information

PEPFAR articulated a goal of having evidence-based programs from the outset. To meet this goal, the OGAC Office of Strategic Information (SI), which is responsible for using SI to guide and coordinate PEPFAR performance planning and reporting, was established (GAO, 2011a). The first Five-Year Strategy defined strategic information as "the systematic collection, analysis, and dissemination of information about reaching the Emergency Plan's objectives, as well as the related programmatic activities funded to reach these goals" (OGAC, 2004, p. 73). Strategic information was used as an organizing concept because '*WHO was just starting to use the term strategic information, and that resonated with us—the use of information for program improvement and operations—so, we decided to use that name—gathering of information—it had to be strategic and it had to be used'* (NCV-3).[1,2]

Initially, the OGAC SI office had an annual budget of around $33 million for centrally-funded SI activities but over time, funding has been reduced to less than $10 million annually (NCV-2-USG). At the partner country level, from FY 2006 to FY 2011, approximately four to five percent of total funding for PEPFAR partner country activities was budgeted for SI activities, excluding staff salaries (see Figure 11-1) (OGAC, 2005a, 2006d, 2007f, 2008c, 2010d, 2011f, 2011g). These activities have included monitoring and reporting partner results, as well as surveillance, surveys, and efforts to strengthen partner country health information systems (OGAC, 2008a, 2009c, 2010c). Reflecting an increased focus on country ownership, FY 2012 Country Operational Plan (COP) guidance advised mission teams that activities planned under the SI budget code should aim "to build individual, institutional, and organizational capacity in country" for strategic information activities (OGAC, 2011e, p. 68).

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[1] Single quotations denote an interviewee's perspective with wording extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

[2] Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Noncountry Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types: **United States**: **USG** = US Government; **USNGO** = US Nongovernmental Organization; **USPS** = US Private Sector; **USACA** = US Academia; **Partner Country**: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia; **Other: CCM** = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**; ONGO** = Other Country NGO

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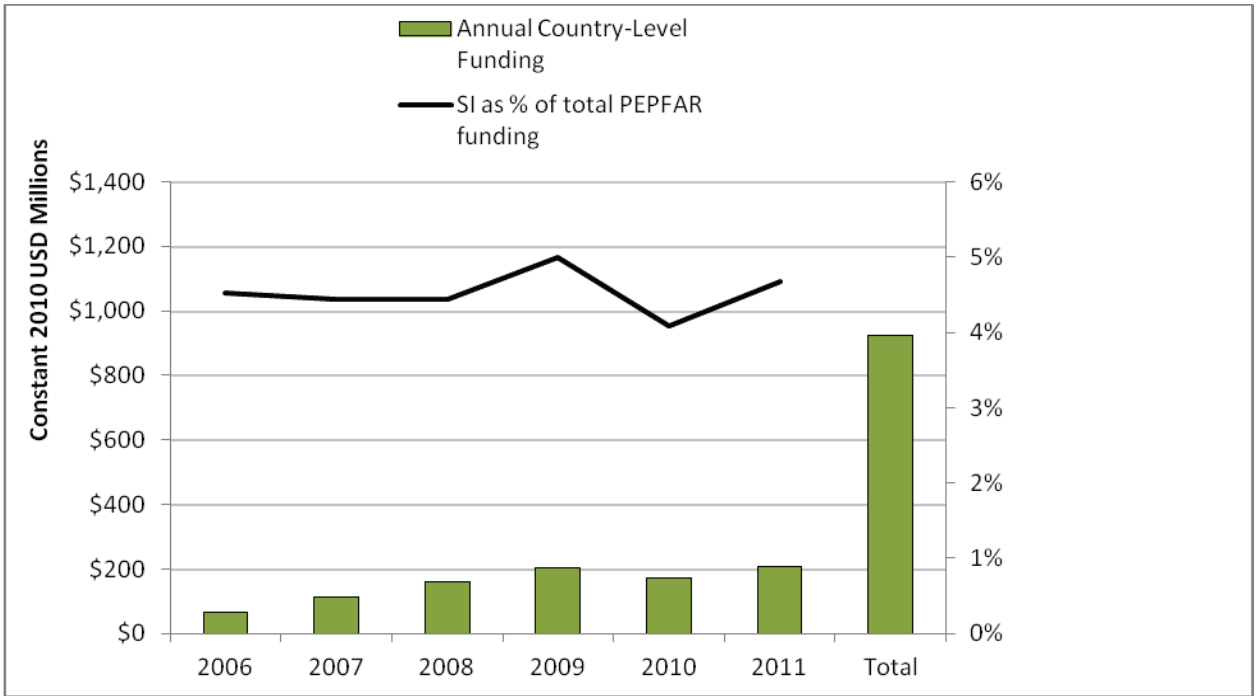

FIGURE 11-1 PEPFAR funding for country-level strategic information in constant 2010 dollars and as percent of total PEPFAR funding.
NOTE: This figure represents funding for all PEPFAR countries as planned/approved through PEPFAR's budget codes for country-level Strategic Information activities. The budget codes are the only available source of funding information disaggregated by type of activity, and are therefore used in this report as the most reasonable and reliable approximation of PEPFAR investment by programmatic area. Data are presented in constant 2010 USD for comparison over time. See Chapter 4 for a more detailed discussion of PEPFAR's budget codes and the available data for tracking PEPFAR funding.
SOURCE: (OGAC, 2005a, 2006d, 2007f, 2008c, 2010d, 2011f, 2011g).

PROGRAM TARGETS AND PRIORITIES

Setting Program Targets

Setting priorities and targets is one important aspect of planning and managing programs. Subsequently monitoring and assessing progress and performance in meeting these targets is critical for program management. When PEPFAR was authorized in 2003, it was established with an emphasis on accountability by setting specific performance targets and recognizing the necessity of monitoring and evaluation to assess the performance of the PPEFAR-supported programs.[3] The initial 5-year goals for the 15 focus countries were to provide treatment to 2 million HIV-infected people; prevent 7 million new HIV infections; and provide care to 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children (OGAC, 2004). The treatment and care 5-year targets were determined based on 50 percent of the estimated need for the focus countries with input from economists based at UNAIDS and NIH (Donnelly, 2012; IOM, 2007) (NCV-2-USG). The 5-year prevention targets were based on cost

[3] United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong.,1st Sess. (May 27, 2003).

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estimates from UNAIDS and approximately half of the expected new infections in the focus countries (Donnelly, 2012; IOM, 2007). With reauthorization under the 2008 Lantos-Hyde Act and ongoing PEPFAR activities, the main cumulative targets for treatment, prevention and care have increased steadily (see Table 11-1). In December 2011, on World AIDS Day, President Obama announced an increase in PEPFAR's target number of people on treatment from 4 to 6 million by the end of 2013 (The White House, 2011).

TABLE 11-1 Key PEPFAR Targets Under Legislation and Strategy Mandates

	United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	**Lantos-Hyde Reauthorization Act**	**PEPFAR 5-Year Strategy**	**Presidential Declaration, World AIDS Day, 2011**
Date Target Set	2003	2008	2011	December, 2011
Target Timeframe	FY 2004–2008	Through FY 2013	Through FY 2014	End of 2013
Targets	Treatment of **2 million**	Treatment of **at least 3 million**	Treatment of **more than 4 million**	Treatment of **more than 6 million**
	Prevention of **7 million** new infections	Prevention of **12 million** new infections	Prevention of **more than 12 million** new infections	
	Provision of care to **10 million**, including OVCs	Provision of care to **12 million**, including **5 million OVCs**	Provision of care to **more than 12 million**, including **5 million OVCs**	
		Training & retention of **140,000** new health care workers	Training & retention of **more than 140,000** new health care workers	

SOURCES: (Government; Kaiser Family Foundation, 2012; The White House, 2011).

To accomplish the overall PEPFAR I targets, each partner country mission team was assigned a target to achieve during the initial 5-year implementation period (OGAC, 2003). Starting in FY 2009, under PEPFAR II, targets were determined at the partner country level by PEPFAR mission teams (OGAC, 2008a, 2009c, 2010c, 2011e).

To inform the targets for each upcoming fiscal year, which are determined as part of the Country Operational Plan (COP) process, mission teams look at programmatic results from previous years (240-33-USG; 636-1-USG). Ideally, targets should be set based on data, including estimated need, and in at least one partner country, there appears to have been an evolution toward increased use of data by mission teams to determine program targets (240-33-USG). However, the epidemiological data needed to support rational targeting are not always available and there is variability in the reliability of data that are available (461-16-USG; 461-18-USG). Mission teams described working closely with implementing partners to set program targets (116-1-USG; 461-16-USG; 461-18-USG). One mission team described the target setting process as

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> *'[We] work with implementing partners to set targets based on the partners' budget, disease burden, and previous performance. [We] then aggregate implementing partner's targets and adjust for overlap to get the overall PEPFAR target. Always need to ensure that their target doesn't exceed the national number.'* (461-16-USG)

However, the targets are not always realistic and achievable; as one implementing partner interviewee stated about the organization's program targets, *"[It] feels like being asked to make an elephant fly"* (166-10-USNGO).

Use of Program Targets

Interviewees described using targets for program accountability and planning. At the headquarters level, OGAC interviewees described comparing data reported by mission teams to the targets set in the COP (NCV-2-USG; NCV-7-USG). At the partner country level, mission teams used targets for COP planning and to assess whether implementing partners met their goals. Program targets were seen as having limited utility for program management by some mission teams (461-16-USG; 196-1-USG). Other mission teams, however, found the information more useful for program planning (116-1-USG; 636-1-USG):

> *'In particular for the PMTCT and treatment indicators, the PEPFAR team has had a process to look back at programmatic results from previous years to inform the targets for the upcoming fiscal year. These programmatic results are useful when developing consensus around the targets and planning of the activities to be implemented in the next year. So, indicator data are used programmatically to inform the managers on how to implement the program especially when trying to scale up.'* (636-1-USG)

OGAC is working toward more closely linking program monitoring targets to financial information. Initially, targets were set using best guess estimates of what the money could buy given the costs at the time, without knowing the real costs or knowing what the partner country health system could absorb, particularly in the areas of treatment and care (NCV-11-USG). In 2012, OGAC began an expenditure analysis in ten countries to better understand the range of unit costing for PEPFAR's core services in order to help mission teams build budgets and more accurately estimate costs (NCV-11-USG) (C. B. Holmes et al., 2012). This type of expenditure analysis will become a routine process after this initial study (C. B. Holmes et al., 2012). The increased emphasis on tying targets to financial cost may be due to the fact that, as one interviewee put it, '*the budget now provides constraints and [we] have to really think about how to leverage resources*' (NCV-2-USG). The targets are '*more useful and more realistic now*' (NCV-2-USG).

Interviewees described an inherent tension between trying to meet program targets while also trying to implement interventions such as investing in quality programs, health systems strengthening efforts, building capacity, and focusing on prevention. These types of activities contribute to PEPFAR goals but could result in lower numbers reached for the program targets

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than investing directly in implementing service delivery (331-43-USG; 587-12-USG; 166-3-USG; 166-6-USG; 166-10-USNGO; 116-7-USG; 272-15-PCNGO). As an example, one mission team interviewee described how the focus on program targets can conflict with efforts to build capacity:

> *'PEPFAR funds civil society to do specific projects but this doesn't teach them how to engage the government, motivate staff, etc. PEPFAR is set up to fund organizations to achieve PEPFAR outcomes/targets. It is hard for PEPFAR to help civil society grow into these roles while also achieving PEPFAR targets.'* (166-4-USG)

A PEPFAR-funded NGO described the role of trying to achieve the targets as

> *'Ultimately it becomes a number crunching exercise. We are chasing the numbers. We have to find a balance of achieving the target but also rendering a quality service to the OVC. Sometimes it is just the figures that makes a difference—if you do not achieve the target you get "rapped on the knuckle" but if you achieve the target nobody ever asks you if can ensure the quality of the services. We try and render quality services and also meet the targets.'* (272-15-PCNGO)

Use of Evidence to Prioritize Activities

PEPFAR has emphasized the use of epidemiological data and intervention effectiveness data to determine priority activities and target populations for implementation in partner countries (NCV-13-ML; NCV-16-USG; NCV-27-ML; NCV-28-ML; NCV-29-ML) (see also the sections later in this chapter on PEPFAR support for epidemiological data and for evaluation and research). Despite this emphasis on using evidence to drive PEPFAR activities, there are examples, particularly from early in PEPFAR implementation, where evidence-informed strategies were not employed, such as the emphasis on the abstinence and be faithful components of the ABC prevention strategy and the lack of approval for needle exchange programs despite epidemiological data supporting the success of comprehensive programs that included needle exchange among people who inject drugs ((IOM), 2007; Lyerla, Murrill, Ghys, Calleja-Garcia, & Decock, 2012).

However, there are also clear examples where PEPFAR has functioned as a learning organization, shifting the focus of its activities to respond to new evidence. One such example is in the area of voluntary male medical circumcision (VMMC) to prevent HIV/AIDS via sexual transmission. After WHO and UNAIDS released normative guidance regarding the benefits of VMMC in 2007, PEPFAR began implementing VMMC in countries with high HIV prevalence and low male circumcision rates and it has since become the largest supporter of VMMC for HIV prevention globally (Goosby, 2012; WHO, 2012). Other examples of PEPFAR's programs evolving over time to reflect the available knowledge and evidence include moving to a combination prevention approach for prevention of sexual transmission, moving to comprehensive prevention approaches for people who inject drugs, and shifting the initiation threshold for treatment to higher CD4 counts (Lyerla et al., 2012; Needle et al., 2012; OGAC, 2010a). (See also Chapter 5, Prevention, and Chapter 6, Care and Treatment.)

Although PEPFAR policy has changed in response to emerging scientific evidence, PEPFAR has not typically moved ahead of global standards. PEPFAR usually changes its

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internal policies only after normative bodies, like the WHO, release appropriate guidelines (NCV-7-USG). The USG is, however, heavily involved in the process for developing these normative guidelines. For example, OGAC technical working groups (TWGs) include representatives from WHO and UNAIDS, and when these organizations develop new guidelines, they are typically cleared by members of the OGAC TWGs (NCV-7-USG).

In terms of implementing policy changes within PEPFAR, headquarters-level TWGs are engaged in putting evidence together, which then goes to the Deputy Principals, followed by the Ambassador (United States Global AIDS Coordinator), who makes the final decisions about a policy change or moving forward on new topics (NCV-7-USG). PEPFAR previously had a Scientific Steering Committee that met regularly to ensure that PEPFAR programs were "scientifically sound" (OGAC, 2007c). Since 2011, the PEPFAR Scientific Advisory Board (SAB) has provided guidance to the Ambassador on "scientific, implementation and policy issues" related to the HIV/AIDS response (OGAC, 2011a) (NCV-7-USG). See section titled "Implementation Science: The Way Forward" later in this chapter for additional discussion of the SAB.

> **Conclusion:** Target setting has been used to focus PEPFAR activities and for program planning and accountability. PEPFAR has utilized epidemiologic data, normative guidelines, and intervention effectiveness data to drive program activities. Despite some exceptions, especially in the first phase of implementation, PEPFAR has based its programs on available evidence and responded to new knowledge and scientific evidence as it has emerged.

Alignment of Targets and Priorities with Partner Countries

In PEPFAR II, there has been an increased emphasis on aligning PEPFAR targets with partner country priorities. As reflected in FY 2010 COP guidance, "Annual technical area summary targets should be based on USG support and should feed into the national program 5-year goals set through a strategic planning process led by the host country government and supported by key stakeholders" (OGAC, 2010c, p. 52). The need for increased coordination with partner country governments in setting PEPFAR targets was reflected by a mission team interviewee:

> *'Going forward we need to have more discussions and involvement with the Ministry of Health. If PEPFAR is going to support the national program then targets should be based on that. There needs to be more communication among [PEPFAR mission team] TWGs and with the Ministry when target setting.'* (461-18-USG)

One mission team described current alignment with the government as '*the PEPFAR team takes the government vision and targets (from the HIV plan) and tries to align by saying, "Here's what we can do to meet your goals*"' (240-19-USG).

One mechanism for increased partner country alignment is the PEPFAR Partnership Framework structure (OGAC, 2009b) described in more detail in Chapter 10. Partnership Frameworks are intended "to provide a 5-year joint strategic framework for cooperation between the USG, the partner government, and other partners to combat HIV/AIDS in the country through technical assistance and support for service delivery, policy reform, and coordinated financial

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commitments" (OGAC, 2009b, p. 3). As of FY 2012, 22 partner countries had signed Partnership Frameworks (OGAC). Ideally, targets and priorities that are set based on a country's Partnership Framework would result in alignment between PEPFAR and partner country government. In one country, USG interviewees described how the Partnership Framework process is a key aspect of annual COP planning and has helped to align PEPFAR and national priorities (116-1-USG; 116-4-USG), with PEPFAR saying to the partner country government, "*We will put your priorities ahead of ours*" (116-1-USG). A partner country government interviewee in this same country reflected the USG's efforts to align with the partner country priorities:

> "*Must commend the efforts that PEPFAR has made in recent years. PEPFAR has tried as much as possible to harmonize and align with country priorities, for example, through the Partnership Framework. This has been advocated at the highest level. This is a strong achievement.*" (116-16-PCGOV)

PEPFAR's priorities and country government priorities, however, may not always align. In one partner country, for example, government interviewees described how during the Partnership Framework process, the priorities that the country wanted to set within prevention did not match PEPFAR's priorities (587-7-PCGOV; 587-8-PCGOV). Despite some exceptions, interviewees across partner countries felt that the Partnership Framework structure was helping to improve alignment of PEPFAR and partner country priorities (116-4-USG; 116-16-PCGOV; 166-10-USNGO; 272-5-PCGOV; 272-36-USG).

PROGRAM MONITORING DATA

PEPFAR's largest and most sustained effort to create knowledge has been the generation of program monitoring data to track results and report on PEPFAR achievements to Congress. The following sections describe several interrelated aspects of PEPFAR's program monitoring system: collection and reporting, indicator selection and appropriateness, alignment and harmonization with partner countries and other stakeholders, data quality, and data use.

Collection and Reporting

Program monitoring data are collected by staff at PEPFAR-supported sites such as clinics and community-based programs. Partners who implement programs with PEPFAR funds collate PEPFAR indicator data from the sites they operate or support and report these data to their respective PEPFAR funding agency in-country, e.g., USAID, CDC, etc. (GAO, 2011a). Data from different implementing partners are aggregated by agency and then across mission team agencies before being submitted to OGAC by the in-country PEPFAR SI Liaison (GAO, 2011a). Implementing partners and site-level staff often also carry out data collection and reporting to meet their own organizational reporting requirements as well as reporting requirements for partner countries. The degree to which this data reporting uses indicators and processes that overlap with PEPFAR varies; these issues are discussed in more detail later in this section of the chapter.

OGAC provides guidance defining the indicators in PEPFAR's program monitoring system and the level at which each indicator is to be reported (see Table 11-2). PEPFAR mission

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teams report data from required indicators centrally to the OGAC SI office on an annual basis, with a subset of indicators (n=7) also reported semi-annually (GAO, 2011a). Over the course of PEPFAR, there have been a few iterations of program monitoring indicator guidance released by OGAC (OGAC, 2005c, 2007e, 2009d). As summarized in Table 11-2, the first round of indicator guidance, released in 2005, defined 64 indicators to be reported annually to OGAC. The next indicator guidance, issued in 2007, increased the number of centrally reported indicators to 72. The Next Generation Indicators (NGIs) guidance, introduced in 2009 for reporting beginning in FY 2010, reduced the number to 31 centrally, routinely reported indicators (25 programmatic indicators, 1 additional programmatic indicator if a partner country has a signed Partnership Framework, and 5 national level indicators).

TABLE 11-2 Number of PEPFAR Indicators by Reporting Status and Year of Indicator Guidance

	2005	2007	2009
Routinely Reported to OGAC	64	76	31
Not Routinely Reported to OGAC	23	23	123
Essential for PEPFAR mission teams	-	-	31
Recommended for PEPFAR mission teams	23	23	92
Total	**87**	**99**	**154**

NOTE: One indicator defined in the 2009 guidance is routinely reported only from programs that have signed a Partnership Framework with the partner country. A previously not routinely reported indicator was elevated to being routinely reported starting in fiscal year 2011, increasing the total number of routinely reported indicators to 32.
SOURCES: (OGAC, 2005c, 2007e, 2009d, 2012b).

With the introduction of the NGIs, OGAC created a new category of indicators (n=31), that are essential for mission teams to collect but do not have to be routinely reported centrally (see Table 11-2). The rationale for this level of indicators is to ensure that mission teams have specific data available at the partner country level to respond to ad-hoc requests for information from Congress (NCV-2-USG). OGAC indicator guidance also includes definitions for additional indicators that are recommended for mission teams to use for program management, if applicable to that country's program; however, these indicators are not reported centrally. The number of this type of indicator increased substantially with the introduction of the NGIs, from 23 indicators to 92 recommended indicators (see Table 11-2). The evolution of indicators in the new guidance is discussed in more detail later in this section of the chapter.

From FY 2006 to FY 2009, COPs and program monitoring data were submitted from PEPFAR mission teams to OGAC via an electronic, internet-based system called the Country Operational Plan Reporting System (COPRS) (OGAC, 2005b, 2006c, 2007d, 2008a). A second iteration of the system (COPRS II) was to be launched in July 2009 after being redesigned with input from "[…] a series of focus group discussions with USG field teams, TWGs, PEPFAR Coordinators, and the Deputy Principals to come up with a solution and long-term vision of a unified system for foreign assistance […]" (OGAC, 2009c, p. 35). Although a contractor was hired to work on developing COPRS II, contractor issues led to the system not being completed and, as a stop gap measure, OGAC utilized spreadsheets for data submission (NCV-2-USG). Concurrently, the U.S. Office of Management and Budget (OMB) was working on an effort to

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consolidate and reduce the number of data systems used within the Department of State (DoS) and requested that OGAC begin using an existing DoS system called FACTS Info (NCV-2-USG). The COPRS II development effort was canceled and OGAC has had a process of transitioning to FACTS Info (NCV-2-USG). The PEPFAR module in FACTS Info was launched in January 2012 and includes all historical program data (OGAC, 2012c). The new system is being used to support all business cycles including the COP, Annual Program Results (APR), and Semi-Annual Program Results (SAPR) (OGAC, 2012c). Moving forward, OGAC would like for the FACTS Info system to be able to generate useful reports to the field; support internal analytics; and be used to link program monitoring data to financial data, UNAIDS data, and Global Fund databases (NCV-2-USG).

Although temporary, the lack of a reporting database system for FY 2010 and FY 2011, which coincided with the committee's partner country visits, had negative ramifications for mission teams—using the program monitoring data for analysis was cumbersome and not having a system to access past years of data submitted was an issue (240-8-USG; 240-33-USG; 331-1-USG; 331-48-USG). In spreadsheet form, data were *"hard to manipulate"* and, you '*couldn't look at the data across the country level*' (331-1-USG). As one interviewee stated, '*It boggles the mind that a multi-billion dollar program is run by spreadsheets*' (331-1-USG).

Another consequence of shifting data systems is that OGAC's ability to access and utilize data across the various databases and systems that have been used to collate program monitoring data is limited. Only a small number of indicators were made available to the committee in response to requests for data from PEPFAR I. As a key requirement for knowledge management, it is critically important for OGAC to have all program monitoring data available in a usable format.

> **Conclusion**: PEPFAR's system of indicators to monitor program activities has faced technological challenges that have made it difficult for both PEPFAR and external stakeholders to utilize and access data, and it is critical for these challenges to be resolved for ongoing monitoring of the program. As technology is updated and new data systems adopted, historical data also need to be maintained and accessible to allow for assessments of trends going back to the earliest years of implementation.

Indicator Selection and Evolution

Interview data collected by the committee during country and non-country visits suggested that, '*What gets measured gets done*' (NCV-2-USG; NCV-23-USNGO; 272-36-USG; 396-1920-USG). OGAC's selection of indicators for program monitoring therefore, clearly plays an important role in which program activities are prioritized in partner countries. The primary areas of programmatic activity captured by PEPFAR's program monitoring indicators and the number of indicators that have been centrally reported in each area, based on the different iterations of indicator guidance, are summarized below in Figure 11-2.

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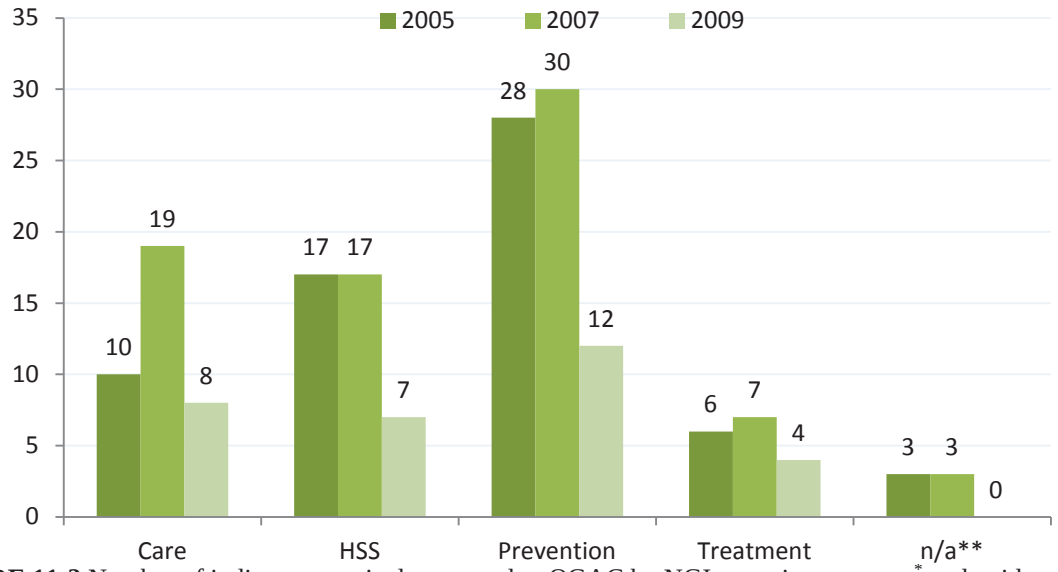

FIGURE 11-2 Number of indicators routinely reported to OGAC by NGI reporting category* and guidance year.
*Indicators defined in the 2005 and 2007 indicator guidance were categorized according to 2009 NGI Guidance categories to allow for comparison over time.
**In 2005 and 2007, OGAC had a set of indicators that were defined as impact indicators that were designed to look at the broad impact of programs. These indicators cannot be classified as falling into any specific NGI reporting category as they cut across program areas.
NOTE: HSS=Health Systems Strengthening.
SOURCE: (OGAC, 2005c, 2007e, 2009d).

Determining indicators for PEPFAR program monitoring has historically been a multi-stage process. The first iteration of indicators (2005) was determined by discussion among the relevant USG agencies, including CDC, USAID, HRSA, Peace Corps, and DoD, with consideration of existing indicators being used by USG agencies, as well as indicators being used globally (NCV-3-USG). The initial indicators were also vetted by partner country mission teams (NCV-3-USG). The process of determining the NGIs, which led to a dramatic change in the program monitoring indicators, involved convening a PEPFAR interagency TWG which included multilateral partners like WHO, PEPFAR-funded implementing partners, and civil society participants (OGAC, 2009d). OGAC was able to involve partners and contractors working in the field to a larger extent during the process for determining the NGIs than in previous indicator determination processes (NCV-3-USG).

Although evolution of indicators is appropriate as PEPFAR has matured and activities have changed, revision of program monitoring indicators creates challenges for mission teams and implementing partners:

> *'The transition from the old to the new indicators is a challenge; most existing registers and tools need to be adjusted and levels of disaggregation need to be adjusted for proper reporting. There is often not enough money for advocacy, adjusting registers, and re-training workers. Quality assurance is also a challenge when old tools are not eliminated or withdrawn from the field and there is not widespread adoption of the new tools—when there are not*

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> *enough tools available, people will revert to using antiquated tools.'* (331-34-USNGO)

To address these challenges, OGAC HQ and mission teams have provided technical assistance around collection of the new indicators, however there is still some confusion about what the new indicators mean and how to collect them (331-1-USG; 587-9-USG; 636-1-USG; 396-56-USNGO).

Another challenge with revision of indicators is that the introduction of new indicators and elimination of previous indicators, as seen with PEPFAR's transition to the NGIs, limits the ability to look at trends in program performance over time. Only nine PEPFAR indicators can be tracked across all partner countries for the duration of PEPFAR because these indicators are both reported centrally to OGAC and have indicator definitions that have remained consistent over time (see Table 11-3).

TABLE 11-3 PEPFAR Indicators Consistent Across the Duration of PEPFAR

NGIs Reporting Area	Indicator Definition	Indicator Level
Care		
	Percent of HIV-positive patients in HIV care or treatment (pre-ART or ART) who started TB treatment	PEPFAR Output
Health Systems Strengthening		
	Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests	PEPFAR Output
Prevention		
	Number of HIV-positive pregnant women who received antiretrovirals to reduce risk of mother-to-child-transmission	PEPFAR Output
	Percent of HIV-positive pregnant women who received antiretrovirals to reduce the risk of mother-to-child-transmission	National Outcome
	Number of individuals who received Testing and Counseling services for HIV and received their test results	PEPFAR Output
Treatment		
	Number of adults and children with advanced HIV infection newly enrolled on ART	PEPFAR Output
	Number of adults and children with advanced HIV infection receiving antiretroviral therapy	PEPFAR Output

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Percent of adults and children with advanced HIV infection receiving antiretroviral therapy	National Outcome
Percent of adults and children known to be alive and on treatment 12 months after initiation of antiretroviral therapy	PEPFAR Outcome

SOURCES: (OGAC, 2005c, 2007e, 2009d).

Despite losing the ability to follow some indicators long-term with the transition to the NGIs, the NGIs were seen by some interviewees as an improvement as they reflected feedback from the field, resolved issues with earlier indicators, increased clarity around some indicators, and decreased reporting burden (331-23-USNGO; 331-34-USNGO). However, there were still issues with the NGIs including confusion around definitions, difficulties with measurement, and perception by some interviewees that there were still too many indicators (587-9-USG; 331-1-USG; 587-9-USG; 636-1-USG; 396-56-USNGO). Additionally, the indicator changes led to challenges including the need for staff retraining, new data collection tools, and loss of ability to examine time trends (331-34-USNGO; 331-23-USNGO; 272-27-USG).

Conclusion: PEPFAR's program monitoring system has evolved over time to include a greater number of indicators but with fewer indicators that are centrally reported, which has resolved some challenges with clarity of definitions and reporting burden. There is a need for a PEPFAR program monitoring strategy which can respond to feedback, adapt to emerging program priorities, and accurately reflect program activities and outcomes. However, this adaptability over time needs to be balanced with the reality that changes in indicators place a burden on partner country programs and limit the comparability of PEPFAR monitoring data, hampering the ability to monitor trends.

Program Monitoring Indicator Appropriateness

Program monitoring indicators are designed to be used by implementing partners and mission teams to assess program performance; the indicators are not designed to "adequately capture every aspect of a comprehensive program" (OGAC, 2009d, p. 5). Despite this caveat, many interviewees expressed frustration that the indicators did not reflect their activities and were not well aligned with what interviewees perceived as OGAC program priorities. Areas that interviewees identified as not being well-captured include efforts related to tuberculosis; changing social norms including stigma reduction; policy development; and overall health system strengthening, including strategic information activities and laboratory strengthening (331-1-USG; 587-12-USG; 196-6-USG; 196-26-USG; 636-9-USACA; 935-9-USG; 542-6-ML; 396-8-PCNGO; 396-18-USG; 396-1920-USG; 166-4-USG; 461-18-USG).

PEPFAR country programs with a strong focus on capacity building and technical assistance in particular noted that they were not able to report on these prioritized program activities due to lack of relevant indicators (331-1-USG; 331-3-USG; 196-1-USG; 196-6-USG; 196-28-USG; 542-6-ML). Although they don't contribute to the '*big numbers that are meaningful to Congress*' (196-28-USG), there is a need to be able to track and document these types of activities to recognize their importance and evaluate these types of approaches, especially as PEPFAR transitions to a more

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country-led program approach. PEPFAR indicators also do not capture service delivery quality well, despite a stated intention to include this component (OGAC, 2009d). When local programs emphasize program quality, which can sometimes reduce the numbers treated and numbers accessing care, efforts are not measurable and attributable in the indicators (331-3-USG, 331-43-USG).

Another key issue cited by interviewees was that the PEPFAR indicators are focused on input and outputs and not on outcomes and impact, making it difficult to determine the effectiveness of PEPFAR's effort (587-9-USG; 587-22-USG; 166-23-USG; 461-4-USG; 461-14-USG; 396-15-USNGO). The routinely reported indicators are weighted more towards outputs than outcomes and impact and, the NGIs, introduced in 2009, have no impact indicators (see Table 11-4 below). This lack of ability to measure impact is a serious issue at both the country program and the central OGAC level; as one interviewee stated, '*When you invest this much and spend this much time, you need to look at impact'* (587-22-USG).

TABLE 11-4 Number of PEPFAR Indicators Routinely Reported to OGAC by Year of Guidance and Level of Indicator

	2005	2007	2009
PEPFAR Output	40	52	23
PEPFAR Outcome	20	20	3
PEPFAR Impact	4	4	0
National Output	0	0	2
National Outcome	0	0	3
National Impact	0	0	0
Total	**64**	**76**	**31**

NOTE: Indicators are either required and reported centrally to OGAC or collected for use by the country teams but not reported centrally. Starting in 2009, in addition to the recommended indicators there was a new category created of not reported but essential indicators (n=31).
SOURCE: OGAC, 2005; OGAC, 2007; OGAC, 2009.

To address indicator limitations, some mission teams and their implementing partners have developed custom indicators to allow for better monitoring of partners and initiatives (196-1-USG; 116-1-USG; 116-7-USG; 461-17-PCNGO; 934-21-USG). Examples of custom indicators include nurse exam passing rates; indicators to track reproductive health services; detailed OVC measures; measures of reduction in stigma; capacity building measures; training indicators; quality improvement targets; health systems strengthening measures; TB activity-related indicators; and process indicators for lab strengthening (196-USG; 116-1-USG; 116-7-USG ; 461-17-PCNGO; 934-21-USG). These custom indicators have enabled partners to provide more information about their programs and give more detail about how programs are performing and contributing to the national program (116-1-USG). These custom indicators are primarily used by mission teams and have not been adopted by OGAC. In one case, described by a mission team interviewee, '*the country team developed indicators [to reflect efforts around technical assistance] but OGAC rejected them*' (196-28-USG).

Conclusion: The current PEPFAR indicators do not reflect all of PEPFAR's stated prioritized goals and activities and are focused primarily on input and outputs and not on outcomes and impact. For these reasons, the program

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monitoring system has limited utility for determining the effectiveness of PEPFAR's efforts.

A subsequent section of this chapter will describe PEPFAR's evaluation and research activities and the chapter culminates with recommendations for how these activities can complement program monitoring data and be strategically coordinated to address the need to monitor program performance and to assess effectiveness and impact.

Alignment with Partner Country HIV/AIDS Monitoring and Evaluation Systems

To facilitate a more coordinated response to the HIV/AIDS epidemic, the 2004 Consultation for the Harmonization of International AIDS Funding, which brought together representatives from governments, donors, international organizations and civil society, determined three key principles for donor harmonization known as the "Three Ones Principles" (UNAIDS, 2004). These principles stipulate that each country should have *one* agreed HIV/AIDS Action Framework, that there should be *one* National AIDS Coordinating Authority, and the Third One, which called for donors to endorse "*One* agreed country-level monitoring and evaluation (M&E) system" (UNAIDS, 2004). The Third One Principle has proven especially challenging as donors struggle to reconcile their own reporting requirements with existing country M&E systems.

During PEPFAR I (2004-2008), the high level of investment, the rapid expansion of HIV services and the pressure to gather information to report results and demonstrate feasibility and scalability of HIV/AIDS service delivery programs, led to the creation of parallel M&E systems (Porter et al., 2012). Aligning with partner country M&E systems was complicated by the fact that many countries had weak HIV/AIDS M&E systems and most of these systems were not fully functional (Porter et al., 2012).

Interviewees in partner countries described how, initially, PEPFAR emphasized developing evaluation M&E capacity to report for PEPFAR, rather than improving existing partner country M&E systems (331-24-PCGOV; 587-2-USG; 587-9-USG; 636-1-USG; 636-9-USACA; 166-4-USG; 166-12-USG; 166-34-PCGOV; 272-27-USG; 461-11-PCGOV). Reasons cited for PEPFAR's parallel M&E system included that the existing partner country systems did not capture the information needed for OGAC to report to Congress (636-9-USACA; 166-1-USG; 166-10-USNGO; 166-12-USG; 272-27-USG; 461-15-USG; 461-20-PCPS; 934-21-USG), that there were multiple systems within the government making it difficult to integrate and align with the existing systems (331-34-USNGO; 196-8-ML; 116-16-PCGOV; 396-1920-USG), and that there were issues with quality of the partner country data and questions about data ownership (461-15-USG).

At the site level, with inadequate alignment of reporting and no single country-level M&E system, implementers collect data not only for government indicators but also for PEPFAR indicators and any additional indicators required by each implementing partner (116-12-PCNGO; 166-4-USG; 461-17-PCNGO). PEPFAR often requires a lot more information than the government (636-9-ACA; 116-12-PCNGO; 166-4-USG; 166-15-USACA; 272-27-USG) and collecting data for both partner country M&E systems and PEPFAR places a large burden on staff:

> *'There is a long list of NGIs data, but it is a challenge to get that data. It is not routinely reported in the national system so it requires additional data collection which is a burden on limited facility staff.'* (NCV-6-USNGO)

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In one partner country, for example, the need to report to PEPFAR was described as having a negative impact on reporting to the Ministry of Health because the same staff collect information for both systems (461-15-USG; 461-16-USG):

> *'The public sector sites that PEPFAR supports have to report to both PEPFAR and the Ministry of Health. At these sites, PEPFAR becomes the priority because they have money and the government becomes the second priority. The public sector staff that have to report to both PEPFAR and the MOH spend a significant amount of time on reports. Staff positions are not filled and the technical staff's time is filled with reporting.'* (461-15-USG)

OGAC's shift to the NGIs for program monitoring, described earlier in the chapter, was done in part with the goal of increasing alignment with country M&E systems. As described in the NGIs guidance, the shift to the NGIs "[…] attempts to minimize PEPFAR-specific reporting requirements to allow PEPFAR mission teams more flexibility to design M&E plans in-line with host countries and strikes a better balance between support for USG reporting needs and national M&E systems" (OGAC, 2009d). Although interviewees described some challenges with alignment and reporting burden as ongoing even after the introduction of the NGIs, many noted that with PEPFAR II there has indeed been much more progress aligning with national M&E systems (240-20-ML; 331-18-USNGO; 587-9-USG; 166-1-USG; 272-27-USG; 461-1-USG). Box 11-1 highlights some of these alignment efforts. More emphasis has also been placed on strengthening national systems of data collection and reporting (240-20-ML; 636-1-USG; 636-18-ONGO; 166-4-USG; 272-27-USG; 461-20-PCPS).

Box 11-1
Select PEPFAR Efforts to Align with Partner Country M & E Systems

- Revision of national data collection tools to ensure that PEPFAR indicators incorporated into and aligned with the Ministry of Health (MOH) M&E system. (331-18-USNGO; 636-9-USACA; 636-18-ONGO; 166-12-USG; 461-18-USG)
- Efforts to streamline PEPFAR indicators with MOH indicators. (636-9-USACA; 636-18-ONGO; 166-1-USG; 166-4-USG; 166-12-USG; 166-15-USACA; 272-27-USG; 461-15-USG; 461-18-USG)
- Cooperative agreements to unify partner country HMIS systems and efforts to integrate vertical systems in a particular country (331-24-PCGOV; 196-8-ML)
- Use of indicators already being gathered by the national system as a proxy for PEPFAR indicators. (587-9-USG)
- Health workers collect one set of data that is separated out when it is aggregated for

PEPFAR has articulated a goal of aligning its monitoring and evaluation system with partner country governments and has made some progress towards this goal; however, in general, alignment efforts have not yet fully succeeded nor have they achieved the desired

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magnitude of reduction in reporting burden for partner countries and implementing partners. As national health information systems are strengthened, there should be less need for PEPFAR to rely on separate systems in order to obtain information. "Building national M&E systems require sustained efforts over long periods of time with local leadership, commitment, and extensive stakeholder engagement" s(Porter et al., 2012, p. S122). As PEPFAR continues its efforts, alignment with partner country M&E systems is imperative as it is a critical component of country ownership (Holzscheiter, Walt, & Brugha, 2012). Further discussion of PEPFAR and national health information systems can be found in Chapter 9 on Health System Strengthening.

Harmonization with Global HIV/AIDS Indicators and Global Multi-Lateral Reporting Systems

Harmonization of Global HIV/AIDS Indicators

> *'U.S. government operations in general have accountability. But, the monitoring framework for programs should be really harmonized with other donors. Because, it's such an incredible waste of money and of time, particularly for the poor nationals who have to fill in a different form for each donor but on the same things. And then each time a little bit different. That undermines capacity in countries.'* (NCV-14-ML)

There have been several global initiatives to harmonize HIV/AIDS indicators, though there are still hundreds of indicators in use (NCV-7-USG). One such initiative, called the Monitoring and Evaluation Reference Group (MERG), is sponsored by UNAIDS (Porter et al., 2012). The goal of this initiative is to harmonize HIV/AIDS indicators globally and it has played an important role in convening agencies and helping actors come to consensus (NCV-7-USG). The MERG utilizes an anonymous indicator review process for proposed indicators (NCV-7-USG). With MERG input, UNAIDS developed a core set indicators which countries report on biannually know as the United Nations General Assembly Special Session (UNGASS) indicators (OGAC, 2009d; UNAIDS, 2009). The development of these indicators has allowed for comparisons across countries on key HIV/AIDS indicators globally and over time.

When PEPFAR introduced the NGIs, a stated goal was to increase harmonization with global HIV/AIDS indicators (OGAC, 2009d). Table 11-5 shows the level of harmonization of the NGIs with UNGASS indicators and other global indicators used by WHO, UNAIDS and the Global Fund, based on OGAC's self-classification (OGAC, 2009d). Of the NGIs that are required to be routinely reported to OGAC headquarters, 34 percent were not harmonized with either UNGASS indicators or other global indicators (OGAC, 2009). The lack of harmonization with global indicators may be a reflection of activities that are unique to PEPFAR; however, it contributes to the continued need for parallel M&E systems in order to collect PEPFAR program monitoring data.

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TABLE 11-5 Level of Harmonization of Next Generation Indicators with Global Indicators

	Harmonized w/ UNGASS Indicators	Harmonized w/ Other Global Indicators	PEPFAR-Specific Indicators (Not Harmonized)	Total
Total (%)	**44 (29)**	**63 (41)**	**47 (31)**	**154**
Routinely Reported to OGAC	10 (32)	10 (32)	11 (34)	31
Not Routinely Reported to OGAC	34 (28)	53 (43)	36 (29)	123

SOURCE: (OGAC, 2009d)

Harmonization of Reporting with other Multilateral Organizations

OGAC has worked closely with both UNAIDS and the Global Fund to harmonize data reporting. OGAC meets separately every 6 months to a year with UNAIDS and the Global Fund to compare data which has led to improved data quality and consistency of reported data (NCV-3-USG, NCV-21-ML). The Global Fund and OGAC now do joint releases of results to provide explanations to the public for data overlap and have provided shared monitoring guidance to countries (NCV-21-ML) (The Global Fund to Fight AIDS, 2011). The Global Fund and OGAC have started using common indicators but there are always some separate reporting requests from either side (NCV-21-ML).

> *'Some countries are partially funded by PEPFAR and partially funded by the Global Fund. So, have come up with financial criteria of minimum thresholds for the contribution of PEPFAR and the Global Fund towards national results. That was used to be able to deal with some of the overlap. The next stage was calculating overlaps to publish a Global Fund figure, a PEPFAR figure, and then a joint figure, which showed the unique number of individuals reached by both. The next stage is to start to harmonize around the impact and the outcome data to start to put together from both programs in countries where see changes in mortality, morbidity and prevalence, to start to agree on those.'* (NCV-21-ML)

PEPFAR's Contribution to the Development of Global Indicators

In addition to being an active participant on the MERG, OGAC has worked with multinational organizations to identify and develop program monitoring indicators. For example, in the area of gender, OGAC, together with civil society, national governments, and UN partners, identified eight key areas that should be measured around gender and HIV (NCV-10-USG). OGAC and UN partners compiled indicators to monitor nutrition and HIV that are not mandated by any one donor but that serve as a resource for countries that are interested in monitoring and

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evaluating their nutrition and HIV efforts (NCV-17-USG). Generally, OGAC has tried to serve as a resource for countries as they are putting together platforms around their programmatic efforts (NCV-17-USG).

> **Conclusion:** The need to quickly collect data and measure results at the onset of PEPFAR contributed to the development of PEPFAR-specific data collection systems, which has limited harmonization with partner countries and the global HIV/AIDS community. OGAC has worked closely with global actors like UNAIDS and the Global Fund to harmonize program indicators and validate reporting. With recent efforts, PEPFAR has also made progress in modifying its program monitoring system to reduce reporting burden and to improve alignment with partner country programs. However, further modifications could be made to improve clarity of indicators, including eliminating PEPFAR-specific language in the indicator guidance; further reducing the reporting burden; improving indicator harmonization with global indicators; and better alignment with partner country HIV monitoring and health information systems for data collection at the program and country level.

Data Quality

PEPFAR implementing partners are responsible for validating and aggregating program monitoring data and ensuring data quality from each of their sites (GAO, 2011a). OGAC has provided data quality assurance tools for use at sites to address common data quality issues like double counting (multiple counting of individuals for the same indicator). However, data quality remains a challenge (GAO, 2011a; OGAC, 2007a).

Double counting was an issue that was mentioned by several interviewees (331-8-PCNGO; 331-23-USNGO; 587-9-USG; 587-18-PCGOV; 461-14-USG; 461-18-USG; 240-15-USG). The lack of unique identifiers in some countries and people getting tested multiple times in different locations has contributed to double counting in the area of voluntary counseling and testing (331-8-PCNGO; 331-23-USNGO; 587-9-USG; 587-18-PCGOV; 461-14-USG; 461-18-USG). Double counting was also an issue in the area of care and support (240-15-USG). Interviewees reported a few strategies for reducing the amount of double counting, including

> *'Work with implementing partners to verify overlap in the output indicators. If don't have sufficient proof of service provided, don't count the services in their reported numbers. Have a process for rationalization to avoid having partners work on the same sites. Partners agree on who gets to count and report cases and services.'* (461-1-USG)

More broadly, various data quality assessment initiatives were described by implementing partners and mission teams (166-12-USG; 272-27-USG; 934-21-USG). One mission team described a process of re-abstracting medical charts to verify data and asking questions to assess processes and protocol at directly-funded NGO and treatment sites (587-9-USG). Other mission teams described using a tool developed by the organization MEASURE/Evaluation for data quality assessments (587-3-USG; 636-18-ONGO). Some mission teams hired partner organizations to do

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data quality assessments and to work with implementing partners on data quality processes (636-18-OTHNGO, 461-1-USG, 461-20-PCPS). One such organization described the benefits of their data quality assessment work:

> *'In the beginning, people were apprehensive of the data quality assessments. They thought it would affect their funding, but now implementing partners are grateful and it helps them see their strengths and weaknesses and helps partners strengthen where they are weak. […] There has been spillover from the data quality assessments and now many of the partners are doing data quality assessments themselves.'* (461-20-PCPS)

The PEPFAR SI Liaison in-country, representing the Coordinator's office, is responsible for the final steps of assuring data quality and for submission of data to OGAC (GAO, 2011a). In many countries, SI Advisors from headquarters are invited to validate data before submission (GAO, 2011a). If there are issues with the data, the OGAC SI team communicates with mission teams to clarify the issues. Recently, OGAC has instituted a more formal process where all SI Advisors, as well as the SI support persons to the various country-level TWGs, contribute to Mission Team data review (GAO, 2011a).

Due to the lack of an operating program monitoring database as described earlier in this chapter, in fiscal years 2010 and 2011, mission teams reported program monitoring data to OGAC using spreadsheets (OGAC, 2009c, 2010c). Data were verified by OGAC staff using data cleaning spreadsheets (Microsoft Excel) and data cleaning checklists (NCV-2-USG). OGAC prioritized data cleaning of seven key indicators that are submitted annually to Congress with cleaning of the other indicators '*taking an additional 2-3 weeks*' (NCV-2-USG). The data clearance process was described by OGAC SI staff as more than a validity test—'*OGAC is not just checking to make sure that the files submitted by the countries are there, but there is a creditability and reliability check—is what the countries are reporting sensible for the type of program they have?'* (NCV-7-USG).

Although OGAC interviewees described their evolving and multistage processes for data collection, validation, and availability, the committee's experience with PEPFAR program monitoring data raised some concerns. When the committee requested program monitoring indicators, these data, beyond the seven key indicators that are reported annually to Congress, were not readily available. When indicator data were made available, the committee's examination of these data revealed numerous discrepancies. A similar observation has been made by others (Bryant et al., 2012). These data discrepancies led the committee to question the mission team and OGAC HQ verification processes. These data issues, along with limited data availability, made it difficult for the committee to fully assess PEPFAR's efforts (see also Chapter 2 on the evaluation scope and approach and the more detailed description of methods in Appendix B).

Use of Program Monitoring Data

Data Use at OGAC Headquarters

At OGAC headquarters, one of the primary uses of program monitoring data is to provide annual reporting to Congress and to respond to ad hoc congressional requests (NCV-2-USG). '*The*

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data reporting played a huge role in getting funding. [PEPFAR was] one of few international programs reporting results' (NCV-3-USG). Additionally, program monitoring data reported by mission teams was described as being at the '*heart of internal decision making at OGAC'* (NCV-7-USG). These data are used for budgets, models, congressional budget justifications, and for the strategic plan (NCV-7-USG). OGAC also reported using these data to track '*Where they've been and where they think they're going […] the data led, in part, to the ability to push for the 2013 treatment target of six million'* (NCV-7-USG). Program monitoring data are also used for programmatic decision making, informing how to engage with partner countries, informing what technical assistance countries need, and monitoring partner countries' response to the HIV epidemic (NCV-2-USG).

Data Use by Mission Teams and Implementing Partners

Mission team interviewees described using program monitoring data for multiple purposes. Most commonly, program monitoring data were used by mission teams to examine achievements from prior years, review and monitor partner performance, and to guide priority activities (240-15-USG; 636-1-USG; 166-12-USG; 272-22-USG; 461-16- USG; 461-20-PCPS; 587-9-USG; 196-1-USG; 116-1-USG). Data were also used to analyze partner overlap by region (461-16-USG, 461-20-PCPS); determine programmatic trends for different partners (636-1-USG); and help partners to set appropriate targets (240-33-USG; 636-1-USG).

Although PEPFAR mission teams provided examples of how PEPFAR program monitoring indicator data were useful for evaluating program performance, overall, interviewees described how the burden of reporting indicator data interfered with the ability to consistently utilize the data in a meaningful way (240-1-USG; 331-48-USG; 587-22-USG; 461-15-USG; 934-2-USG). The high reporting burden limited available time to look at the data (240-3-USG; 461-16-USG) and much of the program monitoring data were not used beyond the purpose of reporting to OGAC (461-3-USG; 331-1-USG; 272-25-USG). As one interviewee stated, '*PEPFAR has an onerous reporting burden "way, way beyond the pale […]"'* and '*reporting pulls limited staff attention away from where it should be focused — monitoring and continual assessment with field visits*' (587-22-USG). Additionally, discontinuing use of COPRS I, as described earlier in the chapter, led to limited ability to manipulate program monitoring data for analysis which affected mission team utilization of the data (331-1-USG).

Implementing partners also bemoaned the heavy burden of reporting program monitoring data, particularly on clinical staff (NCV-6-USNGO; NCV-8-USACA; NCV-14-ACA; 396-8-PCNGO), and how it resulted in limited utilization of the data (461-15-USG). As one interviewee described:

> *'In the current system we collect everything but very little [data] will be analyzed and utilized for our program or for policy advocacy. Very little. I think that's like 20 percent of data. So now we try to collect anything and just put it in the corner. So I think that we can review the term and the workload for the people we brought in the program it means we can save costs and have more time to improve the program.'* (396-8-PCNGO)

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This view was reinforced by a mission team interviewee:

> *'In the service delivery sites and at the districts the numbers are not being analyzed or used […]. Sites are concerned with moving the data out and up. As long as the number goes out the door the sites are not worried about it and everybody is happy as long as the report gets out.'* (461-15-USG)

In addition to the burden of reporting, data were not perceived by interviewees as beneficial for improving patient outcomes:

> *'Indicators—doing monthly reporting is totally burdensome. Facilities do not see the data as helping the patient and [data are] seen as something you have to do because of the program. It would be fine if the report was useful in and of itself but that is not always the case. In some clinics, have multiple people working all day on the data and [their] whole job is reporting. […] All of the reporting of indicators is not benefitting the patients; you just have to do it because you are in the PEPFAR program.'* (NCV-8-USACA)

As one USG interviewee stated, '*If they could show sites how the indicators are useful for program management then the process of collecting the indicators would become meaningful for the sites'* (587-9-USG).

As described previously, the introduction of NGIs reduced the number of centrally reported indicators (see Table 11-2) in response to feedback from the field about the burden of reporting program data. Although some improvement with the introduction of the NGIs was noted by interviewees (331-23-PCGOV; 331-34-USNGO), the number of indicators being reported was still perceived as burdensome (587-9-USG; 461-15-USG; NCV-6-USNGO; NCV-8-USACA). '*PEPFAR is asking for low level indicators to be reported at the high level when they are only needed at the facility level*' (461-15-USG). Another interviewee stated that there were '*Too many indicators, overwhelming, purpose is not clear and not useful for country decision making*' (587-9-USG).

Data Use by Track 1.0 Partners[4]

The four Track 1.0 partners involved in early implementation of PEPFAR-supported care and treatment programs represent a subset of implementing partners that are active in multiple countries and that have distinct opportunities and capabilities for data use. In addition to reporting applicable program monitoring indicator data to mission teams within the partner countries in which they implement programs, Track 1.0 partners also submit a separate, core set of facility-based treatment and care data to CDC. Additionally, Track 1.0 partner country offices also report results separately to the headquarters of their own organizations.

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[4] Track 1.0 Partners in this report refers to four partners that were the primary large-scale implementers of ART in PEPFAR's centrally funded Track 1.0 program (for more information, see Appendix C, Methods). These partners also implemented other HIV services and programs, and there were also other centrally funded Track 1.0 partners in other program areas.

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Track 1.0 partners support sites in multiple countries and have been able to use site-level data to identify and share best practices across Track 1.0 partner countries. For example, as one Track 1.0 partner described:

> *'An advantage to being in several countries was that we were able to show differences among countries and site data. It was useful for the programs to see what other countries are doing and learn from each other. Used the data for program improvement, mortality coming from opportunistic infections, adherence failure, and infant infection rates. In-country teams responded to the data and made changes based on what learned from other sites.'* (NCV-4-USACA)

Additionally, Track 1.0 partners have used data to target technical assistance and improve sites (NCV-4-USACA; NCV-5-USACA). For example, one Track 1.0 partner used data to look at clinics where there were no children on ART and determined that the issue was related to an issue with availability of pediatric drug formulations (NCV-4-USACA). Another Track 1.0 partner described doing an annual facility survey to understand the context in which its care and treatment sites operate (NCV-5-USACA). The survey, used to monitor sites and target technical assistance, provided information about access to family planning, availability of male circumcision and a range of prevention services, as well as information on availability of TB laboratory diagnostics (NCV-5-USACA).

Conclusion: There are some good examples of the use of PEPFAR program monitoring data at the Mission Team, implementing partner, and headquarters levels, but the preponderance of the data collected does not seem to be routinely utilized. One major contributing factor is PEPFAR's requirement for collection and reporting of a large amount of program monitoring data which has placed a large administrative burden on implementing partners and mission teams that detracts from efforts for data analysis and use.

Summation for Program Monitoring Data

PEPFAR has placed a strong emphasis on collecting data to monitor the performance of the programs it supports, for which there have been benefits. As one interviewee stated, *'[…] there are very few programs like PEPFAR that can give you results on how many people are on treatment, PMTCT, etc.'* (240-33-USG). Also, the PEPFAR approach has led to an increased emphasis on measurement. In the words of one interviewee:

> *'[The partner country] did not see M&E as an important issue in the system. Usually people would do work, give assistance and then go away; documentation was very poor. Now there are systems in place and people appreciate that the systems have to stay—PEPFAR helped with this though, work is still needed.'* (461-20-PCPS)

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Although PEPFAR's emphasis on collecting data for monitoring and evaluation is commendable, its value is limited if the process is so cumbersome that it results in limited ability to utilize the data. OGAC headquarters, mission teams, implementing partners, and partner country governments have different constraints that limit use of data. At OGAC HQ level, only a subset of program monitoring data are cleaned and available in a usable manner and changes in database systems have limited the ability to access and use data. At implementing partner and mission team level, the ability to use data is limited due to reporting burden and perception that these data are of little utility. Partner country governments experience some of the same challenges as implementing partners, and also in many cases, have limited capacity for data analysis and use.

As PEPFAR moves towards greater alignment with partner country M&E systems, there will be less ability to attribute results to PEPFAR. This is consistent with an appropriate shift to a focus on measuring contribution to a country-led response. This shift could result in a reduced number of PEPFAR-specific indicators, which could help alleviate the burden of reporting across PEPFAR and contribute to increased effective use of data.

PEPFAR SUPPORT FOR EPIDEMIOLOGICAL DATA

PEPFAR has been instrumental in supporting partner country surveillance efforts. At the onset of PEPFAR, there were limited epidemiological data available for understanding the drivers of the HIV epidemic in partner countries and for informing decisions in implementing a response. Consequently, PEPFAR invested heavily in increasing surveillance of HIV/AIDS in partner countries to monitor the epidemic, supporting local surveys and baseline studies, and developing methods to model the scope of the epidemic (GAO, 2012) (Lyerla et al., 2012).

PEPFAR has supported surveillance systems within partner countries including support for nationally representative household surveys like the Demographic Health Survey, behavioral surveys like the Integrated Biological and Behavioral Surveillance, drug resistance surveys, antenatal care surveys, and HIV case and incidence estimation, as well as providing financial and political support for surveys on populations at elevated risk of HIV infection and transmission (116-1-USG; 116-4-USG; 166-4-USG, 196-1-USG; 196-8-ML; 196-10-PCGOV; 196-11-USNGO; 196-13-OGOV; 240-9-USG; 240-12-USG; 272-13-USG; 331-3-USG; 331-10-PCGOV; 331-14-USG; 331-15-USG; 331-24-PCGOV; 396-6-PCGOV; 587-9-USG; 636-1-USG; 934-21-USG; 934-24-PCGOV; 461-1-USG). As one mission team interviewee described support for these efforts, *'survey data is very strong and has been useful in giving evidence of what is happening in the epidemic'* (272-27-USG). As highlighted by a partner country government interviewee:

> *'I think the PEPFAR program enhanced our capacity on surveillance on HIV testing in country to enhance prevention care and support for HIV. And I highly appreciate CDC support not only for HIV/AIDS but for many other activities. We receive [surveillance] support from CDC both technical support and financial support on many activities. We have support from CDC to do IBBS. I think that maybe the best information we have about HIV/AIDS [situation] in country. Beside surveillance we receive support for estimation prediction, also very important. […] And we have I think has a good picture about HIV/AIDS in the country'* (396-6-PCGOV).

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In addition to the use of program monitoring data, as detailed earlier in the chapter, PEPFAR-supported surveillance and survey data have been used by partner country governments and other country stakeholders to better understand drivers and monitor trends for country epidemics, to contribute to and influence planning for the national response, and to influence national policies, in some cases, resulting in increased attention to previously underserved populations or service needs (396-6-PCGOV; 396-1920-USG; 396-53-USNGO; 272-22-USG; 272-25-USG; 166-23-USG ; 196-11-USNGO; 331-10-PCGOV; 331-ES; 331-24-PCGOV; 196-ES). For example, a national HIV/AIDS behavioral risk survey funded by USG and other donors with MOH changed some of the priority areas for both PEPFAR and the MOH in terms regions targeted and target populations: *'Now, instead of being more anecdotal, have more evidence and now more able to target programming'* (166-23-USG). In another partner country, a PEPFAR partner worked with provincial governments to provide training on how to collect and analyze data and then, on how to use the data for planning and evaluating programs (396-53-USNGO).

A range of stakeholders also described PEPFAR mission team staff as using epidemiological data to focus activities and provide services based on evidence (331-43-USG; 331-22-PCNGO; 196-28-USG; 116-1-USG; 116-12-PCNGO; 166-7-PCGOV; 396-1920-USG; 240-9-USG ; 272-25-USG). For example, mission teams described how information was gathered on who was infected and what behaviors were driving the epidemic and then interventions were developed based on those behaviors, including focusing on best practices in populations at elevated risk (331-14-USG, 396-12-USG). One mission team interviewee described using epidemiological data to focus PEPFAR-supported activities:

> *'[…] which districts PEPFAR supports is primarily driven by epidemiology—places with high prevalence with groups that needed to be reached. There is also ongoing dialogue with the government. But, burden is the driver of where PEPFAR works.'* (196-28-USG)

Conclusion: PEPFAR has provided financial and technical support for collecting epidemiological information in partner countries. This was widely seen as a positive contribution; informing decisions and priorities in planning the HIV/AIDS response and implementing HIV programs, encouraging and facilitating responsiveness to the epidemic and identifying the needs in partner countries.

PEPFAR SUPPORT FOR DATA USE BY PARTNER COUNTRY STAKEHOLDERS

In FY 2008, OGAC SI endorsed the overarching goal of "know your epidemic/know your results," in keeping with the UNAIDS approach introduced in 2007 (OGAC, 2008b; UNAIDS, 2007). Part of this initiative was aimed at helping partner countries and members of civil society "to collect, analyze, critically review, disseminate, interpret, display, and strategically use data at all levels" (OGAC, 2008b, p. 191). PEPFAR's effort to support the use of routine monitoring data and epidemiological data by partner country stakeholders to inform the HIV response is described only very briefly here. Further discussion of PEPFAR's efforts on building capacity in partner countries for the collection and use of health data information can be found in Chapter 9 on Health System Strengthening. In addition, PEPFAR's support for data collection to support

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planning of program portfolios and joint planning with partner countries is discussed where relevant in the program area chapters in Part III of this report.

The PEPFAR approach to implementing programs was described by some interviewees as leading to an increased emphasis on measurement that has had a positive effect (461-14-USG; 272-15-PCNGO; NCV-5-USACA; 240-8-USG; 636-18-ONGO; 396-55-USG; 331-14-USG; 116-23-USPS; 166-23-USG; 272-22-USG; 461-18-USG). One USG interviewee described PEPFAR's contribution to creating an evidence-based culture as the legacy of PEPFAR's work in the partner country (240-8-USG). In addition to supporting collection of epidemiological data, discussed in detail in the next section of this chapter, PEPFAR has carried out several activities to increase data use among partner country governments. Efforts have included mentorship (240-12-USG; 636-18-ONGO), providing training to district government employees on data use (636-18-ONGO; 196-1-USG), strengthening data and data use in the MOH (636-18-ONGO; 166-4-USG; 166-9-USG/OBL/ML; 272-17-USG; 396-1920-USG), working on creating an evidence-based culture (240-8-USG; 166-4-USG; 461-16-USG), and data use workshops (461-16-USG; 396-5-USNGO). PEPFAR has successfully stressed the importance of local data collection and use for decision making by local government including the establishment of district M&E teams (636-18-ONGO; 396-55-USG). PEPFAR has also worked with partner country governments to utilize data to change policies and better target programming (331-14-USG; 116-23-USPS; 166-23-USG; 272-22-USG; 461-18-USG).

Track 1.0 partners have been active in promoting partner country data use (166-15-USACA). One Track 1.0 partner described providing automated data reports as a mechanism for feedback both at the site and country level, eliminating the burden of report making as in many countries, there is a limited statistical analysis capacity (NCV-5-USACA). This Track 1.0 partner also encouraged implementing facilities to present and discuss their data with each other at meetings, contributing to ownership of the data collected (NCV-5-USACA). Additionally, in at least one partner country, a Track 1.0 partner provided funds to help the government develop a data warehouse for patient-level data (NCV-5-USACA). By participating on national TWGS, Track 1.0 partner staff presented and discussed data with government counterparts, encouraging partner country data use (NCV-5-USACA).

Despite these efforts, increasing partner country data use has been hampered by an ongoing lack of capacity within partner country governments and partner country organizations (116-23-USPS; 166-4-USG; 166-7-PCGOV; 166-9-USG/OBL/ML; 272-15-PCNGO; 461-20-PCPS). High turnover of staff within the government and partner organizations has also been a challenge (116-23-USPS, 396-56-USNGO). Successfully increasing use of data by partner countries was seen by some interviewees as being linked to the long-term sustainability of PEPFAR's efforts (331-1-USG; 396-39-USG).

Conclusion: PEPFAR has invested in building the capacity of partner countries to plan for, collect, manage and use HIV data, which has implications for the larger health system. Through these investments, PEPFAR has contributed to fostering a culture of evidence among country partners, including country-based implementing partners and partner country governments.

PEPFAR-SUPPORTED EVALUATION AND RESEARCH ACTIVITIES

History and Evolution of PEPFAR-Supported Evaluation and Research

PEPFAR has included an emphasis on evidence-based programming from its onset, highlighting the need for evaluation and research in addition to program monitoring data to serve

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as evidence to inform efforts (OGAC, 2004). As a result, PEPFAR has actively supported some form of evaluation since its inception; however, policy constraints on engaging in research and program priorities limited the initial role of research within PEPFAR (OGAC, 2004, 2012d). As PEPFAR programs and priorities evolved from an emergency response towards a more sustainable response to the HIV epidemic, PEPFAR leadership increasingly recognized the importance of evaluation and research in capturing, utilizing, and maximizing knowledge created through PEPFAR, as well as in ensuring contributions to the global knowledge base on effective HIV/AIDS interventions and program implementation (OGAC, 2009e; Padian et al., 2011). [5]Subsequently, the role of evaluation and research within PEPFAR has expanded.

Both research and evaluation have important roles to play within PEPFAR and can contribute to implementing effective evidence-informed programs. Although research and evaluation utilize similar tools and methodologies and may draw from similar data sources, they have notably different aims, uses, and audiences (Fain, 2005; Levin-Rozalis, 2003; Small, 2012). The aims of research include: adding new knowledge to a field, proving that a particular factor caused a particular effect, and producing results that are generalizable beyond an individual project/program (Fain, 2005; Levin-Rozalis, 2003; Small, 2012). In contrast to this, the purpose of evaluation is "not to prove, but to improve" (Stufflebeam, 2007), p. 2). Evaluation is specific to a particular project or program; it aims to produce outcomes used by decision makers to determine the best mechanisms to achieve program goals, assess program effectiveness, and assess whether goals are being met or not (Fain, 2005; GAO, 2011b; Levin-Rozalis, 2003). Despite an evolving role of research in PEPFAR, which is described in the following sections, defining appropriate and allowable research activities within PEPFAR was and remains a challenge, and there remain no clear distinctions between these separate but complementary aims of research and evaluation.

The Role of Research from PEPFAR 1 to PEPFAR II

The first phase of PEPFAR (PEPFAR I) was initiated as an emergency response to HIV/AIDS focused on rapid implementation and scale up of prevention, treatment and care programs (OGAC, 2009e); as such, basic infrastructure for monitoring and evaluation existed (USAID, 2011b), but "state-of the art monitoring, evaluation and research methodologies were not integrated or systematically performed" (Padian et al., 2011), p. 1). In PEPFAR I, research was seen as having two roles 1) to produce new knowledge about HIV/AIDS interventions and implementation and 2) to assess PEPFAR programs and inform policies through targeted research (OGAC, 2004). As the primary focus of PEPFAR I was rapid scale up and implementation of programs, leadership felt that PEPFAR efforts would be better spent on implementation while other USG organizations better suited to conduct research focused on creating new knowledge (OGAC, 2005b).

At the time, the USG supported a wide variety of HIV/AIDS research through the NIH, CDC, and USAID from which PEPFAR could draw new knowledge ranging from basic clinical and social science research to applied and operations research; studies focused on multiple topics including therapeutic and preventative regimens, microbicides, vaccines, ART, PMTCT, ABC, male circumcision, injection safety, nutrition, and psychosocial issues for orphans and vulnerable

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[5] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

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children (IOM, 2007). The intention was for OGAC to work closely with leadership at NIH, CDC, and USAID to ensure their research priorities aligned with PEPFAR goals and needs in order to leverage these external research efforts to inform PEPFAR policy and program decisions (OGAC, 2005b).

Beyond this collaboration, PEPFAR did, in some special cases, fund targeted evaluation and research to address PEPFAR-specific questions (OGAC, 2005b). For many PEPFAR stakeholders, however, it was unclear what research if any was allowed with PEPFAR I funding. Descriptions of research in PEPFAR I legislation and strategy seemed to proscribe against using PEPFAR funds for research, and many country mission teams and implementing partners perceived a ban on using PEPFAR funds for research (IOM, 2007). This perceived research proscription was frequently mentioned during interviews with headquarters and implementing partners involved in PEFPAR from the inception. In the words of one interviewee: "[…] *you couldn't use the word research or operational research"* (NCV-4-USACA), and another interviewee described how people are *"baffled as to why there was no research components in the first years of this program, and why it was absolutely disallowed because we did all this work and we're not able to really learn from it or do anything"* (NCV-8-USACA). Finally, one interviewee described how research and evaluation became conflated by OGAC to get around research restrictions, in the words of the interviewee: *"In the first phase of PEPFAR, OGAC could not use the word research, so people referred [to research activities] as evaluation"* (NCV-7-USG).

Over time, leadership recognized that although PEPFAR is not intended to be a research organization, research was important to optimizing programs and maximizing the impact of knowledge and experiences created through PEPFAR (IOM and NRC, 2010). Recognizing this, PEPFAR II reauthorization legislation and the second Five-Year Strategy helped clarify the research and evaluation policy to encourage these activities within PEPFAR (OGAC, 2009e).[6] The reauthorization legislation and second Five-Year Strategy called for integration and expansion of research (biomedical research, health services research, impact evaluation research, and operations research) within PEPFAR to assess program quality, effectiveness, and population-based impact; optimize service delivery; and contribute to the global evidence base on HIV/AIDS interventions and program implementation (OGAC, 2009e).[7]

Evolution of PEPFAR-Supported Evaluation and Research Activities in PEPFAR 1 and II

As PEPFAR priorities and programming progressed, the frame within which PEPFAR conceptualized evaluation and research activities expanded from the initial Targeted Evaluations (TEs) to Public Health Evaluations (PHEs) Phases I and II to the current Implementation Science and Impact Evaluations. As the frame has evolved, the scope, allowable methods, funding mechanisms, oversight entities, and priorities of these research and evaluation activities have changed. Table 11-6 summarizes this evolution of PEPFAR-supported evaluation and research over time. Throughout this evolution, research and evaluation remained comingled in the operational structures of TEs and PHEs, with no clear articulation of the distinctions between PEPFAR's research and evaluation activities and aims. The following sections focus on activities that have been implemented during PEPFAR I and into PEPFAR II, while a subsequent section

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[6] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008)

[7] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

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will discuss in more detail the new research and evaluations activities being implemented under the Implementation Science umbrella, which were only just beginning as this evaluation was under way.

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TABLE 11-6 Evolution of PEPFAR-Supported Evaluation and Research Activities

Program (Fiscal Year)	Scope	Methods	Funding Mechanism	Oversight	Program Priorities
Targeted Evaluations (2005-2006)	Rapid answers to specific, measurable and focused questions about program implementation to improve services and identify best practices	Rigorous assessments including pre- and post-test results with a comparison or control group	Mission/ country and centrally funded Funded through COP	Scientific Steering Committee and Targeted Evaluation Subcommittee Minimal central oversight	Country Driven
Targeted Evaluations (2007)	Answer specific questions around efficacy and best practices to produce generalizable results and contribute to program sustainability	Rigorous assessments including pre- and post- test results with a comparison or control group	Funded through COP	Scientific Steering Committee and Targeted Evaluation Subcommittee Minimal central oversight	Technical Working Group Driven
Public Health Evaluations Phase 1 (2008)	Answer questions around program effectiveness, compare program models, answer operational questions and determine program outcome and impact with shift in focus from individuals to communities and populations	Rigorous, scientifically sound research methodology using experimental or quasi-experimental designs including (but not limited to) randomization, modeling, advanced statistical techniques, and comparison groups	Funded Centrally	Scientific Steering Committee and PHE Subcommittee Subcommittee has more responsibility and is able to convene multi-agency PHE evaluation teams representing (CDC, DOD, NIH, HRSA, USAID) Increased central support and coordination oversight	Globally significant priorities generated at country, central, and technical working group level

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Program (Fiscal Year)	Scope	Methods	Funding Mechanism	Oversight	Program Priorities
Public Health Evaluations Phase 2 (2009-2010)	Answer questions of global significance, program impact and effectiveness, comparative evaluations of interventions and programs, and operational questions	Rigorous, scientifically sound research methodology using experimental or quasi-experimental designs including (but not limited to) randomization, modeling, advanced statistical techniques, and comparison groups	Funded Centrally	Scientific Steering Committee, PHE Subcommittee and PHE Evaluation Teams Increased central support and coordination	Country Driven Align with globally significant priorities
Implementation Science (2011-present)	Focused on improving uptake, implementation and translation of research findings into practice	Scientifically rigorous research methods using randomized experimental designs, quasi-experimental methods, or advanced mathematical techniques (e.g. simulation, mathematical optimization, and decision science)	Funded Centrally[a] Concept proposals required through Implementing Agencies	Implementation Science Steering Committee *(formerly known as PHE Subcommittee)* Central oversight Implementing Agency managed	Scientific Advisory Board[b] Driven Align with country research needs and priorities

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Program (Fiscal Year)	Scope	Methods	Funding Mechanism	Oversight	Program Priorities
Impact Evaluations (2012-present)	Systematic study of the change attributable to a particular intervention, such as a project, program, or policy	Uses experimental or quasi-experimental approaches to establish a counterfactual	Funded though COP	Implementation Science Steering Committee Central oversight at concept stage Country managed at implementation stage	Country Driven Linked to specific programmatic activities

[a] Implementation Science RFAs are funded centrally and managed through Implementing Agencies. These mechanisms include the NIH Implementation Science Supplement, NIH Implementation Science RFA, NIH Implementation Science IDU RFA, NIH Implementation Science PMTCT RFA, CDC Implementation Science Funding Opportunity Announcement (Foe), and USAID Implementation Science Annual Program Statement (APS)

[b] SAB is comprised of members that represent academia, advocates, international experts, the HIV/AIDS community, partner country governments, multilateral and bilateral agencies, foundations, and nongovernmental organizations

SOURCE: (Bouey, 2011; OGAC, 2010b, 2011d, 2012d; Padian et al., 2011).

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Targeted Evaluations

Targeted Evaluations (TEs) began in 2005 to provide an evidence base, beyond routine program monitoring and evaluation or surveillance, to inform program planning and implementation (OGAC, 2006b)(OGAC, 2005). The goals of targeted evaluations were to assess program outcomes, indicate whether programs achieved their goals, and to identify potential best practices for scale up (OGAC, 2005b, 2006a, 2006b). In the words of OGAC staff, TEs were "studies that provided rapid answers to specific, measurable, and focused questions about health program implementation to improve services and identify best practices" (Bouey, 2011, p. 4). The allowable scope and study methods of TEs were influenced by "legislative sensitivities on use of PEPFAR funds for research" (Bouey, 2011, p. 4). Randomization was not allowed and study methods mainly included quasi-experimental designs using natural controls or pre-and post test results with a comparison or control group (Bouey, 2011) (OGAC, 2005b).

Study priorities for TEs were mainly country-driven with most proposals submitted through COPs; these proposals were reviewed and selected by a Targeted Evaluation sub-committee, which included representatives from USG agencies involved in PEPFAR. Additionally, this subcommittee, in coordination with a Scientific Steering Committee and implementing agencies, developed the priorities for centrally-funded studies, developed proposal selection criteria and oversaw selected studies (OGAC, 2005b). There was little control from headquarters level (OGAC) over TEs (Bouey, 2011; OGAC, 2011d). Studies were funded either through central funds or country-level budgets (OGAC, 2005).

TEs that were funded in 2005 and 2006 aimed to address questions around the efficacy of programs in the areas of prevention, care, treatment and service delivery approaches for HIV/AIDS (OGAC, 2006b). Specifically, these studies assessed the following areas: abstinence/ be faithful, condoms and other prevention, prevention, PMTCT, treatment (ARV drugs and services), palliative care (for basic health care and support and for TB/HIV), orphans and vulnerable children, counseling and testing, and strategic information. Countries that received funding for targeted evaluations in 2005 and 2006 included Guyana, Haiti, Kenya, Mozambique, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia. A few multi-country studies were also funded (IOM, 2011).

In 2007, the scope of the targeted evaluations expanded from studies focused on questions about individual program implementation to include studies designed to answer questions around efficacy and best practices with the goal of producing generalizable results to contribute to program sustainability. Randomized trials were still not allowed (Bouey, 2011). In this round, TEs were no longer centrally funded, evaluation priorities were driven by TWGs at the country level and proposals were submitted and funded solely through the COP and country budgets. According to one interviewee, TWGs and implementing partners developed the research agendas based on gaps they saw in the field (NCV-3-USG). Proposals were still reviewed and selected by the targeted evaluation sub-committee who also continued to oversee selected evaluations, with continued minimal oversight from central headquarters (Bouey, 2011; OGAC, 2011d). One headquarters interviewee highlighted the importance of the introduction of TEs within PEPFAR as they provided a mechanism to look at program effectiveness which the program monitoring indicators did not address (NCV-3-USG). Although TEs were an important step in establishing evaluation and research in PEPFAR, the interviewee also noted challenges including varying quality across evaluations and internal bickering over evaluation priorities and control of funding (NCV-3-USG).

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Public Health Evaluations—Phase I and II

In 2006, the concept of Public Health Evaluations (PHEs) was introduced as a new approach to evaluation and research within PEPFAR. One OGAC interviewee described the introduction as being, in part, a response to the varying quality of TEs (NCV-3-USG). In the words of another headquarters interviewee, the PHEs *"would allow OGAC to have more control over what was happening and the quality of the work"* (NCV-7USG).The 'Blueprint for Public Health Evaluations in PEPFAR' document described PHEs as a broader concept than TEs, with an expanded range of allowable methodologies, and a new management structure (OGAC, 2006a). Whereas the purpose of TEs was to answer questions about program implementation and efficacy to identify models and best practices for potential scale-up, PHEs broadened this scope, recognizing a need for increased studies and methodologies to answer critical questions over time and allowing investigators to assess the impact of programs on populations (OGAC, 2006a). Study design methodology was expanded to allow rigorous, scientifically sound research methodology using experimental or quasi-experimental designs including, but not limited to randomization, modeling, advanced statistical techniques, and comparison groups (Bouey, 2011; OGAC, 2011d) (OGAC, 2007d).

With the introduction of the first phase of Public Health Evaluations (PHEs I) in 2008, the focus of PEPFAR evaluations shifted from individuals to populations and the goals evolved to implement studies to guide PEPFAR, inform policy, assess impact, and contribute knowledge to the global HIV/AIDS community (OGAC, 2010b). Some PHE I goals remained similar to the TE's specifically, answering questions related to program effectiveness and quality, identifying models and best practices, and some goals were new including determining program outcome and impact (Bouey, 2011) (OGAC, 2007d). PHEs I also focused on encouraging local partner involvement to build capacity. Funding for PHEs was initially provided through both central and country budgets, but eventually PHEs were no longer funded through country budgets and only funded centrally with awards based on merit in a competitive funding process (OGAC, 2008a) (OGAC, 2007d) (NCV-7-USG).

In addition to an expanded scope and methodologies, a new oversight mechanism was introduced for PHEs. The TE subcommittee evolved into the PHE subcommittee, an interagency technical policy group with representatives from HHS, USAID, the Census Bureau, DOD, and the Peace Corps. The PHE subcommittee had increased responsibility and an ability to convene multi-agency PHE evaluation teams (OGAC, 2006a). Study priorities were generated and driven by the central level, country mission teams, TWGs, and other members of the PEPFAR community (OGAC, 2006a). Proposals were sent once per year to the PHE subcommittee, who would review concepts and recommend funding levels to the Scientific Steering Committee (OGAC, 2008a). The Scientific Steering Committee would then make recommendations to the Global AIDS coordinator who made final funding decisions. Topics prioritized for PHEs were prevention, treatment, care and cross-cutting issues such as gender, and orphans and vulnerable children. (IOM, 2007) Multi-country evaluations were eligible for funding as well (OGAC, 2007d).

In 2009, a second phase of Public Health Evaluations (PHEs II) was introduced which further expanded the scope of PEPFAR evaluations; the goals of PHEs II were to answer questions of global significance, assess program impact and effectiveness, perform comparative evaluations of interventions and programs, and encourage in-depth studies beyond routine program evaluation. The main focus was on bridging research and practice with a call for concepts that examined the real world effectiveness of interventions with proven efficacy, cost

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effectiveness of delivering these programs at scale, as well as optimizing efficiency (OGAC, 2010b). Beyond questions of global significance, there was still an emphasis on allocating funding to country-specific questions to respond to host country or local implementation needs and provide partner country capacity building opportunities (OGAC, 2008a, 2009c). The study methodologies from PHEs I to PHEs II did not change (Bouey, 2011; OGAC, 2010b, 2011d), and funding continued to come centrally with PHE awards granted based on a competetive proposal, review, and selection process (OGAC, 2008a). PHE concepts and priorities were country-driven through proposals submitted annually by PEPFAR USG country teams, which were reviewed and selected by the Scientific Steering Committee, PHE Subcommittee and PHE Evaluation Teams. This submission, review, and approval process occurred separately from the COP submission and review process (Bouey, 2011; OGAC, 2009c, 2011d). The FY 2010 PHE guidance and call for concepts emphasized priority for PHE proposals with the following elements: country driven concepts answering questions of importance to the partner country, participation of local partner country institutions and investigators, and partner country reasearch capacity building elements (OGAC, 2010b).

In 2012, GAO completed a mixed-methods study that examined PEPFAR's evaluation activities, which included a review of PEPFAR PHEs. As part of this study, the GAO requested and received from OGAC a list of 18 PHEs that had been completed as of November 2011. Additionally, OGAC indicated that there were 82 other PHEs initiated and ongoing as of November 2011 (GAO, 2012). According to the GAO, the 18 completed PHE studies covered the content areas of prevention of mother-to-child transmission (PMTCT), counseling and testing, care and support (adult and pediatric), adult treatment, and prevention of sexual transmission (GAO, 2012). In December 2012, the IOM committee made a similar request to OGAC for a comprehensive list of all PHEs awarded from 2008 to 2010 (Phase I and II). As described further in the following sections, OGAC was unable to provide the committee with a list of all PHEs awarded and completed, but did provide a list of PHEs that were currently ongoing as of December 2011. These 83 continuing PHE studies addressed the content areas of PMTCT, prevention, care, and treatment (including resistance monitoring), counseling and testing, orphans and vulnerable children, service delivery, and health system strengthening. Of these continuing PHEs, six were multi-country studies (7 percent) and the remaining 77 (93 percent) were single country studies. According to the information provided by OGAC, PHEs were being conducted in 17 countries. Figure 11-3 displays the number of ongoing PEPFAR PHE studies in each of these countries (OGAC, 2011b, 2011c).

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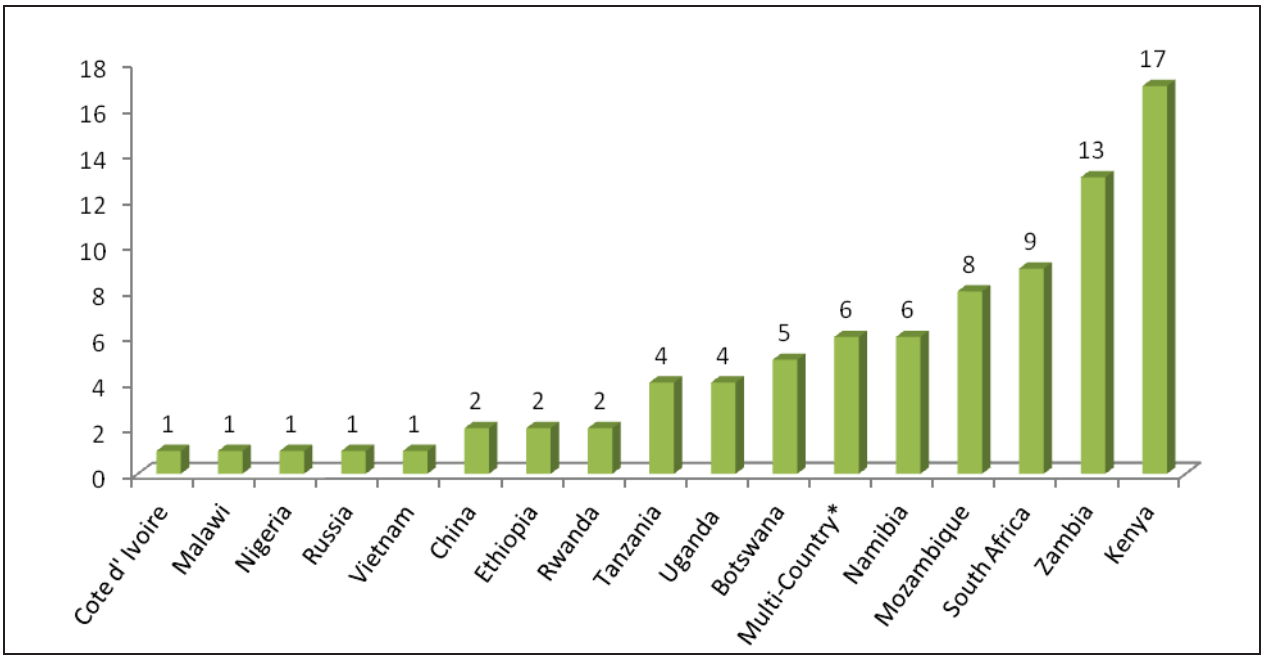

FIGURE 11-3 Ongoing PEPFAR PHE studies, by country, December 2011.
NOTE: This figure represents the breakdown of research activities as of December 15, 2011. Figure compiled from a list of continuing PHEs for FY 2012 received from OGAC.
*Multi-Country Study Countries: Cote d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Tanzania, Thailand, Uganda, and Vietnam.
SOURCE: (OGAC, 2011b, 2011c).

Additionally, the information OGAC provided listed the implementing partners for 73 of the 83 PHEs. The majority of these PHEs (n=65) were being implemented solely by one partner organization, eight PHEs, however, were being implemented in partnership between two or more implementing partner organizations. This joint implementation usually involved a US-based organization partnering with one or more organizations based in PEPFAR partner countries. Overall, there were 41 unique organizations involved in implementing the 73 continuing PHEs. These organizations were based in the United States, PEPFAR partner countries and other non-PEPFAR countries (see Figure 11-4) and represented academia, government, NGOs, private sector, and research organizations.

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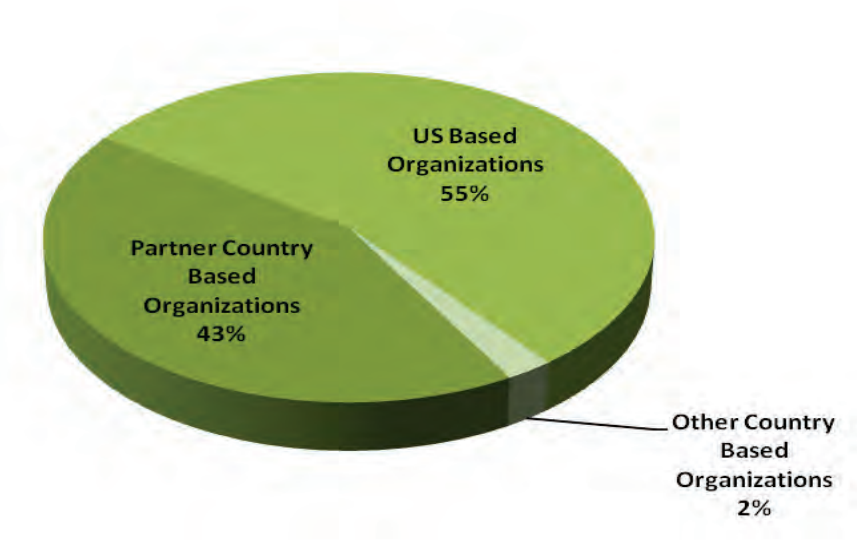

FIGURE 11-4 Organizations implementing ongoing PEPFAR PHE studies, by country of origin , December 2011. NOTE: Figure compiled from List of Continuing PHEs for FY 2012 received from OGAC. Figure represents the percentage by country of origin for the 41 unique organizations involved in implementing the 73 continuing PHE. SOURCE: (OGAC, 2011c).

Although only a snapshot of ongoing PHEs at a particular time, the list provided by OGAC illustrates that PEPFARimplemented PHEs covering an array of content areas in a multitude of countries, and that these PHEs were implemented by organizations based both in the United States and partner countries with a handful implemented in partnership between U.S. and partner country organizations.

Results of TEs and PHEs

OGAC was not able to provide the committee with an up-to-date list of completed TEs and PHEs, and it is difficult to identify independently which TEs and PHEs have resulted in published reports or journal publications. In a response to a separate request for PEPFAR-supported publications described later in this chapter, USAID and CDC did provide publications lists in which almost 400 journal publications were specified as resulting from PEPFAR-supported TEs, PHEs, impact evaluations, or operations research. These publications ranged in their purposes including assessing: feasibility, effects, effectiveness, cost effectiveness, and impact of interventions. Additionally the publications covered a wide range of technical areas including care and support (adult and pediatric), counseling and testing, prevention (PMTCT, biomedical prevention, prevention of sexual transmission, harm reduction, prevention with positives, and prevention in populations at elevated risk), health systems strengthening (commodities and technologies, financing, integration, workforce, and service delivery), orphans and vulnerable children, gender, treatment (adult and pediatric, resistance, adherence, and retention), vulnerable populations, stigma, and strategic information. A few interviewees also noted that analysis and findings from PHE studies were disseminated, published (NCV-5-USACA, 166-20-USG), and used for programmatic changes (NCV-6-USNGO), however interviewees also noted that due to the lengthy PHE application, review, and procurement processes study findings often became obsolete by the time the PHE was completed (461-3-USG; 461-14-USG; NCV-31-USG).

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Although this provides some sense of the scope of these efforts, this information is not comprehensive for all TEs and PHEs. Without a more complete understanding of the outputs of the TE and PHE efforts supported by PEPFAR, it was not possible for the committee to draw any conclusions about the extent to which findings from these evaluations have been used and have affected PEPFAR-supported programs.

Other PEPFAR-Supported Evaluation and Research Activities

In addition to providing formal support for evaluation and research across a range of technical areas through TEs and PHEs, PEPFAR has provided support for a wide array of additional evaluation activities employed at the macro level, the headquarters level, implementing agency level, and the country level. At the macro level the GAO, OIGs, and Congressional Budget Office perform periodic audits and evaluations of portions of the PEPFAR program. Additionally, the IOM was tasked with performing an independent evaluation of PEPFAR I, as well as the evaluation presented in this report (Simonds, Carrino, & Moloney-Kitts, 2012). At the headquarters level, in 2009, the interagency TWGs were tasked with developing and submitting State of the Program Area (SOPA) documents to OGAC. The SOPAs, completed by TWGs across program areas, were used to review the current status of the program area as well as identify promising practices, lessons learned, challenges, emerging issues, and future directions of the TWGs (IOM and NRC, 2010; Reyes, 2009). At the implementing agency level, CDC and USAID manage and implement periodic evaluations of programs and interventions covering a wide variety of technical areas including prevention, treatment, orphans and vulnerable children, strategic information, and health system strengthening (GAO, 2012). Finally, at the country level, PEPFAR mission teams and implementing partners not only participate in the routine data collection and reporting described previously in this chapter, but also carry out basic program evaluations (BPE). BPEs, similarly to PHEs, are used to guide PEPFAR programming and policies but they are focused specifically on local program implementation and the direct effects of programs on the population receiving program resources (OGAC, 2010b, 2011e). These studies were described as methodologically simpler than PHEs with results that are not generalizable beyond individuals enrolled in the program (OGAC, 2010b). Unlike PHEs, funding for BPEs comes through country budgets in the COPs and the studies are managed through country and regional teams (OGAC, 2010b, 2011e).

According to the GAO study, OGAC generally defers to implementing agency evaluation policies as guidance and also defers to implementing agencies or country and regional teams to plan evaluations of headquarters managed and country level activities, respectively. The State Department, CDC, and USAID all have established evaluation policies or frameworks that are applicable to PEPFAR programs (GAO, 2012). The CDC issued an evaluation framework for all CDC programs in 1999, which “summarizes essential elements of program evaluation, clarifies program evaluation steps, and reviews standards for effective program evaluation” (GAO, 2012, p. 18). In 2011 USAID published an evaluation policy to replace previously issued guidance and help improve the number and quality of USAID program evaluations. The policy provides a definition of evaluation and clear guidance on the purpose of evaluation, what should be evaluated, approaches for conducting evaluation as well as disseminating and using results (GAO, 2012; Office of Learning, 2012). Finally, the State Department issued an evaluation policy in 2012, applicable to OGAC and other State bureaus, which provides a framework for implementing program and project evaluations (GAO, 2012). Although the recent 2012 PEPFAR operational plan guidance provided some direction on evaluation, defining various types of evaluation and research (GAO, 2012), OGAC has not issued its own overarching evaluation

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framework or evaluation plan to guide evaluation activities occurring at the headquarters and country level.

Beyond the evaluation activities described above, PEPFAR also supports other activities in PEPFAR partner countries linked to generation of evidence, including support for surveillance and surveys, strengthening monitoring systems at the country level, and building partner country research capacity. As described previously in this chapter, PEPFAR has supported HIV surveillance in partner countries, local surveys and baseline studies, and modeling to assess the scope of the epidemic. As described in Chapter 9, PEPFAR supports the development and strengthening of monitoring systems including national health management information systems, HIV M&E systems, and facility and community-based monitoring systems (GAO, 2012). Finally, PEPFAR provides support to build partner country research capacity; several interviewees described how PEPFAR mission teams and implementing partners provide in-country research support to local institutions and government agencies conducting research (934-44-PCACA; 166-1-USG; 396-55-USG; 166-5-USG).

PEPFAR Evaluation and Research in PEPFAR I and II: Successes and Challenges

As described in the previous section, over time PEPFAR has supported an immense number of research and evaluation activities through a variety of mechanisms across a wide range of technical areas. Results and outcomes of PEPFAR-supported research and evaluation activities (research results, evaluation outcomes, PEPFAR program data, surveys, and publications) have been used to inform and improve PEPFAR programs and strategic planning (196-28-USG; 116-1-USG; 116-12-PCNGO; 166-7-PCGOV; 240-9-USG; 272-25-USG; 331-22-PCNGO; 331-14-USG; 331-43-USG; 396-12-USG; 396-1920-USG), to influence country-level policies and national planning (116-23-USPS; 272-22-USG; 272-25-USG; 272-27-USG; 396-1920-USG; 396-53-USNGO), and to contribute evidence to the knowledge base on improving HIV/AIDS interventions and program implementation (272-24-USG; 272-25-USG; 272-36-USG; 461-4-USG; 461-8-PCGOV; NCV-10-USG). Interviewees noted, for example, how PEPFAR support for surveillance, surveys, evaluation, and operational research provided data and results that have been used by partner country governments to influence national policies on male circumcision, microbicides, effective PMTCT, and dual therapy (272-22-USG; 272-25-USG; 272-27-USG). One interviewee described the studies that implementing partners do and the influence that PEPFAR has on policies, guidelines, and standards as *"tremendous"* and having a *"major impact"* (272-22-USG).

Interviewees also described how knowledge created and disseminated through PEPFAR has contributed to the global knowledge base on effective HIV/AIDS interventions and implementation. Interviewees pointed out PEPFAR studies that produced evidence showing nurses could effectively deliver treatment (272-36-USG), influenced PMTCT regimens (272-24-USG; 461-8-PCGOV), provided an opportunity to gather evidence on prevention and treatment in discordant couples (461-4-USG), provided evidence on microbicides (NCV-10-USG), and produced evidence used to change implementing partners perceptions on gender (272-25-USG). As described later in this chapter, PEPFAR implementing agencies and partners have created a vast amount of knowledge that has been disseminated internal and external to PEPFAR. Publications, books, conference abstracts, technical guidelines, and training materials have been produced and disseminated as a result of PEPFAR support.

Despite these successes, headquarters and country-level interviewees identified several barriers and limitations related to PEPFAR-supported research and evaluation activities, including barriers to conducting research activities, research gaps, and challenges in monitoring and tracking PEPFAR-supported evaluation and research activities.

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Interviewees identified PEPFAR restrictions as barriers to conducting research activities. Specifically, they noted legislative restrictions on the types of research that could be conducted in PEPFAR (NCV-4-USACA; 272-12-USNGO) as well as cumbersome and lengthy research review and approval processes (NCV-2-USG; NCV-5-USACA; NCV-8-USACA; NCV-31-USG; 461-1-USG; 461-3-USG; 461-14-USG; 396-6-PCGOV; 116-12-PCNGO; 396-5-USNGO; 240-8-USG; 196-1-USG; 461-16-USG; 272-25-USG) as barriers that discouraged researchers from engaging in PEPFAR-supported research. One implementing partner described research activities they considered implementing but ultimately did not because they might have been considered research activities that were restricted. These included collecting data on HIV drug resistance, performance-based financing (comparing the performance of costly sites to less costly sites), and systematically using data to improve clinical care and outcomes (NCV-4-USACA).

A multitude of interviewees across countries described the PEPFAR evaluation and research application processes as cumbersome, lengthy, complex, and difficult which deterred many from participating (NCV-2-USG; NCV-5-USACA; NCV-8-USACA; NCV-31-USG; 461-1-USG; 461-3-USG; 461-14-USG; 396-6-PCGOV; 116-12-PCNGO; 396-5-USNGO; 240-8-USG; 196-1-USG; 461-16-USG; 272-25-USG). Several interviewees described spending a lot of time working on PEPFAR research proposals that never went anywhere or became obsolete by the time they were approved (NCV-8-USACA; 461-3-USG; 461-14-USG). In the words of one interviewee: *"There is so much pressure to do PHEs, but they are the biggest waste of time in PEPFAR. [I] don't ever want to be involved in a PHE again"* (461-3-USG). Additionally, one headquarters interviewee described the PHE central review process as *"very long"* and not conducive to applying outcomes to programs on the ground that may change quickly, *"If it takes three years to get a study off the ground, it really, you know, it's really not optimal […], because it's a bit too late in the day by the time you get your results"* (NCV-31-USG).

Although PEPFAR has supported some form of evaluation from the beginning of the program and the allowable research and evaluation activities have continued to expand, research gaps remain and were identified by interviewees across countries. These gaps included a need for more program evaluation at the country level (331-5-ML; 272-6-ML; 166-23-USG; 240-15-USG; 272-32-PCNGO); local evidence generation (240-15-USG); costing studies (NCV-2-USG); studies to identify effective, efficient, and affordable service delivery models (396-18-USG; 396-39-USG; 396-45-USNGO; 396-59-USG); evaluation of integration models of HIV services (240-24-USG); more data around populations at elevated risk and drivers of the epidemic (331-7-PCNGO; 331-14-USG; 166-5-USG; 636-9-USACA; 240-9-USG); and more technical area-specific research such as in the areas of prevention and treatment.

Beyond the barriers to conducting research and the research gaps, there is a challenge in tracking and monitoring the PEPFAR-supported evaluation and research activities that are being carried out. OGAC does not have a centralized system that tracks PEPFAR-supported evaluation and research activities over time. In order to assess the evolution of PEPFAR-supported evaluation and research activities over time, the committee requested from OGAC a comprehensive list or series of lists that document all PEPFAR-supported research activities from the inception of PEPFAR including all approved TEs, PHEs (I and II), and Implementation Science studies (completed, closed/terminated, and ongoing). OGAC could not provide the committee with a comprehensive list over time, and instead they provided a couple lists of currently ongoing PHEs from 2011 and newly awarded NIH Implementation Science grants from FY 2010. These lists included only ongoing studies and excluded studies that were completed, closed, or terminated between 2005 and 2010. One headquarters interviewee stated that *"OGAC never successfully managed to track the work that was being accomplished [research and evaluation—TEs PHEs, and IS]"* (NCV-7-USGOV). OGAC did inform the committee that they are currently constructing a tracking system for PEPFAR evaluations (NCV-31-USG) (OGAC, 2011b).

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Overall, interviewees described the manner in which PEPFAR previously handled support for research activities as resulting in missed opportunities to evaluate PEPFAR, to learn from and improve programs, and to assess impact from the beginning which interviewees linked to sustainability (NCV-4-USACA; NCV-8-USACA). As noted by one interviewee, there was

> *'A need for operational research from the beginning of PEPFAR but it was not approved in PEPFAR I. PEPFAR operated under the approach of "ready, fire, aim," not "aim, fire, re-aim, re-fire" […] this was the wrong approach but was pushed by leadership in the beginning.'* (NCV-4-USACA)

Commenting on PEPFAR's research restrictions, another interviewee said: *"it's a funny thing to run such a huge, large-scale program about a clinical condition and say, "No research, absolutely zero research." You can't be learning anything about what you're doing"* (NCV-8-USACA). This limited PEPFAR's ability to perform implementation and operations research that could have further contributed to the evidence base on effective HIV/AIDS interventions and implementation (NCV-5-USACA; 396-55-USG; 240-24-USG; 240-8-USG; 587-12-USG; 587-6-CCM; 272-27-USG). It also contributed to a missed opportunity to collaborate with local institutions and build in-country research capacity which interviewees also linked to sustainability (NCV-4-USACA; NCV-8-USACA; 196-1-USG; NCV-9-USG; 331-6-CCM). As one commented, *"you can have the money but if you don't have the capability in your country to do research, to answer your own problems locally, you're constantly going to be dependent on folks having to fly in and do all this […] work for you"* (NCV-9-USG).

The overall sense that PEPFAR's initial lack of support for research activities was a missed opportunity was exemplified by the reflections of one interviewee:

> *"It was very disappointing to us that we weren't able to […] keep the research perspective as we developed programs […] you could learn a lot from it if you set the systems up correctly and have a nice base for not only collaborators like ourselves, but also our partners in-country to be able to utilize electronic databases and do retrospective clinical analyses or something[…] We were discouraged from PEPFAR from the outset [from doing research] they didn't want us to have informed consents […] and would do audits to make sure we weren't doing research […] now PEPFAR is putting a lot of money into implementation science research but it's a little late […]"* (NCV-8-USACA)

Conclusion: Despite recent efforts to strengthen research and evaluation activities, the manner in which PEPFAR initially approached research activities was a missed opportunity to establish, from its inception, robust mechanisms to evaluate its programs, assess impact, contribute to the global knowledge base, and develop in-country research capacity.

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Summary

Although OGAC officially supported some form of research and evaluation in PEPFAR since 2005 (through TEs and PHEs), completed studies were few in number, incongruent in the range of questions, and not integrated within a comprehensive framework that articulated the purpose and goals of evaluation and research within PEPFAR (Padian et al., 2011). Additionally, throughout TEs and PHEs research and evaluation remained comingled concepts. There was no overarching strategy that clearly articulated the distinctions between the research aims and evaluation aims within PEPFAR and how research and evaluation activities would work together to address these aims.

The Way Forward: Implementation Science

To address the challenges described in the preceding sections, OGAC in 2010 introduced and began to adopt what they have termed an Implementation Science (IS) approach for PEPFAR-supported research and evaluation; this represented an expansion of the traditional country-driven PHEs to research-driven studies implemented by the larger research community (C. Holmes, 2012). The umbrella of IS "[…] runs the gamut from routine monitoring and evaluation through operational research and impact evaluations with more rigorous scientific designs to randomized controlled trials" (OGAC, 2011b, p. 1). The IS framework, which was introduced in a journal editorial, was described as a single framework for the collection and use of information across PEPFAR. The three main components of the IS framework are monitoring and evaluation, operational research, and impact evaluations. IS focuses on improving program delivery; answering questions on the efficiency, effectiveness, and impact of programs; identifying and adopting successful delivery models; answering questions PEPFAR is uniquely poised to investigate; and making evidence-informed decisions for PEPFAR activities and programs (C. Holmes, 2012; Padian et al., 2011). Additional goals include aligning with partner country national research priorities and building research capacity among individuals and institutions at the country level (Padian et al., 2011).

Similar to PHE II, IS studies are centrally funded, but IS introduced a new mechanism for concept submission, review, and approval. Applications are submitted in response to request for applications (RFAs) for research and evaluation issued through three USG agencies—NIH, CDC, and USAID; concepts are reviewed and selected, funding is awarded, and studies are managed separately through these implementing agencies (OGAC, 2011e). This new approach was intended to minimize OGACs role in awarding and managing the process and help address the challenges of the lengthy approval and review process from the PHEs (NCV-7-USG; NCV-31-USG).

Specific eligibility criteria varies by implementing agency, but RFAs from each agency are open to U.S. and non-U.S.-based nongovernmental organizations, nonprofit organizations, and for-profit organizations (willing to forego profit) including academic institutions, community based organizations, foundations, faith-based organizations, and host country organizations. Unlike PHEs, USG agencies and PEPFAR mission teams are not eligible to apply for the RFAs, as USG agencies do not apply for funds from other USG agencies (HHS, 2012; NIH, 2011; OGAC, 2012a; USAID, 2011a), which, according to one headquarters interviewee, caused some *"backlash"* (NCV-7-USG). Applications also now are required to have an *"affiliation with a local partner"* to encourage collaboration and place emphasis on engaging with *"either a local government entity or a local university or a local NGO"* (NCV-31-USG).

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Study methods for IS remained similar to PHEs II methods allowing randomized experimental designs, quasi-experimental methods, or advanced mathematical techniques (e.g., simulation, mathematical optimization, and decision science) (Bouey, 2011; OGAC, 2011d, 2012d; Padian et al., 2011). Study concepts, however, are no longer country-driven; instead, PEPFAR evaluation and research priorities and direction are currently driven by the SAB (OGAC, 2012d, 2012f) which was formed to *"properly advise"* PEPFAR (NCV-11-USG) and open OGAC up to input from *"non-USG people"* (NCV-7-USG).

The SAB includes 51 members which represent the HIV/AIDS community, academia, international experts, partner country governments, multilateral and bilateral agencies, foundations, advocates, and nongovernmental organizations (Bouey, 2011; OGAC, 2011d, 2012f). Box 11-2 lists SAB members' institutions, grouped by institution type as well as the number of members that come from a particular institution in parenthisis (OGAC, 2012g). The role of the SAB is to inform the science that drives PEPFAR by providing guidance to OGAC on "scientific, implementation, and policy issues related to the global HIV/AIDS response" (OGAC, 2012f, p. 1). Specific roles include advising on both "broad scientific matters" as well as "emergency and short-notice scientific issues" relevant to PEPFAR, reviewing the quality of evidence being used to inform PEPFAR policies and guidance, reviewing research programs, and identifying evidence gaps and new opportunities (OGAC, 2011a, p. 2; 2012f). The SAB functions through semi-annual meetings as well as periodic conference calls. The board's inaugural meeting was held in Washington DC in January 2011; there have been two additional meetings since, the most recent in October 2012. Additionally, the SAB has formed three working groups, Combination Prevention Working Group, Most at Risk Populations Working Group, and Data Working Group; these groups are comprised of subsets of SAB members who hold conference calls on a more frequent basis to dialog around the particular topic area of the working group (OGAC, 2011a, 2012e, 2012f).

BOX 11-2
Institutional Affiliations of Scientific Advisory Board Members

Academia (members=19)

- Columbia University (1)
- Division of Infectious Diseases, University of California San Diego (1)
- Emory University (1)
- Family Health International (1)
- Harvard University (1)
- Imperial College, School of Public Health (2)
- Johns Hopkins Bloomberg School of Public Health (2)
- Johns Hopkins University School of Medicine, Infectious Disease Division (1)
- Makerere University School of Public Health (1)
- Perinatal HIV Research Unit, University of the Witwatersrand/Chris Hani Baragwanath Hospital (1)
- Rutgers, The State University of New Jersey (1)
- The London School of Hygiene and Tropical Medicine (1)
- UCLA Center for Community Health & Global Center for Children and Families (1)
- University of California, San Francisco (1)
- University of North Carolina at Chapel Hill (1)

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- University of Zimbabwe College of Health Sciences, Harare (1)
- Vanderbilt University Institute for Global Health (1)

U.S. Government (members=11)

- Department of Defense (1)
- National Institute of Health/National Cancer Institute (2)
- National Institute of Health/National Institute of Allergy and Infectious Diseases (2)
- National Institute of Health/NIH Clinical Center (1)
- Office of the U.S. Global AIDS Coordinator (2)
- Agency for International Development (1)
- Centers for Disease Control and Prevention (2)

Multilateral/Intergovernmental body (members =5)

- Global Fund (1)
- Joint United Nations Programme on HIV/AIDS (UNAIDS) (1)
- The World Bank (1)
- World Health Organization (2)

NGO (members=10)

- Center for Global Development (1)
- Desmond Tutu HIV Center (2)
- Education, Training, Research Associates (1)
- Elizabeth Glaser Pediatric AIDS Foundation (1)
- Mayo Clinic (1)
- ONE Campaign (1)
- Results for Development Institute (1)
- The Bill & Melinda Gates Foundation (2)

Philanthropy/Private Sector (members=2)

- Collaborative Fund for HIV Treatment Preparedness (1)
- Merck & Co., Inc. (1)

Research Organization (members=4)

- Baron Edmond de Rothschild Chemical Dependency Institute of Beth Israel Medical Center (1)
- Human Science Research Council (1)
- MRC Gender & Health Research Unit (1)
- South African Centre for Epidemiological Modeling and Analysis (1)

SOURCE: (OGAC, 2012g).

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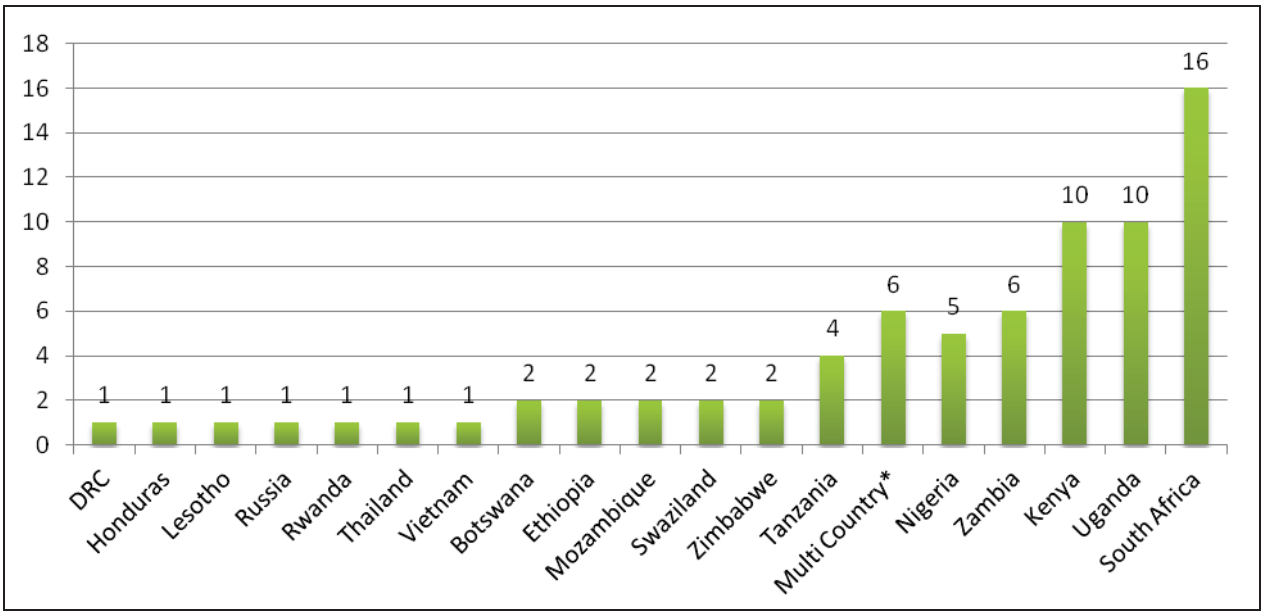

FIGURE 11-5 Implementation science awards, by country.
NOTE: Figure adapted from Scientific Advisory Board Presentation "Implementation Science Updates."
*Multi-Country includes Cote d'Ivoire; Haiti; India; Kenya (x4); Malawi; Mozambique; Peru; South Africa, Southern Africa (IDeA), Tanzania; Uganda (x3), Zambia.
SOURCE: (C. Holmes, 2012).

In 2010, in concert with the introduction of the IS concept, the first RFA for IS was issued by the NIH as 1-year funding supplements to investigators with current NIH funding. Funding was granted "for research and research training being conducted at PEPFAR funded sites" to inform PEPFAR on effective and efficient approaches to HIV prevention, care and treatment (NIH, 2010, p. 1) awards were made to 36 out of 141 applications submitted (Bouey, 2011). Following this, from 2011-2012, additional rounds of RFAs have been issued by the NIH, CDC, and USAID. As of October 2012, 74 IS awards had been made in total (including the initial 36 NIH supplement) and these studies address the content areas of PMTCT (n=23), VMMC (n=5), early treatment/treatment as prevention (n=3), improving care and treatment cascade performance (n=19), and building on an HIV platform to address multiple health outcomes and multi-sectoral approaches (n=24). Of these IS studies 6 are multi-country and the remaining 68 are single-country studies; overall, IS studies are being conducted in 23 countries (See Figure 11-5).

Overall, there were 41 unique organizations involved in implementing the 74 IS studies. These organizations were based in the United States, PEPFAR partner countries, and other non-PEPFAR countries (see Figure 11-6) and represented academia, NGOs, private sector firms, and research organizations. As the committee only received a snapshot of ongoing PHE studies in 2010, not a comprehensive list of awarded and completed TEs and PHEs over time, they were unable to review and assess changes over time in the distribution of study content area, study country, implementing partner organization type, and country between TEs, PHEs, and IS. These parameters would be useful for PEPFAR to track to assess progress towards the IS goal of better matching research activities to the research needs and unique research opportunities within PEPFAR as well as the aim of involving more local entities in the research.

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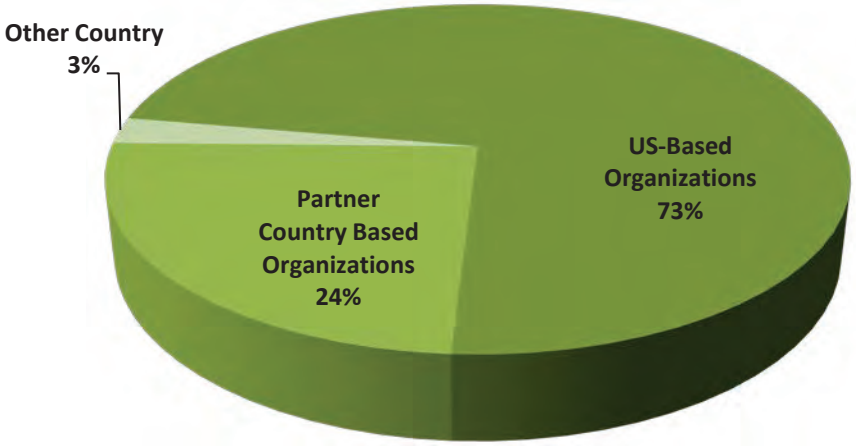

FIGURE 11-6 Organizations implementing PEPFAR IS studies, by country of origin, October 2012.
NOTE: Figure compiled from information in Scientific Advisory Board Presentation "Implementation Science Updates."
SOURCE: (C. Holmes, 2012).

Impact Evaluations

An additional component of the IS initiative, begun in 2012, is impact evaluations. These are studies that address questions of local priority that are conducted in coordination with in-country partners and local government (Goosby, 2012). As described by an interviewee, impact evaluations were created to address a gap that was created, with the introduction of the IS RFA process, for mission team-led and -managed research (NCV-7-USG). After the RFA structure was established,

> *"It was felt that there was still a bit of a gap because we did not really have a way for the [mission teams], where there were sort of burning questions and particular interest by the partner government, to be able to do a more larger-scale, more rigorous implementation science study. They didn't really have a mechanism to be able to initiate those. And that was the idea behind the impact evaluations. To be able to set up a process in which the countries would be able to mobilize those."* (NCV-31-USG)

Proposals for impact evaluations are submitted through the COPs from the mission teams and funding for the studies comes out of the individual mission team's budget (Goosby, 2012). These studies are intended to use the methodologies of randomized experimental or quasi-experimental design and produce results with causal attribution assessing what would have occured had the program not been implemented (Padian et al., 2011).

Impact evaluation proposals were accepted for the first time in 2011, as part of a pilot phase. According to one interviewee, five proposals came in and of these, three were reviewed, and eventually there was *"only one that really made it through the whole process* […]. *But it was*

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a pilot year" (NCV-31-USG). This interviewee went on to describe how the 2011 pilot was used to review lessons learned and develop mechanisms to overcome some of the barriers, and stated hope that more impact evaluations in 2012 would meet the criteria for funding (NCV-31-USG).

A major limitation of the current vision for impact evaluations is that evaluation studies using randomized controlled methods, while important for some purposes such as establishing efficacy of an intervention, are neither appropriate nor reasonable for evaluating most HIV interventions being implemented in real-world settings. Many of the criteria necessary for robust randomized controlled studies, such as random assignment of the intervention and control group and high-intensity implementation of the intervention over a long period of time with continued adherence to intervention or control group, are neither feasible nor suitable in the field (Thomas, Curtis, & Smith, 2011). The design of an evaluation needs to match the interventions being evaluated, purpose of the evaluation, desired findings, target audience for the findings, and what decisions will be made as a result of the findings. Habicht describes three types of evaluation designs: adequacy, plausibility, and probability. Adequacy evaluations assess a program or impact by comparing it with "previously established adequacy criteria;" these evaluations assess whether or not objectives were met and do not require a control group (Habicht, 1999, p. 11). The lack of control group, however, makes it difficult to conclude that outcomes/impacts are due to the program. Plausibility evaluations go a step further than adequacy evaluations, they utilize "opportunistic" or "non-randomized control groups" and before and after comparisons to "rule out" external factors that may have led to observed outcomes/impacts (Habicht, 1999, p. 13). Finally, probability evaluations go a step further, requiring randomized intervention and control groups to ensure that "there is only a small …probability" that observed differences between the program and controls are due to "confounding, bias, or chance" (Habicht, 1999, p. 14). Depending on the type of intervention and the stage of implementation, evaluation methodologies beyond randomization and probability need to be considered for PEPFAR's IS initiative, including impact evaluations.

Summary

PEPFAR's new IS approach has represented steps to make a distinction between research and evaluation through the RFAs and articulation of the impact evaluation concept. The most recent articulation of the IS is the publication in which it was originally described (Padian et al., 2011), and OGAC has not yet released guidelines or a plan of action for its IS agenda. The article does not clearly describe the separate but complementary roles of monitoring, evaluation, and research within PEPFAR—failing to clearly articulate each area's scope and aims, intended audience, and methods and activities—therefore it is the committee's assessment that the article does not serves as a sufficient framework for IS.

> **Conclusion:** Despite challenges, PEPFAR has made progress in carrying out evaluation and research activities over time. PEPFAR has moved from an early proscription against research, to using TEs and PHEs to work within research restrictions, to the recent creation of what holds promise as more useful processes for establishing priorities, managing activities, documenting "what works," expanding PEPFAR's technical leadership, disseminating research and evaluation findings, and continually improving the effectiveness and impact of PEPFAR However, even as the roles of research and evaluation within PEPFAR have expanded, defining appropriate and allowable activities remains a challenge —

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there has not been clarity about the separate but complementary activities and aims for evaluation and research within PEPFAR.

Although the committee was not charged with developing a comprehensive research agenda for PEPFAR, the committee did draw on the available information in the content areas of recent, ongoing, and planned evaluation and research efforts supported by PEPFAR to identify some of the major gaps that warrant more emphasis going forward. Reflecting not only on the information presented here but also on the more topic-specific assessments from prior chapters in this report, some of the major gaps include: research on behavioral and structural interventions, especially in the areas of prevention, gender, nonclinical and OVC care and support, and treatment retention and adherence; longitudinal outcome studies, especially for care and treatment and OVC programs; and research on health systems strengthening interventions across the WHO building blocks, that assess setting- and system-specific feasibility, effectiveness, quality of services, and costs for innovative models.

KNOWLEDGE TRANSFER AND LEARNING WITHIN PEPFAR

A key aspect of knowledge management is transferring insights, experiences, strategic information, best practices, and lessons learned within an organization. The efficient and timely transfer of knowledge is critical to successfully using the knowledge an organization has acquired and created to improve and change the way work is accomplished. Knowledge has the greatest impact when it is shared broadly (Garvin, 1993). For PEPFAR to capitalize on knowledge to improve the effectiveness of its programs it must be able to efficiently capture and transfer strategic information, research results, evaluation outcomes, experiences, best practices, and lessons learned within PEPFAR so that PEPFAR staff, implementers, and other stakeholders at all levels can use and apply this knowledge to improve activities and efforts in support of the HIV response.

Levels, Pathways, and Mechanisms of Knowledge Transfer within PEPFAR

PEPFAR is a large and complex entity comprised of multiple levels and stakeholders spanning many countries. PEPFAR functions through two main levels, the central headquarters level and the country level, and within these levels there are a multitude of stakeholders involved in coordination, oversight, and program implementation. Stakeholders at the headquarters level include the Office of the U.S. Global AIDS Coordinator (OGAC) — which serves as the administrative and formal organizational unit of PEPFAR, as well as several government implementing agencies utilized in the response for their core expertise: Department of Commerce (DOC), Department of Defense (DoD), Department of Health and Human Services (HHS) (including CDC, NIH, HRSA, FDA), Department of Labor (DOL), Department of State (DOS), Peace Corps (PC), and U.S. Agency for International Development (USAID). At the country level, stakeholders within PEPFAR include the U.S. interagency mission teams comprised of representatives from the implementing agencies who coordinate and oversee PEPFAR program activities at the country level as well as implementing partners (IP) which can include U.S.- and partner country-based: academia/universities, governmental organizations, nongovernmental organizations (NGOs), international NGOs, multilaterals, and private-sector organizations who implement PEPFAR programs.

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For knowledge to have the greatest impact possible within PEPFAR, multiple types of knowledge must be transferred efficiently within, between, and across PEPFAR levels and stakeholders. Due to size and complexity, there are many potential pathways for knowledge transfer within PEPFAR, depicted in Figure 11-7. Knowledge transfer could occur within each of the entities in PEPFAR, e.g., within OGAC, within a USG mission team in a country, or within a particular implementing partner; this is depicted by circular arrows in the figure. Additionally, as depicted by solid straight arrows, knowledge transfer could occur between levels or entities—between the headquarters level and the country level, e.g., between OGAC and the U.S. interagency mission teams at the country, or between entities in a particular level, e.g. between a U.S. Interagency mission team and implementing partners in a particular country, etc. Finally, knowledge transfer could occur across PEPFAR countries, e.g., across U.S. interagency mission teams in different countries or across implementing partners in different countries; the dotted arrows represent the points at which knowledge transfer could occur across countries. Given the size, span, and complexity of PEPFAR and the vast number of potential pathways of knowledge transfer, it can be difficult to determine which pathway and what scale of knowledge transfer is appropriate, efficient, and sufficient.

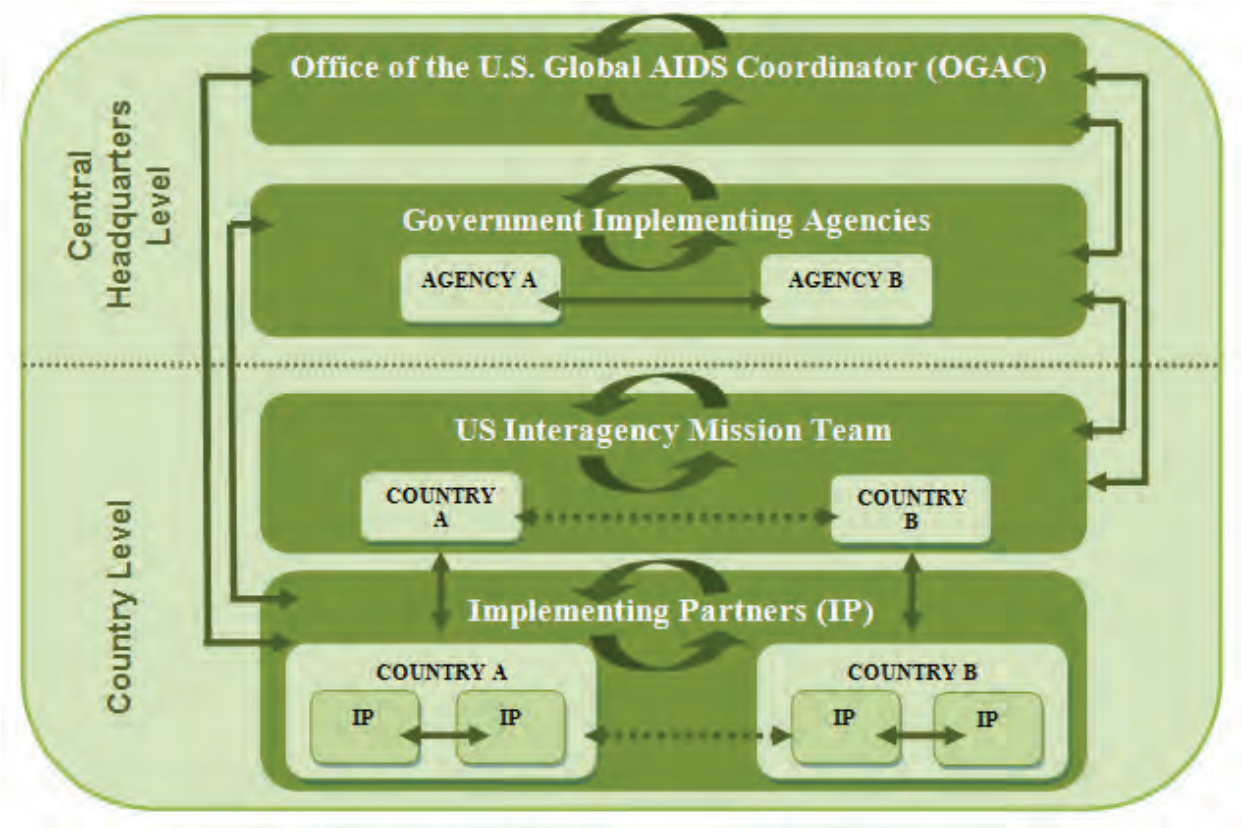

FIGURE 11-7 Potential pathways of knowledge transfer within PEPFAR.

PEPFAR stakeholders have established and utilized a multitude of ways to transfer a wide range of knowledge within, between, and across PEPFAR levels, entities, and countries. As described in depth previously in the chapter, PEPFAR has a system for routine reporting of program monitoring data. OGAC utilizes semiannual and annual reports and COPS to routinely gather not only programmatic data from country programs but also other information related to

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PEPFAR programs and activities, progress toward targets, and strategic direction and planning. The types of knowledge transferred in PEPFAR and mechanisms used to share knowledge, however, go well beyond reporting of program monitoring data and other routine reporting, as described in more detail below from the perspective of interviewees involved in PEPFAR implementation. The types of knowledge shared and the scale of sharing varies depending on the pathway of transfer.

BOX 11-3
Pathways of Knowledge Transfer in PEPFAR, Beyond Routine Reporting

Knowledge Transfer from Central Headquarters to All of PEPFAR

- From OGAC to: to all of PEPFAR (NCV-2-USG; NCV-3-USG; NCV-7-USG; NCV-10-US; NCV-17-USG)

Knowledge Transfer from Central Headquarters to the Country Level

- From OGAC to:
  - The country level (Stakeholders not specified) (934-43-U.S.G; NCV-7-U.S.G; NCV-10-U.S.G; NCV-17-U.S.G; NCV-18-U.S.G)
  - U.S. interagency mission teams at the country level via government implementing agencies at the HQ level (934-43-U.S.G; NCV-2-U.S.G)
  - Implementing partners at the country level (NCV-10-U.S.G)
- From OGAC headquarters technical working groups to:
  - The country level (Stakeholder not specified) (NCV-17-U.S.G; NCV-18-U.S.G)
  - U.S. interagency mission teams at the country level (934-43-U.S.G; NCV-11-U.S.G)

Knowledge Transfer from the Country Level to Central Headquarters

- From country level (stakeholder not specified) to OGAC headquarters technical working groups (NCV-18-U.S.G)
- From U.S. interagency mission teams at the country level to OGAC via government implementing agencies at the HQ level (NCV-2-U.S.G) or PEPFAR Country Coordinators (934-43-U.S.G)

Knowledge Transfer within the Country Level

- From U.S. interagency mission team to implementing partners in a country (116-1-U.S.G; 166-12-U.S.; 272-36-U.S.G; 396-19-U.S.G; 461-20-PCPS; NCV-11-U.S.G)
- Between implementing partners in a country (116-1-U.S.G; 240-14-U.S.PS; 272-36-U.S.G; 331-14-U.S.G; 396-19-U.S.G; 461-16-U.S.G; 461-20-PCPS; 636-1-U.S.G NCV-7-U.S.G)
- From implementing partners to U.S. interagency mission team in a country (396-5-U.S.NGO)
- Within a particular implementing partner in a country (396-5-U.S.NGO; 396-56-U.S.NGO; NCV-5-U.S.ACA; NCV-8-U.S.ACA)
- Within the U.S. interagency mission team in a country (166-12-U.S.G; 396-19-U.S.G; 396-57-U.S.G)

Knowledge Transfer Across Countries

- Across U.S. interagency mission teams in different countries (240-9-U.S.G; 272-36-U.S.G; 396-18-U.S.G; 396-19-U.S.; 934-43-U.S.G; NCV-9-U.S.G; NCV-17-U.S.G; NCV-18-U.S.G)
- Across implementing partners in different countries (116-1-U.S.G; 396-9-PCGOV; NCV-7-U.S.G; NCV-18-U.S.G)

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Pathways of Knowledge Transfer

Interviewees described various specific pathways through which the vast amount of knowledge in PEPFAR is transferred among different stakeholders, summarized in Box 11-3. The preponderance of interviewees described knowledge transfer from the headquarters level to the country level, at the country level, and across countries. There were fewer reports of knowledge transfer from the country level up to headquarters. At the headquarters level, however, interviewees did report bi-directional sharing of best practices (NCV-18-USG) and policies (NCV-2-USG) between the country level and headquarters, utilizing headquarters technical working groups (NCV-18-USG), individuals working within government implementing agencies (NCV-2-USG), or country coordinators (934-43-USG) as conduits of information from the field up to headquarters. As one interviewee noted:

> *"It's important for us who are assigned to different countries to meet about all the countries to discuss what's happening and to ensure that, […we] know what each other are learning and what's kind of rising to the top as a promising intervention that should be tested in other areas."* (NCV-18-USG)

Types of Knowledge Transferred by Different Pathways

The types of knowledge interviewees described as shared within PEPFAR, beyond routine program monitoring data, are summarized in Table 11-7 mapped to the multiple different stakeholder pathways through which these types of knowledge are transferred. Interviewees described how information, data and evidence, and policies and guidelines were transferred from the headquarters level to the country level as well as at the country level. The preponderance of interviewees described sharing of experiences as primarily occurring at the country level (240-9-USG; 240-14-USG; 331-14-USG, 396-9-PCG; 396-19-USG; NCV-5-USAC) and across countries (116-1-USG; 934-43-USG; NCV-5-USACA; NCV-9-USG; NCV-18-USG; NCV-17-USG). There were fewer reports of experiences being shared between the headquarters level and the country level. A few interviewees did, however, note times when experiences in the form of best practices (NCV-18-USG), and case studies (NCV-18-USG) were transferred from headquarters to the country level.

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TABLE 11-7 Types of Knowledge Transferred in PEPFAR, Beyond Routine Reporting

Type of Knowledge	HQ to Country Level	Country to HQ	At Country Level	Across Countries	Level not specified
Information (116-1-USG; 166-12- USG; 272-36- USG; 396-19-USG; 396-57-USG; 934-43-USG; NCV-2-USG; NCV-7-USG; NCV-8-USACA; NCV-17-USG; NCV-18-USG)	X		X	X	
Data and Evidence					
Data (NCV-10-USG; 116-1-USG; 636-1-USG; 461-16-USG; NCV-5-USACA NCV-8- USACA)	X		X		
Programmatic Indicator Data (other than routine reporting) (NCV-3-USG; NCV-7-USG; 396-19-USG; 396-5-USG; 166-12- USG; 461-20-USG; NCV-5-USACA)	X		X		
Program Results (461-20-USG)			X		
Evidence (NCV-10-USG; 934-43-USG; NCV-17-USG; NCV-18-USG)	X			X	
Research (NCV-18-USG)	X				
Policies and Guidelines					
Targets (NCV-2-USG; NCV-2-USG)	X				
Policies (NCV-2-USG; NCV-2-USG)	X	X			
Program Guidelines/Guidance (NCV-11-USG; NCV-10-USG; NCV-17-USG)	X		X		
Feedback (116-1-USG; 396-56-USG; 934-43-USG; NCV-5-USACA)		X	X		
Experiences					
Experiences (NCV-18-USG; NCV-9-USG; NCV-17-USG; 396-9-PCG)	X		X	X	
Best Practices (934-43-USG; 331-14-USG; NCV-18-USG; NCV-5-USACA)	X	X	X	X	
Country Case Studies (NCV-18-USG)	X				
Challenges (240-14-USG; 116-1-USG)			X	X	
Innovation (396-19-USG; NCV-5-USACA)			X		
Intervention targeting (240-9-USG)			X		
Lessons Learned (396-19-USG; NCV-18-USG; 396-18-USG; NCV-5-USACA)			X	X	X
Successes (240-14-USG)			X		
Successful Transition Models (396-18-USG)					X

Mechanisms of Knowledge Transfer

In general, organizations utilize a variety of mechanisms to spur the process of knowledge transfer ranging from reports, to presentations, to study tours, to personnel rotation programs and training. Reports and presentations are popular mediums for knowledge transfer as they can summarize a large amount of knowledge for wide distribution, and study tours are popular among large organizations wanting to transfer knowledge across a wide geographic

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reach (Garvin, 1993). Although reports, presentations, study tours, and other passive mechanisms may be useful in transferring information, data and evidence, and policies and guidelines, they can be "cumbersome" in transferring knowledge that is tacit, difficult to articulate, and/or resides in the experiences of personnel. The literature points to personnel rotation programs as a more effective method to transfer implicit knowledge as it is more easily absorbed through experience (Garvin, 1993).

Based on the qualitative interview data, within PEPFAR, both active and passive knowledge transfer mechanisms are used and the types of mechanisms described by interviewees fell into five main categories: intermediaries, meetings (both PEPFAR-supported and external), reports and published guidelines, online technology, study tours and staff rotation (see Table 11-8). Similar mechanisms of knowledge transfer were described across interviewees, however, the scale of use and particular mechanism used depended on the pathway of knowledge transfer.

TABLE 11-8 Mechanisms of Knowledge Transfer in PEPFAR

Mechanism of Knowledge Transfer	HQ to Country Level	Country to HQ	At Country Level	Across Countries
Intermediaries				
Country Coordinators 934-43-USG; 240-33-USG; 396-57-USG; 935-27-USG	X	X		X
Headquarters TWG 934-43-USG; NCV-11-USG; NCV-17-USG	X	X		
Technical Advisors NCV-2-USG; NCV-18-USG	X	X		
Implementing Agencies 934-43-USG; NCV-7-USG	X			
PEPFAR-Supported and External Meetings				
Conference Calls 934-43-USG; 935-27-USG; NCV-11-USG; NCV-17-USG; NCV-18-USG	X		X	X
Conferences 331-14-USG; 396-19-USG; NCV-7-USG; 587-25-ML; 166-25-USG; 272-16-PCNGO			X	X
Meetings 116-1-USG; 272-36-USG; 461-20-PCPS; NCV-5-USACA; NCV-17-USG; NCV-18-USG	X		X	X
Annual Coordinators Meeting 934-43-USG; 935-27-USG		X		X
Country-Level Partners Meeting 272-36-USG; 636-1-USG			X	
Multi-Country Meetings within an Implementing Partner NCV-5-USACA; NCV-8-USACA			X	X

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TABLE 11-8 Continued

Mechanism of Knowledge Transfer	HQ to Country Level	Country to HQ	At Country Level	Across Countries
Meetings (Continued)				
PEPFAR Annual HIV/AIDS Implementers' Meeting 116-1-USG; 272-36-USG; 935-27-USG; NCV-7-USG; NCV-17-USG	X		X	X
Technical Area Forums NCV-18-USG				X
Workshops 240-14-USPS; 461-16-USG; 461-20-PCPS			X	
Reports/Guidelines				
Presentations 396-5-USNGO			X	
Published Guidelines NCV-10-USG	X			
Responses to Data Requests 166-12-USG; 461-20-PCPS			X	
Routine Reports 396-19-USG; 461-20-PCPS			X	
Online Technology				
Databases 396-19-USG; NCV-5-USACA; NCV-8-USACA			X	
Listservs 396-57-USG			X	
PEPFAR Extranet Site NCV-2-USG; NCV-17-USG	X		X	
Routine Electronic Bulletins NCV-5-USACA; NCV-18-USG	X		X	
SharePoint Website 396-57-USG; NCV-7-USG	X		X	
Technical Area-Specific Websites NCV-10-USG; NCV-18-USG	X			
Webinar NCV-5-USACA; NCV-18-USG	X		X	
Staff Rotation/Study Tours				
Staff Rotation 396-18-USG; 396-23-USG; 935-27-USG; 935-28-USG; NCV-2-USG; NCV-9-USG; NCV-18-USG; NCV-31-USG		X		X
Study Tour 240-9-USG; 396-9-PCGOV; NCV-9-USG				X

Across PEPFAR, similar mechanisms are used to facilitate knowledge transfer, but their use varies depending on the pathway of transfer. OGAC headquarters shares knowledge with the field through intermediaries (934-43-USG; NCV-2-USG; NCV-11-USG; NCV-17-USG; NCV-18-USG), reports and published guidelines (NCV-10-USG), meetings (934-43-USG; NCV-17-USG), and multiple forms of online technology (NCV-2-USG; NCV-17-USG; 396-57-USG; NCV-7-USG). Similarly, at the country level, stakeholders use many of these same mechanisms to transfer knowledge including meetings (116-1-USG; 240-14-USPS; 272-16-PCNGO; 272-36-USG; 331-14-USG; 461-16-USG ; 461-20-PCPS; 636-1-USG; NCV-5-USACA; NCV-11-USG), reports (166-12-USG; 396-5-USNGO; 396-19-USG; 461-20-PCPS), and online technology (396-19-USG; 396-57-USG; NCV-5-USACA; NCV-8-USACA). To transfer knowledge across countries, however, informal staff exchange (396-18-USG; NCV-18-USG; 935-27-USG; 935-28-USG) and study tours (240-9-USG; 396-9-PCGOV; NCV-9-USG) were described as mechanisms of transfer in addition to intermediaries (934-43-USG; 935-27-USG; 240-33-USG; 396-57-USG; 934-43-USG) and various types of multi-country meetings (116-1-USG; 272-36-USG; 396-19-USG; 934-43-USG; NCV-5-USACA; NCV-7-USG; NCV-8-USACA; NCV-18-USG; 587-25-ML; 166-25-USG). Examples of the various mechanisms are described in more detail in the sections that follow.

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Intermediaries

Intermediaries were mainly described by interviewees as a tool specific to transferring knowledge bi-directionally between headquarters and the country level (see table 11.8). Many interviewees described how intermediaries in the form of TWGs (934-43-USG; NCV-11-USG; NCV-17-USG), technical advisors (NCV-2-USG; NCV-18-USG), government implementing agencies at headquarters (934-43-USG; NCV-7-USG), and country coordinators (932-43-USG) at the country level served as conduits of knowledge between headquarters and the countries. As one headquarters interviewee described, headquarters TWGs and advisors transfer knowledge to mission teams in-country that then in turn transfer knowledge to implementing partners:

> *"The technical working groups for PEPFAR are comprised of really experts in the field. And they* […] *spend probably 60 percent or more of their time traveling to countries. And the focus of their work is with our country teams* […] *like the prevention guidance, when it was rolled out, we did a series of phone calls, we did Q and A's, we did open lines, we then had people going out doing prevention portfolio reviews with our country teams. So that they could figure out how to realign and more to the guidance, how to stage their change over time* […] *But it's always headquarters, for the most part, is working with our country teams. Not with partners that do the actual implementation. But then our country teams will be having these kinds of meetings with the partners, and working with them. So that's basically how it moves out and how we use our technical folks."* (NCV-11-USG)

A country-level interviewee echoed this, noting that most knowledge comes through headquarters TWGs and government implementing agencies, rather than directly from OGAC, describing OGAC as doing a *"decent job"* of sharing knowledge (934-43-USG). Country coordinators can also serve as intermediaries to transfer knowledge between OGAC and the country teams (934-43-USG) as well as across countries (240-33-USG; 396-57-USG; 934-43-USG; 935-27-USG); these intermediaries were described by one interviewee as a *"clear channel of communication"* between OGAC and the country teams (934-43-USG). Another interviewee described communication between country coordinators as mechanisms to transfer knowledge across countries— sharing differences across programs as well as ideas of how to handle similar challenges (935-27-USG). The use of intermediaries was described by many interviewees as a main mechanism to transfer knowledge from headquarters to the country level. Intermediaries in turn use other mechanisms to transfer knowledge within the partner countries.

Meetings

Various meeting types were described by the preponderance of interviewees as tools to share knowledge through three pathways: (1) between headquarters and the country level, (2) at the country level, and (3) across countries (see Table 11-8). Specific meeting types included single and multi-country conference calls (934-43-USG; NCV-11-USG; NCV-17-USG; NCV-18-USG), attendance at conferences (331-14-USG; 396-19-USG; NCV-7-USG; 587-25-ML; 166-25-USG; 272-16-PCNGO), periodic country coordinator meetings (in person or by phone) (934-43-USG; 935-27-USG), country-level implementing partners meetings (272-36-USG; 636-1-USG), multi-country meetings of a particular implementing

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partner (NCV-5-USACA; NCV-8-USACA), PEPFAR's annual HIV/AIDS Implementers' Meeting (116-1-USG; 272-36-USG; 935-27-USG; NCV-7-USG; NCV-17-USG), technical area specific forums (NCV-18-USG) , and workshops (240-14-USPS; 461-16-USG; 461-20-PCPS).

PEPFAR's annual Implementers' Meeting is a forum for PEPFAR staff and implementing partners to exchange knowledge, discuss issues, transfer information, and share lessons learned and best practices (IOM and NRC, 2010). Six HIV/AIDS Implementers' Meetings were held between 2004 and 2009. The first meeting was held in South Africa with 100 attendees limited to USG personnel and focused on the management and structure of PEPFAR (IOM, 2007). Over time, the Implementers' Meetings included more attendees and expanded to include individuals and organizations involved in PEPFAR implementation, as well as other stakeholders involved in the global HIV/AIDS response. The meeting evolved to become a forum for networking and dialog among implementers and PEPFAR staff to share implementation lessons learned, best practices, information, and barriers experienced (OGAC, 2009a).The most recent meeting, "Optimizing the Response: Partnerships for Sustainability," was held in 2009 in Namibia with over 1,500 participants, 220 oral presentations and 125 poster presentations (OGAC, 2009a). One headquarters interviewee described these meetings as originally designed to allow PEPFAR implementing partners to share information with each other and multilaterals and how the role had expanded to providing an opportunity for south-to-south sharing with increased participant involvement and abstracts and presentations coming from country-specific programs and expanded attendance from international NGOs and local country researchers and implementers (NCV-7-USG).

Similar to PEPFAR's Implementers' Meetings, some interviewees described periodic country-level partners meetings, either in-person or by video, as means to transfer information, data, and best practices among partners at the country level (272-36-USG; 636-1-USG). Beyond these PEPFAR-wide or stakeholder-specific meetings, one headquarters TWG interviewee described the use of technical area-specific forums to transfer knowledge across countries on a particular topic:

> *"We have every couple of years a forum where we bring all the field people together, and we just had one in February that was you know spent four days just going over the latest evidence and discussing how they should be implementing this latest evidence and discussing what's working, what's not working. So that's been another excellent means of communicating."* (NCV-18-USG)

In addition to the formal PEPFAR Implementers' Meeting and country-level partners meetings, some PEPFAR HQ technical working groups have organized various technical exchanges and field-driven learning meetings that serve as mechanisms for internal knowledge transfer focused on specific topic areas. Summary reports of these workshops and meetings were made available online to potentially increase the knowledge transfer to a wider audience. The reports highlight these meetings as platforms for various sharing and exchange including experiences, programming, best practices, strategic planning, successes, opportunities, and challenges. Meeting representatives varied by topic but mainly included PEPFAR staff and partners. Illustrative examples of these meetings include:

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- "Strengthening Gender Exchange in PEPFAR: Technical Exchange of Best Practices, Program Models, and Resource" organized by the PEPFAR Gender Technical Working Group that was held in South Africa in 2009;
- "Field Driven Learning Meeting: Linkages to and Retention in HIV Care and Support Programs" organized by the PEPFAR HIV Care and Support Technical Working Group that was held in Mozambique in 2010; and
- "Meeting the HIV; Maternal, Newborn, and Child Health; and Social Support Needs of Mothers and their Young Children" a field-driven learning meeting organized by several working groups (Care and Support, Prevention of Mother to Child Transmission, Orphans and Vulnerable Children and Food and Nutrition) that was held in Ethiopia in 2011(Bergmann, 2011; Fullem, 2012; Spratt, 2011).

Finally, in addition to meetings organized by PEPFAR, interviewees pointed out that attendance at international and regional conferences or in-country workshops, and participation in national-level technical working groups, although not organized by PEPFAR, serve as informal opportunity for knowledge transfer among PEPFAR stakeholders (116-1-USG; 240-14-USPS; 396-19-USG; 461-16-USG; NCV-7-USG; 587-25-ML; 166-25-USG).

Reports and Published Guidelines

As the literature points out, reports and presentations are a popular tool used by organizations to widely transfer explicit knowledge to an array of stakeholders (Garvin, 1993). PEPFAR has established formal routine reporting systems including annual progress reports (APRs), semi-annual progress reports (SAPRs), and country operational plans (COPs), to transfer knowledge from the country level to headquarters. In addition to these formal reporting channels, interviewees identified presentations (396-5-USNGO), responses to data requests (166-12-USG; 461-20-PCPS), and country-level reporting (396-19-USG; 461-20-PCPS) as tools for knowledge transfer at the country level (see Table 11-8). Mission team interviewees described producing and disseminating country-level and site-level reports and data visualizations of program monitoring data (166-12-USG; 396-19-USG; 461-20-PCPS) and responding to ad hoc data requests (166-12-USG; 461-20-PCPS) as a means to share program monitoring data with implementing partners. Additionally, a headquarters interviewee identified guidelines published by headquarters (NCV-10-USG) as a tool for knowledge transfer between headquarters and the country level.

Online Technology

Advances in technology have produced new mechanisms of knowledge transfer in organizations—the internet, intranets, and other online technologies are extending the reach, accessibility, and diffusion of knowledge throughout organizations. PEPFAR stakeholders have embraced the use of online technology to transfer knowledge internally, utilizing intranet sites, electronic bulletins, websites, and webinars as tools of knowledge transfer (see Table 11-8).

In response to an expressed need at the 2005 Annual Implementer's Meeting for improved: "peer-to-peer communications" to share information and best practices in the field, OGAC established the PEPFAR Extranet site, PEPFAR.net (OGAC, 2007c). This secure website, open to USG personnel working on PEPFAR, was introduced in 2006 as a space for OGAC to share information with the field, including "News to the Field," presentations, policies and guidelines, and public affairs and public diplomacy resources. Additionally it was presented as a space for mission teams, technical working groups ,and PEPFAR staff to network collaborate, and share lessons learned, best practices, presentations, articles, guidelines, and resources (OGAC, 2007b).

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The committee did not have access to the PEPFAR Extranet site to review current content and use for knowledge transfer, but interviewees did note the use of the site as a *'a central node'* for knowledge transfer within PEPFAR, including headquarters TWGs using it to share guidance, scientific literature, reports, and tools with the field (NCV-2-USG; NCV-17-USG).There were mixed messages, however, on the effectiveness of the site as a tool for knowledge transfer, and it is currently being updated in the context of increasing knowledge management (NCV-2-USG). In addition to the extranet site, OGAC utilizes a "Weekly News to the Field" e-mail bulletin as a mode to transfer recent news, updates, and information (guidance, FAQs, best practices, policies, etc.) from headquarters to the field (OGAC, 2007c; Simonds et al., 2012)

In addition to PEPFAR's official online communication tools described above, HQ TWGs and implementing partners have used technology in innovative ways to facilitate knowledge transfer between headquarters and the country level as well as at the country level (see Table 11-8). Examples include developing and using country- and partner-specific databases to overcome the barrier of not having a centralized database at OGAC from which to store, manage, and share program data (396-19-USG; NCV-5-USACA; NCV-8-USACA); using listservs and SharePoint websites to share information among mission teams (396-57-USG; NCV-7-USG); supporting technical area-specific websites that give implementing partners access to evidence, research, and information on a particular topic (NCV-10-USG; NCV-18-US); and hosting online webinars (NCV-5-USACA; NCV-18-USG).

Staff Rotation & Study Tours

Although not formally instituted as a standard knowledge transfer mechanism throughout PEPFAR, some headquarters and country-level interviewees described the use of study tours and staff rotation as informal tools for transferring knowledge across countries as well as between the country level and headquarters (see Table 11-8) (240-9-USG; 396-9-PCGOV; 396-18-USG; 396-23-USG; 935-27-USG; 935-28-USG; NCV-2-USG; NCV-9-USG; NCV-18-USG; NCV-31-USG). In one partner country, for example, the prevention TWG wanted to learn about targeting activities to MSM, and did a study tour to another PEPFAR country to learn from their model (240-9-USG). Another partner country interviewee expressed their gratitude for being able to use PEPFAR funds for study tours:

> *"PEPFAR is very big donors for [us], especially for the national M&E system of our country. Thanks to PEPFAR funding we can […] organize different study tours to overseas to different countries in order to learn from their experience."* (396-9-PCGOV)

Staff rotation was also described as being used for knowledge transfer. Literature on knowledge transfer points to staff rotation programs as "one of the most powerful methods of transferring knowledge," especially knowledge that is tacit and difficult to learn through passive means (Garvin, 1993, p. 10). Interviewees described various forms of staff rotation occurring within PEPFAR, including staff moving between PEPFAR countries, staff moving from the country level to the headquarters level and vice versa, as well as staff working on detail between USG agencies, e.g., a staff member from CDC brought to work on detail at OGAC (396-18-USG; 396-23-USG; 935-27-USG; 935-28-USG; NCV-2-USG; NCV-9-USG; NCV-18-USG; NCV-31-USG). In one partner country, members of a TWG identified PEPFAR staff who had worked in other countries as an opportunity to garner lessons from experiences of other PEPFAR countries specifically, in this case, on transitioning from service delivery to technical assistance. The interviewee noted that although this was not a *"formalized exchange,"* it was used as an opportunity to transfer

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knowledge (396-18-USG). Additionally, a HQ TWG interviewee described successful integration of staff rotation in the TWG as a mode of knowledge transfer across countries. In the words of the interviewee:

> *"So in other words our South Africa* […] *technical lead has spent time in Nigeria working on their program and our Namibia person is about to go to Zambia and spend some time there because we're not the only experts obviously. There's a lot of different very valuable expertise out there and we think it's really great that people have the opportunity to do that."* (NCV-18-USG)

Finally, headquarters interviewees shared that their previous experiences working for PEPFAR at the country level provided them with insight, unique perspective, and ideas that contributed to their current positions at the headquarters level (NCV-9-USG; NCV-18-USG; NCV-31-USG). Similar sentiments were shared by an interviewee working at the country level after previously working at the headquarters level (935-27-USG; 935-28-USG).

Study tours and staff rotation were described as successful tools to transfer experiences, implementation models, lessons, and expertise across PEPFAR; but these methods of knowledge transfer are used on a small scale and not systematically. Staff rotation, if scaled up, used intentionally and strategically, and formally adopted as a standard mechanism in PEPFAR, could provide a useful tool to effectively transfer successful country/partner models of sustainability, country ownership, and technical assistance across PEPFAR.

Summary

In summary, OGAC and PEPFAR stakeholders have developed and utilized a multitude of formal and informal mechanisms to transfer many types of knowledge throughout the different levels of PEPFAR stakeholders. Formal mechanisms systematically implemented by OGAC to facilitate knowledge transfer include routine reporting from the country-level APRs, SAPRs, and COPs, periodic teleconferences, the PEPFAR Annual Implementer's meeting, the PEPFAR Extranet site, the use of intermediaries as conduits of information to the field, and weekly "News to the Field" e-mails. Informal mechanisms of knowledge transfer not systematically implemented across PEPFAR include various meetings, conferences, forums, country-level reports, use of online technology databases, websites and webinars, and staff rotation and study tours.

PEPFAR Knowledge Transfer Barriers and Limitations

Simply creating, collecting, or acquiring knowledge within an organization is not enough for an organization to learn and improve performance. Knowledge must be disseminated widely and used for the greatest impact (Garvin, 1993). Although PEPFAR has been successful in establishing and using a wide variety of formal and informal mechanisms to transfer knowledge systematically and intermittently throughout PEPFAR, barriers to knowledge transfer exist and there is still a perceived need for more formalized mechanisms for transferring experiences across countries and implementing partners.

One main barrier to knowledge transfer is related to the lack of a strategic approach to knowledge transfer and limitations of current systems and processes. OGAC has not articulated goals, purposes, and a plan of action for knowledge transfer in PEPFAR. OGAC has issued

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several strategy, progress, and guidance documents: PEPFAR Five-Year Strategies, annual reports to congress, guidance documents on collecting and reporting program monitoring data, guidance documents on evaluation and research activities, as well as a published article outlining PEPFAR's implementation science plan (OGAC, 2005c, 2006a, 2007e, 2009d, 2010b; Padian et al., 2011). Although these documents describe knowledge creation and acquisition and may mention an increased emphasis on transparency or dissemination, none of these describe clear goals nor a detailed plan for how program data, results from evaluations, and experiences (lessons learned, best practices, models) will be systematically transferred and shared either internally or externally to PEPFAR, beyond routine reporting to OGAC.

Other knowledge transfer barriers identified by interviewees were related to determining: the right knowledge to transfer, the appropriate scale of knowledge transfer, and the correct mechanisms of transfer (272-36-USG; 396-57-USG), and a lack of stakeholder engagement in transfer processes (396-57-USG). As one mission team interviewee observed, *'the problem is knowing when to and when not to share something, inclusiveness can lead to an excess of information'* (396-57-USG). Another interviewee stated that in-country partners meetings, in their particular country, did not work as a knowledge transfer mechanism, due to the vast number of implementing partners in country, but that video conferences were a useful and effective alternative (272-36-USG). Finally, one interviewee pointed out that having a knowledge transfer mechanism in place, in this case a SharePoint site to share data across agencies and teams, did not guarantee the site would be utilized by staff (396-57-USG).

Beyond the challenges in the current knowledge transfer systems and processes there is a perceived need for more formalized mechanisms for transferring experiences (lessons learned, best practices, innovations, and models). Much of this perceived need was articulated by mission teams and country-level implementing partners who reported a need for more formalized mechanisms for transferring knowledge across countries, implementing partners, and implementation sites. Country-level interviewees recognized the opportunity to learn from the experiences of other countries and vocalized a desire for information and best practice sharing regionally and globally (196-8-ML; 934-46-PCGOV); cross-country exchange programs (331-22-PCNGO) and opportunities for transfer of lessons learned between countries (331-23-USNGO; 587-23-USG; 587-25-ML; 272-36-USG; 542-11-PCNGO; 396-18-USG). This need for increased knowledge transfer across countries was expressed strongly by multiple interviewees. In the words of one interviewee:

> *"I think that a lot more work can be done, cross-fertilization of lessons learned in different countries. A specific example within the [Region X] is that when I was working in [Country A], for example, oodles of effort and resources went into making sure that they developed this awesome electronic medical record […] Wonderful work done around that. Then I go to [Country B] and I see amazing work being done [on] their community-based […] data collection system. Amazing work that we weren't able to get done in [Country A]. Two countries that were PEPFAR countries in this region. Why there hasn't been like exchange visits, or some means of sharing those lessons learned, I don't know. But evidently, that's not necessarily a priority to someone. So that might be a good thing to look towards in the future. But regionally,*

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> *you know, making sure that any resources that have shown […] promise for the future are shared with other countries."* (587-25-ML)

When describing sharing within regions and among countries, one interviewee stated that there were lessons to be learned across countries but that process for sharing were not systemized, and that PEPFAR doesn't seem to want to spend money on regional meetings (272-36-USG). Another interviewee expressed a desire to see more collaboration among regions and countries with programs facing similar epidemics, noting that some of this sharing happens on an ad hoc basis but that it is not a PEPFAR-run activity (396-57-USG). In addition to country-level interviewees' viewpoints, one headquarters interviewee reinforced this need for mechanisms of cross-country exchange after attending a GHI meeting and seeing knowledge transfer across countries. In the words of the interviewee:

> *"It was fascinating, just kind of like the hunger that was there, the hunger that got satisfied from people actually having that opportunity to exchange information, to talk about problems. And we [OGAC] all realize that for years we've been talking about south-to-south learning and you know here we were, an opportunity to bring a bunch of countries together. There were never enormous meetings."* (NCV-9-USG)

In addition, when describing knowledge transfer at the country- and implementing partner-level, interviewees vocalized a need for increased exchange of information and success stories across implementing partners and service delivery sites within a particular partner country (116-23-USPS; 166-23-USG; 196-26-USG; 396-25-PCGOV; 396-32-PCGOV; 396-44-PCGOV; 587-23-USG), and some interviewees offered standardized mechanisms to share data between implementing partners (396-05-USNGO) and study tours (396-25-PCGOV; 396-32-PCGOV; 396-44-PCGOV) as solutions to increased knowledge transfer. Many of the informal knowledge transfer mechanisms currently used on a small scale by implementing agencies, technical working groups, mission teams, and implementing partners could be useful tools for more formal scale up and routine use across PEPFAR to enhance knowledge transfer and overcome barriers in the current systems.

> **Conclusion:** Although a wide variety of mechanisms have been successfully established and used to transfer an array of knowledge throughout PEPFAR, more progress is needed to address limitations in current processes and systems and to establish formalized mechanisms to transfer experiences across countries, implementing partners, and sites as systematically as is desired by stakeholders. Without this, there will be missed opportunities to capitalize on best practices and internal lessons learned that could be applied to improve PEPFAR-supported programs.

Lessons Learned on Knowledge Transfer from Implementing Partners

The Track 1.0 partners and other international NGOs, as large PEPFAR implementing partners that manage HIV programs operating in multiple countries with multiple stakeholders involved, face similar challenges as OGAC in transferring an array of knowledge across different

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stakeholders, organizational levels and countries. Across interviewees, at headquarters and country levels, these large implementing partners shared examples of innovative mechanisms used to transfer both explicit and tacit (experiential) knowledge effectively and efficiently throughout their organizations. These mechanisms include: partner or mission team developed databases to store, manage, and disseminate data; periodic webinars; publications; feedback sessions; and multi-country meetings and conferences. OGAC could look to these large implementing partners that operate in multiple countries for innovative models to scale up across PEPFAR to overcome knowledge transfer barriers and increase the efficiency and effectiveness of knowledge transfer throughout PEPFAR.

To illustrate some of the mechanisms used by these partners, Box 11-4 describes innovative approaches used by one PEPFAR implementing partner, "Organization X" (the organization name has been de-identified for confidentiality purposes). Organization X operates in multiple countries and has implemented several knowledge management mechanisms to promote the use of routinely collected data for strategic planning, information sharing with others, and program evaluation. This implementing partner shares knowledge acquired and created by the organization through both active and passive knowledge transfer systems, including a sophisticated database reporting system, reports and periodic bulletins, dissemination meetings, feedback meetings, conferences, and webinar series.

BOX 11-4
"Organization X" Innovative Knowledge Transfer

Database Reporting System
Organization X developed a central database reporting system to capture, integrate, store, manage, analyze, and disseminate reporting data from multiple organizational activities and programs. The Web-based system was launched to streamline and standardize routine data collection as well as increase use of routine data by organization staff for program monitoring, strategic planning, and improving quality of service delivery. All organizational staff from headquarters to the country and site levels have access to the system. System features include: standardized data entry with built in data checks, data navigation by site or activity, system dashboard to summarize data with "real-time" updates, automated summary tables and reports by country and site, exportable reports and raw data, interactive map features to indicate location of services and sites, and triangulation of data sources.

Reports
The organization's database system can be used by staff at any organizational level to produce reports for monitoring programs, documenting progress, and reporting to donors. The organization headquarters disseminates routinely collected data through quarterly, semi-annual, and annual summary reports to partner country governments and funding partners. Additionally, the organization headquarters produces easy-to-read facility- and region-level feedback reports used for guiding program implementation.

Meetings
Organization X uses several types of meetings to transfer tacit and explicit knowledge across implementing partners and sites, including but not limited to:

- Annual meetings of in-country teams, implementing partners, and sites to share data, lessons learned, innovations, and tools across implementing parnters and countries .

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- Feedback meetings where implementing sites in a particular region come together to share data and see how they are doing.

- Organization-wide and country-wide data dissemination meetings held three to four times per year, where the organization headquarters shares their in-depth analysis of the routinely collected aggregate program data and patient-level data with the implementing partners.

Webinars and Online Technology
The organization uses webinars and online technology to transfer and disseminate knowledge across the organization, specifically:

- The organization headquarters runs online webinars series available to all staff. These focus on clinically relevant topics (such as improving effectiveness of adherence in HIV treatment settings, the role of microbicides in HIV prevention, and nurse-initiated and managed ART) as well as dissemination, highlighting data collected and data collection experiences in the field. Webinars are archived online and available for viewing.

- Organization headquarters distributes a periodic electronic bulletin that is sent to implementing partners and sites to highlight aggregate reported program data and illustrate the utility of routinely collected data

- They have a publically accessible webpage that includes online resources such as: guidance, manuals, and tool-kits for different program areas as well as monthly newsletters—highlighting the webinar schedules, program success stories, and current research and activities. Archives of the newsletter are available online.

SOURCE: Website Organization X, Interview with Organization X Headquarters.

PEPFAR'S KNOWLEDGE DISSEMINATION EXTERNAL TO PEPFAR

As described earlier in the chapter, PEPFAR acquires and creates vast amounts of knowledge in the form of routine PEPFAR program monitoring data, additional program and clinical data collected by implementing partners, outcomes and results of evaluation and research activities (TEs, PHEs, BPE, IS, and IE), and data acquired through support of partner country surveillance systems and surveys, as well as tacit knowledge gained through experiences. To have the greatest public health impact, this knowledge needs to not only be transferred within PEPFAR but also disseminated beyond PEPFAR for use by partner countries and the international HIV/AIDS community including other funders, researchers, evaluators, and the public.

Recently there has been increasing recognition by PEPFAR leadership of their responsibility to maximize knowledge created in PEPFAR by disseminating it widely. PEPFAR reauthorization under the 2008 Lantos-Hyde Act and PEPFAR's second Five-Year Strategy both placed an emphasis on improving efforts to disseminate PEPFAR data and findings, expand the publically available data for analysis to inform public health, and continue to contribute to the

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global HIV/AIDS response evidence base[8] (OGAC, 2009e). Additionally, the 2011 article outlining PEPFAR's implementation science plan underscored the need for the next phase of PEPFAR to place an emphasis on the "development and contribution of knowledge about HIV/AIDS program implementation to the global community" (Padian et al., 2011, p. 202). Finally, the 2011 PEPFAR Annual Report to Congress stated that PEPFAR is "redoubling its efforts to apply and disseminate" PEPFAR lessons learned and data (OGAC, 2011h, p. 5). Even prior to the recent emphasis on knowledge dissemination, however, PEPFAR was already, to some degree, disseminating gained knowledge to external stakeholders as illustrated in this section.

Knowledge dissemination external to PEPFAR occurs on many levels. PEPFAR stakeholders share knowledge with Congress, other global HIV/AIDS partners, partner country governments, and the public. Additionally PEPFAR contributes knowledge to the global evidence base around HIV/AIDS program implementation. Across these levels, PEPFAR utilizes various platforms to disseminate knowledge, including published reports, online technology, participation in conferences, routine and ad-hoc reporting, and publications.

Reporting to Congress

OGAC reports a portion of the PEPFAR program monitoring data and updates on progress to Congress on a routine basis through annual reports to Congress as well as ad hoc reports that meet special congressional or White House requests (NCV-2-USG; NCV-3-USG). In addition to being provided to Congress, all the annual reports to Congress from 2005 to 2012 are archived and available to the public online at the PEPFAR website, as well as more than 25 other PEPFAR Reports to Congress from 2004 to present (February 2013). In addition to the Reports to Congress, every 5 years OGAC releases the Five-Year Strategy of the U.S. President's Emergency Plan for AIDS Relief. The most recent 2009 strategy, which is publicly available on the PEPFAR website, reflects on lessons learned during the previous 5 years and outlines the future direction of the program (OGAC, 2009e, 2012h).

Knowledge Sharing with Other Partners and Funders in the Global HIV/AIDS Response

Beyond reporting to Congress, OGAC and PEPFAR stakeholders have implemented a few official and informal mechanisms to share knowledge with other partners and funders in the global HIV/AIDS response. As described previously, OGAC meets separately every 6 months to a year with both UNAIDS and the Global Fund to share and compare data (NCV-3-USG; NCV-21-ML). PEPFAR's relationship and coordination with the Global Fund is discussed in more detail in Chapter 10.

Additionally, interviewees described the Implementers' Meeting as an official mechanism developed by OGAC for systematic active sharing of knowledge with other global partners in the HIV/AIDS response; other mechanisms described by interviewees for this type of exchange were informal and implemented on a country-by-country basis. The PEPFAR Implementers' Meeting, described previously in the chapter, was created by OGAC as an official mechanism of knowledge transfer—open to a multitude of stakeholders including outside

[8] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008)

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partners and funders involved in the global HIV/AIDS response (OGAC, 2009a). The Implementers' Meeting serves as a formal forum created by OGAC for cross-stakeholder sharing, however, an open Implementers' Meeting has not been held since 2009. There was no Implementers' Meeting in 2011 due to scheduling and cost challenges, and in 2012 the meeting was supplanted by the need for PEPFAR to have representation at the 2012 International AIDS Conference (NCV-7-USG) (OGAC, 2012h).

One headquarters interviewee highlighted the Implementers' Meeting as an opportunity for PEPFAR implementing partners to share information with each other as well as other multilaterals such as WHO, UNAIDS, and the Global Fund, but went on to state that multilateral engagement in the meetings has been more limited (NCV-7-USG). One headquarters interviewee reported that OGAC is currently working on developing new methods to share information about PEPFAR countries with the Global Fund to use in decision making and funding selection (NCV-11-USG).

In addition to the Implementers' Meeting, multiple interviewees described informal mechanisms used to share knowledge with external partners and funders, including contributions to partner country reports for UNAIDS and WHO, and meetings and forums. One headquarters interviewee shared that PEPFAR program monitoring data are circulated to some external HIV/AIDS partners by indirect means when these data are used to contribute to partner country national data that is then reported to the UN and WHO (NCV-7-USG). One mission team interviewee stated that they share PEPFAR data directly with UN agencies, and another described regular country level meetings to share data with other donors (461-4-USG), but this was not heard across interviewees as an official mechanisms of knowledge transfer established by OGAC. Finally, in several countries, interviewees described participation in country-level stakeholder and development partner forums (i.e. Global Fund CCM, Health Development Forum, AIDS Development Partners Forum, Development Community meetings), as opportunities used by PEPFAR to share knowledge among stakeholders in the response (116-2-USG; 196-13-OGOV; 240-15-USG; 461-25-ML; 636-9-USACA; 934-43-USG).

A lack of knowledge sharing across partners in the HIV/AIDS response emerged as a theme in interviews with multilateral funders, bilateral funders, and other HIV response partners (196-13-OGOV; 166-9-USG/OBL/ML; 272-6-ML). One bilateral interviewee reflected on the need for better collaboration among funders to work closely together planning from the beginning *"when we're doing designs rather than [when we are] tailoring them and starting to implement them […] that's way too late"* (196-13-OGOV). The interviewee went on to express frustration with PEPFAR for keeping their organization in the dark while re-designing the country program in a country where they were both engaged stating that PEPFAR's processes occurred in a box *"with things happening inside but we [the bilateral organization] didn't know exactly what was happening in the box"* (196-13-OGOV). This view was reiterated by a multilateral interviewee in another country, who noted that PEPFAR was working with the partner country government to streamline HIV/AIDS indicators but they were not very clear on what was happening and emphatically stated, *"just tell PEPFAR to share what they do, we're partners"* (272-6-ML). Finally, other multilaterals and bilaterals working in a partner country pointed out that in-country, PEPFAR holds technical meetings limited to USG and PEPFAR partners, but that it would be beneficial if these conversations happened in a broader environment involving more stakeholders (166-9-USG/OBL/ML). Across interviews, the theme emerged that OGAC lacks formal mechanisms to exchange knowledge with external partners (bilaterals, multilaterals, and other partners) involved in the HIV/AIDS response.

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Knowledge Sharing with Partner Country Governments

At the country level, PEPFAR knowledge dissemination occurs when mission teams and implementing partners share knowledge with partner country governments through meetings and presentations, as well as routine and ad hoc reporting. These multiple avenues of knowledge sharing with partner country governments are described below, followed by the many challenges that nonetheless remain in transparently sharing information between PEPFAR and partner country governments.

Avenues for Knowledge Sharing with Partner Country Governments

Many country level-SI TWGs and implementing partners reported sharing PEPFAR data with the national government (587-9-USG; 166-12-USG; 396-19-USG; 396-56-USNGO; 461-16-USG). One partner country government interviewee confirmed this data sharing between PEPFAR and the national government, stating: *"in terms of data management I think that up to now we have no problem, we share together"* (396-6-PCGOV). Meetings with partner government were described as a common mode to exchange knowledge—including routine coordination meetings (116-2, 4-USG; 272-36-USG; 240-5-PCGOV; 240-7-PCGOV; 240-15-USG; 331-4-PCGOV; 587-7-PCGOV), technical area specific meetings (272-36-USG), Partnership Framework meetings and processes (396-57-USG), and PEPFAR staff participation in national technical working groups (196-20-PCNGO; 396-19-USG; 461-15-USG; 934-2-USG).

Beyond meetings, PEPFAR mission teams share program data and research findings with partner governments through various country-level reports and presentations on an ad hoc basis (240-3-USG; 272-22-US; 396-56-USNGO; 461-1-USG; 542-21-USNGO; 587-3-USG; 934-38-PCACA). Additionally, in several countries, the mission teams share country APR and SAPR results and COPs (240-33-USG) directly with partner country governments (166-12-USG; 240-33-USG; 272-36-USG; 396-19-USG). Some interviewees highlighted that disseminated program data and research findings were then used by partner country governments for UNGASS reporting (396-56-USNGO; 461-15-USG), program planning (272-22-USG), and intervention implementation (542-21-USNGO; 934-38-PCACA). The frequency and scale of use of these mechanisms of sharing, meetings, and reports, seemed to be at the discretion of the individual country mission team or implementing partner.

PEPFAR implementing partners routinely report data into partner government systems. Across several countries, mission teams described how implementing partners are required or encouraged to report and share PEPFAR program monitoring data directly with partner country governments at the national, regional, and district levels as well as government agencies such as the MOH, national AIDS commissions, and provincial AIDS commissions (116-1-USG; 196-22-PCGOV; 272-36-USG; 331-34-USNGO; 496-19-USG; 461-18-USG). Interviewees did not, however, mention how required or encouraged reporting was enforced or tracked. Finally, in addition to routine reporting, a couple PEPFAR implementing partners and mission teams noted sharing data in response to partner country government data requests (166-12-USG; 396-5-USNGO; 461-20-PCPS); another interviewee, however, noted that specific data requests from the government to PEPFAR mission teams may be limited by varying capacity across the government to formulate requests (166-12-USG).

Challenges in Knowledge Sharing with Partner Country Governments

Despite these mechanisms utilized by mission teams in partner countries to share with partner country governments, many interviewees described barriers to knowledge dissemination with partner country governments, including a lack of transparency from PEPFAR around financial data (166-16-PCGOV; 166-19-PCGOV; 240-33-USG; 396-16-PCGOV; 461-8-PCGOV), differing fiscal years (396-

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1920-USG; 396-56-USNGO; 461-4-USG), a lack of harmonization between PEPFAR and partner country reporting systems (166-16-PCGOV; 396-7-PCGOV; 461-20-PCPS), as well as a lack of routine systems for sharing (166-16-PCGOV).

Partner country government interviewees criticized PEPFAR for a lack of transparency around expenditure data. They described challenges in accessing data on how money is being spent, which implementing partners are being funded and at what level, as well as data on costs of activities. Interviewees pointed out that this lack of transparency leads to challenges in monitoring, coordinating, procurement, and planning the national HIV/AIDS response (166-16-PCGOV; 166-19-PCGOV; 396-16-PCGOV; 461-8-PCGOV). This critique has also been voiced by outside researchers who claim PEPFAR is restricting access to data on how public funds are spent, pointing out that other large funders like the Global Fund, are able to have financial transparency while still protecting proprietary implementing partner information (Grosso, Hoan Tram, Ryan, & Baral, 2012). Additionally, differing fiscal years and reporting time frames lead to challenges with sharing data between PEPFAR and partner country governments in a timely and meaningful way (396-19-USG; 396-56-USNGO; 461-4-USG); additionally one mission team interviewee pointed out that when the COP and APR reports are due relatively close together ,there is little time to get feedback from the government prior to report submission (461-4-USG).

A few partner country government and private-sector interviewees cited a lack of alignment between country-level M&E systems and PEPFAR data collection systems, described previously in the chapter, as a knowledge dissemination barrier (166-16-PCGOV; 396-7-PCGOV; 461-20-PCPS). Although several mission team interviewees reported that implementing partners are required or encouraged to report program monitoring data to the national M&E systems (116-1-USG; 272-36-USG; 331-34-USNGO; 496-19-USG; 461-18-USG), in some cases interviewees noted that some PEPFAR implementing partners report data to PEPFAR only and not into the national M&E system (166-16-PCGOV; 396-7-PCGOV; 461-20-PCPS). One partner country government interviewee observed that implementing partners do not feel obliged to report data to the national HIV/AIDS M&E system because they are already sharing the data with PEPFAR (166-16-PCGOV). Another interviewee involved in collecting and managing data for PEPFAR described the repercussions of partners reporting only to PEPFAR and not the national system (461-20-PCPS):

> *"So we get data from them [PEPFAR implementing partners] that comes into our system [PEPFAR's system] but that data that they provide us may not necessarily be in the national system because they haven't been you know reporting their data into the national system […] If we are to strengthen national systems, that's not good because you know it's not appropriate for the national level to be missing out on data of that nature because it's an important contribution […] we are not here permanently [Contractor], we are here to support programs but at the end of the day the country will remain and its systems will need to be strengthened."* (461-20-PCPS)

Finally, one partner government interviewee noted that PEPFAR provides data to the national government when they *"knock on the door"* and request it, but that they would prefer if data (programmatic and financial) flowed automatically between PEPFAR and the partner government (166-16-PCGOV).

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In summary, PEPFAR stakeholders do have mechanisms in place at the country level to disseminate knowledge to partner country governments, but these processes were as not as transparent, routine, and systemized as preferred by some interviewees.

Conclusion: OGAC could contribute to increased coordination among partners in the HIV/AIDS response by developing official routine and systematic mechanisms for knowledge exchange with other partners involved in the response at both the global and country levels, including partner country governments, other donors, and multilateral organizations.

PEPFAR Knowledge Dissemination to the Public and Contribution to the Global Knowledge Base

As one of the largest funders addressing the global HIV/AIDS epidemic, PEPFAR has both the capacity and responsibility to play a significant leadership role in ensuring that knowledge created through the HIV/AIDS response is disseminated broadly for the greatest public health impact, and that data, research results and evaluation outcomes are available to other researchers, evaluators and the public to help accelerate the pace of new knowledge creation. PEPFAR could lead the way in setting new standards of transparency and knowledge dissemination, contributing solutions to common knowledge sharing barriers. As this section will describe, PEPFAR has begun taking steps to facilitate this broader knowledge dissemination to the public and contributing to the knowledge base. As noted earlier, PEPFAR leadership has recognized the importance of knowledge dissemination beyond PEPFAR[9] (OGAC, 2009e; Padian et al., 2011); some knowledge dissemination mechanisms are in place or in the process of implementation to facilitate sharing with the public; OGAC has stated they are planning a formalized dissemination platform (OGAC, 2011b); and PEPFAR implementing agencies and partners have contributed vast amounts of evidence to the global knowledge base on effective HIV/AIDS interventions and program implementation through publications, reports, technical guidance, tools, and participation in conferences. Despite these steps, however, significant strides are still needed to ensure that all knowledge created through PEPFAR is transparent, available and disseminated widely and efficiently.

Public Knowledge Dissemination Mechanisms

PEPFAR stakeholders at the headquarters level and country level utilize various platforms to disseminate knowledge created in PEPFAR to the public and contribute to the global knowledge base on effective HIV/AIDS interventions and program implementation; these platforms range from online technology NCV-7-USG; NCV-10-USG; NCV-11-USG; NCV-18-USG) (OGAC, 2011b), (to participation in meetings and conferences (NCV-4-USACA; NCV-6-USNGO; NCV-7-USG; 116-1-USG; 272-27-USG; 331-23-USNGO; 331-44-USNGO), to reports and publications (NCV-2-USG; NCV-4-USACA; NCV-7-USG; NCV-8-USACA; 196-11-USNGO; 272-22-USG; 272-27-USG; 331-23-USNGO; 396-19-USG; 396-53-USNGO; 461-16-USG).

[9] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293, 110th Cong., 2nd sess. (July 30, 2008).

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Online Technology

OGAC staff, headquarters TWGs, and PEPFAR implementing agencies use various online technology to raise awareness about PEPFAR, share information with the public, and disseminate research and evaluation findings; these technologies include blog posts, Twitter, Facebook, Youtube, Flickr, the official PEPFAR website, and other PEPFAR-supported websites (NCV-7-USG; NCV-10-USG; NCV-11-USG; NCV-18-USG) (OGAC, 2011b). Box 11-5 describes the various websites PEPFAR supports and the types of knowledge disseminated through them.

BOX 11-5
PEPFAR-Supported Websites

PEPFAR public website (www.PEPFAR.gov)
Launched in 2006 to raise awareness about PEPFAR, share information with the public, highlight events and recent news, and disseminate research and evaluation findings. The website provides links to several resources including: the PEPFAR Five-Year Strategy, Reports to Congress, Country Operational Plans, Partnership Frameworks, and limited information on budget information, programmatic data, and publications.

AIDstar-One (http://www.aidstar-one.com/)
Managed by USAID and provides access to a variety of HIV/AIDS resources including: technical area-specific webpages to access resources by topic (e.g., HIV Prevention, HIV treatment); a comprehensive database of HIV program best practices and innovation shared by implementers and program planners; as well as a technical resources section with cases studies, strategic plans, reports, publications, success stories, guidelines, and more to assist public health practitioners develop evidence-informed HIV programs. The resource section can be searched and filtered by resource type, focus area, region, and country. A search of the resource section for PEPFAR returned over 500 resources including guidelines, case studies, tools, reports, documents, events, and more.

Development Experience Clearinghouse (DEC) (https://dec.usaid.gov/dec)
Searchable database of USAID's technical and program related-documentation; users can search, rate, and download documentation and USAID staff and contractors can upload documents. PEPFAR related documents and publications are available here. An advanced search of documents in the database for "HIV/AIDS' and "PEPFAR" resulted in 740 documents.

OVCSupport.net (www.ovcsupport.net/)
Platform for "the exchange of experience, practice, and tools on policy and programming" related to children and HIV. Website sections include: news and exchange, policy and research, programming resources, discussion forums, as well as a library that is searchable by category. Headquarters technical working groups use this website to disseminate research and evaluation findings related to children and HIV. A library search for 'PEPFAR' returned 41 results.

What Works for Women and Girls: (http://www.whatworksforwomen.org)
Provides a review of the data from HIV/AIDS interventions for women and girls from roughly 100 countries. The website gives the public and PEPFAR partners access to literature and evidence on interventions that work for women and girls. Evidence can be sorted by strategy effectiveness (e.g., works, promising), strategy (e.g., prevention, strengthening the enabling environment), keyword, location, and gray rating.

SOURCE: (NCV-10-USG; NCV-17-USG)(AIDStar-Two, 2012; Gay, 2012; JSI, 2012; OGAC, 2012h; USAID, 2012)

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Meetings and Conferences

Beyond online technology, both headquarters and country-level interviewees cited participation at international conferences (NCV-4-USACA; NCV-6-USNGO; NCV-7-USG; 116-1-USG; 331-44-USNGO), scientific meetings (935-27-USG), and periodic stakeholder meetings (331-23-USNGO) as mechanisms used to ensure PEPFAR results are disseminated widely. One headquarters interviewee stated that PEPFAR staff are actively encouraged to submit abstracts to conferences, and highlighted staff attendance and participation at CROI (Conference on Retroviruses and Opportunistic Infections), the 2012 International AIDS Conference, as well as limited participation at ICASA (International Conference on AIDS and STIs in Africa) (NCV-7-USG). At the country level, interviewees described dissemination through presentations at international conferences (331-44-USNGO), abstracts with PEPFAR programmatic data (935-27-USG), and presentations of unpublished data at country level conferences (116-1-USG). A headquarters interviewee did note, however, that USG quotas on the number of USG staff attending overseas meetings are a limitation for using conferences/meetings as a dissemination tool (NCV-7-USG).

Reports and Publications

Finally, a preponderance of headquarters and country-level interviewees highlighted reports and publications as tools to disseminate PEPFAR program activities and program data, lessons learned, research results, and evaluation outcomes (NCV-2-USG; NCV-4-USACA; NCV-7-USG; NCV-8-USACA; 196-11-USNGO; 272-22-USG; 272-27-USG; 331-15-USG; 331-23-USNGO; 396-19-USG; 396-53-USNGO; 461-16-USG). Interviewees noted Annual Reports to Congress, regional and provincial pamphlets, and contributions to UNGASS reports and Universal Access Reports as mechanisms to share programmatic data and special survey data (331-15-USG; 461-16-USG; 396-19-USG; 396-53-USNGO; NCV-2-USG).

In addition to programmatic data, reports and publications are used to share lessons learned. Recently, OGAC contributed to the development and public release of two special issues of scientific journals focused on lessons learned in the first two phases of PEPFAR (NCV-7-USG). The *Health Affairs* special issue, *Assessing The President's Emergency Plan For AIDS Relief* examined PEPFAR successes, lessons learned and next steps and the *Journal of Acquired Immune Deficiency Syndromes* special issue *PEPFAR: Its Vision, Achievements, and New Directions* examined PEPFAR experiences and insights from a scientific and programmatic perspective. Beyond these special publications, headquarters and country level interviewees described other dissemination of PEPFAR data, activities, research results, and evaluation outcomes through publications in professional journals (NCV-4-USACA; NCV-8-USACA; 272-22-USG, 272-27-USG; 331-23-USNGO; 196-11-USNGO), with one interviewee stating *'hundreds of papers'* have resulted from PEPFAR evaluation activities (272-22-USG). Headquarters and country level interviewees identified multiple successful examples of using reports and publications to disseminate knowledge created in PEPFAR. Interviewees, however also identified barriers to utilizing publications as a mechanisms for dissemination of knowledge gained through PEPFAR. These included a lack of in-country capacity to publish (116-1-USG; 331-24-PCGOV), research restrictions (NCV-4-USACA), and multiple levels of approval needed to collect, present and publish data (NCV-4-USACA).

Dissemination Successes

As noted previously, PEPFAR implementing agencies and partners have contributed vast amounts of evidence to the global knowledge base on effective HIV/AIDS interventions and

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program implementation through publications, reports, technical guidance, and participation in conferences. In some cases, PEPFAR publications, research results, and evaluation outcomes have been used to influence policy and modify HIV/AIDS interventions and program implementation. To assess the scale of PEPFAR's contribution to the global knowledge base, the committee requested from each of the four Track 1.0 partners, as well as from OGAC, CDC, and USAID, a list of publications resulting from PEPFAR support; several of the entities noted that the lists they provided were not comprehensive from the beginning of PEPFAR. These separate lists were combined in Endnote and duplicate references were removed to create one extensive de-duplicated list of PEPFAR-supported publications over time. Based on the information provided, between 2004 and March 2012, over 1,700 journal publications have been produced as a result of PEPFAR (see Figure 11-8). This is an underestimate of the total number of publications produced with PEPFAR support as not all stakeholders were surveyed and the count does not include other publications beyond journal publications (reports, pamphlets, case studies, tools, etc). OGAC was not able to provide a comprehensive list of publications.

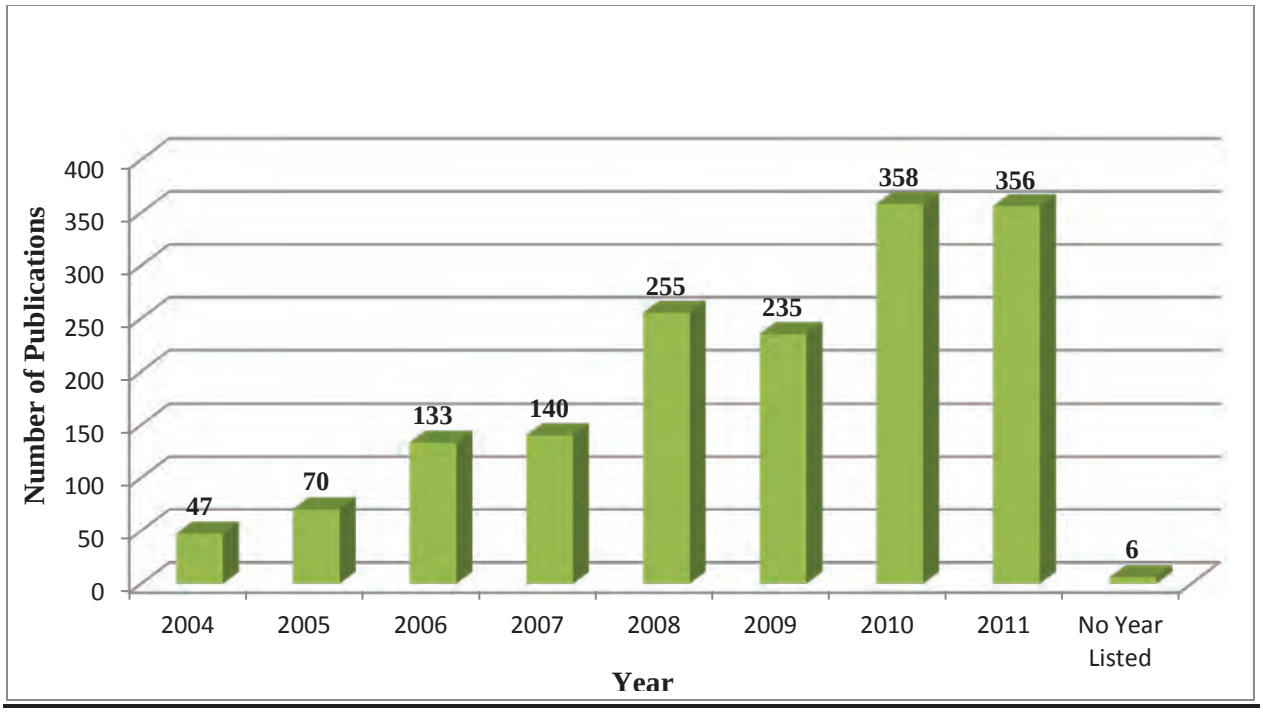

FIGURE 11-8 PEPFAR-supported journal publications, by year, 2004-2011.
NOTE: The figure represents journal publications through 2011, the final complete year in the lists available, which were all received by March 2012. There were 161 publications as of March 2012.
SOURCE: Publication lists received from OGAC, USAID, CDC, and Track 1.0 Partners.

In addition to the publication lists, although not requested, a few entities provided the committee with lists of other dissemination products resulting from PEPFAR funding. Although neither comprehensive nor representative of all PEPFAR stakeholders, from the inception of the program to March 2012, PEPFAR entities surveyed reported 10 books (entities=3); over 950 abstracts (entities=4), over 75 technical guidelines or training materials (entities=3), and over 100 WHO-supported documents (entities=1) that were disseminated as a result of PEPFAR support.

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Beyond producing numerous dissemination products, as described previously, many headquarters and country level interviewees highlighted how knowledge created and disseminated through PEPFAR (research results, evaluation outcomes, PEPFAR program data, surveys, and publications) have been used to influence country-level policies and planning. Interviewees also noted the contribution of PEPFAR to the global knowledge base on improving HIV/AIDS interventions and program implementation (272-24-USG; 272-25-USG; 272-36-USG; 461-4-USG; 461-8-PCGOV; NCV-10-USG). As evidenced above, a large volume of knowledge has been disseminated as a result of PEPFAR in the form of publications, abstracts, technical guidelines, and reports, and in many cases, this knowledge has been used to influence policies and improve HIV/AIDS interventions and program implementation.

Measuring and Tracking Contribution to the Global Knowledge Base

As previously alluded, PEPFAR implementing agencies and partners have created and disseminated vast amounts of knowledge since the inception of the program, yet it is difficult to assess PEPFAR's contribution to the knowledge base due to lack of a centralized system or approach to track publications, abstracts, guidelines, and reports that result from PEPFAR funding. In order to assess the scale of PEPFAR's contribution to the global knowledge base on effective HIV/AIDS interventions and program implementation, the committee requested a comprehensive list of publications that resulted from PEPFAR support, from the beginning of PEPFAR. OGAC could not provide the committee with a comprehensive list over time, and instead they provided a couple lists that together, when de-duplicated, detailed 169 publications and 3 abstracts published between 2006 and 2011. OGAC informed the committee that publications generated through PEPFAR-funded activities are "currently tracked through ad hoc systems and coordination with PEPFAR's implementing agencies" (OGAC, 2011b, p. 1). The lack of a system to track PEPFAR publications was reiterated by a a headquarters interviewee, "*OGAC never successfully managed to track the work that was being accomplished [research and evaluation-TEs PHEs, and IS]"* or *"any reports that come out of that work"* (NCV-7-USGOV). After receiving the initial publication list from OGAC, the committee surveyed the Track 1.0 Partners, USAID and CDC for their lists of PEPFAR-supported publications; while all organizations were able to provide us with lists a couple noted they were unable to provide comprehensive lists. The lists were combined and de-duplicated in Endnote resulting in a single extensive, but not comprehensive list of over 1,700 journal publications supported by PEPFAR from the inception of the program.

Although the committee was able to determine one level of scale of PEPFAR contribution to the global knowledge base, this number is most likely an underestimate as there are an unknown number of additional dissemination products that have not been captured, tracked or enumerated in a central platform. To address this limitation, OGAC informed the committee that they are currently constructing a tracking system for PEPFAR evaluations that will also provide a "comprehensive central repository for PEPFAR-funded publications when it is completed" (OGAC, 2011b). Additionally, according to headquarters interviewees, to better track PEPFAR-funded publications, OGAC is working with USG agencies to track PEPFAR-funded evaluation and research reports, encouraging agencies to cite PEPFAR as a source of funding when they publish, and working with the National Library of Medicine to get a search term for "PEPFAR" in Medline and anything funded by PEPFAR tagged with the PEPFAR search term (NCV-7-USG).

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In addition to lack of a system to track PEPFAR-supported publications, PEPFAR lacks a central repository or tool that the international HIV/AIDS community (partner countries, other funders, researchers, evaluators, and the public) can access and utilize PEPFAR-funded publications, abstracts, reports, and tools and build off the knowledge base created through PEPFAR. The PEPFAR website provides links to some reports, guidance, publications, and other resources, but this is only a small subset of the actual number of knowledge contribution products resulting from PEPFAR funding. The publications section of the website, for example, only provides access to 21 publications that have resulted from PEPFAR support (OGAC, 2012h). The GAO noted this limitation, for evaluation results, in its review of PEPFAR's evaluation activities. The study found that PEPFAR stakeholders use a variety of mechanisms to share evaluation findings, but not all the evaluation reports are online which limits their availability to the public and the utility of the results for stakeholders in the HIV/AIDS response (GAO, 2012). One headquarters level interviewee vocalized one challenge of not having a centralized repository of PEPFAR dissemination products: *"It's hard to search for and find PEPFAR reports"* (NCV-7-USG). As a result of PEPFAR, OGAC, implementing agencies, and implementing partners have successfully contributed vast amounts of evidence to the global knowledge base on effective HIV/AIDS interventions and program implementation in the form of publications, reports, guidelines, tools, and participation in conferences. There is, however, no formalized system for tracking and no central repository for accessing these knowledge dissemination products making it difficult to assess PEPFAR's contribution to the global knowledge base and for the knowledge to be fully utilized for maximum impact.

> **Conclusion:** OGAC would benefit from having a more systematic method to track PEPFAR-funded dissemination products (publications, reports, abstracts, and guidelines) in order to measure and manage their contribution to the global knowledge base on effective HIV/AIDS interventions and program implementation. Additionally, the international HIV/AIDS community would benefit from PEPFAR having a more robust publically available central repository of PEPFAR-funded publications, abstracts, repots and tools from which to share, collaborate, and accelerate knowledge creation.

Data Sharing

Practitioners in the field of public health are starting to realize the importance of data sharing for maximum impact of research outputs and data collection efforts, yet public health still lags behind other research fields in terms of necessary infrastructure, standards, and incentives to facilitate this data sharing (Walport & Brest, 2011). While data sharing is an important goal, prior to establishing effective dissemination systems, stakeholders must create solutions to ensure equitable access to knowledge, efficient dissemination of knowledge, and protection of data privacy, as well as overcome researcher resistance to sharing (Walport & Brest, 2011). As one of the largest funders addressing the global HIV/AIDS epidemic, PEPFAR has the opportunity to play a significant leadership role in making HIV/AIDS monitoring, evaluation, and research data available to other researchers, evaluators, and the public, so that these data are used for the greatest public health impact and to accelerate the pace of new knowledge creation. PEPFAR could lead the way in establishing infrastructure, standards, and

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incentives to encourage sharing of HIV/AIDS data and contribute solutions to address data sharing barriers.

Currently PEPFAR does not have a data sharing policy in place that promotes access to data collected by implementing partners, mission teams, and contractors with PEPFAR support (i.e., program monitoring data, financial data, evaluation outcomes, and research results). As a result, PEPFAR stakeholders collect an immense amount of data with PEPFAR funds that are not readily available to outside researchers, evaluators, and the global HIV/AIDS community for use in new knowledge creation. As described previously, only a limited amount of PEPFAR program indicators and financial data are made publically available via the PEPFAR website, Annual Reports to Congress, and other reports (NCV-2-USG) (OGAC, 2012h), and the program and financial data that are available are usually presented in a report format that is not easily usable by researchers and evaluators as opposed to Excel files or datasets. Additionally, as previously mentioned, when the committee requested PEPFAR program monitoring data from OGAC for purposes of this evaluation, data, beyond the seven key indicators that are reported annually to Congress were not readily available. NGI data were eventually provided to the committee, but only a limited amount of PEPFAR I indicators were available and provided for use in the evaluation.

In addition to program data, many large implementing partners, such as the Track 1.0 partners, have been collecting additional data beyond routine reporting data since the inception of PEPFAR, including cohort data, data on retention and adherence, and mortality data. These data, collected with PEPFAR support, could add significant value to the global knowledge base on HIV/AIDS program implementation and interventions, yet much of these data are not publically available in a usable format to maximize knowledge creation. As there is no PEPFAR policy requiring data sharing, Track 1.0 partners and other stakeholders are not obligated to make data collected with PEPFAR support publically available. The evaluation committee requested access to portions of Track 1.0 partner supplemental data for purposes of the PEPFAR evaluation. All of the partners were very willing to work with the committee sharing insight, information, publications, and presentations as well as open to exploring data sharing possibilities, but only 1 of the 3 organizations with supplemental data were ultimately willing to share data with the committee. Some of the reasons the other two Track 1.0 partners were unable to share data included readiness of the data, the time and resource burden required to prepare the data, and a hesitation to share data in order to preserve data publication rights.

OGAC has created a data working group within the Scientific Advisory Board to address the fact that although large amounts of data are collected through PEPFAR, “researchers, clinicians and even OGAC do not have access to it” (Group, 2011, p. 1). The mission of this data working group is to advise OGAC on “how it can best gather, disseminate and set policy regarding information generated through the PEPFAR program,” and one objective of the group is to “recommend policy and procedures on data management, data access, data sharing, and release of appropriate data” (OGAC, 2012h). Other research fields, U.S. government agencies, and public health entities with established data sharing policies could serve as models for PEPFAR and the SAB data working group on developing infrastructure and standards for data sharing as well as on how to select data of appropriate readiness and utility to share. Additionally, these entities could provide lessons learned on how to ensure equitable access to knowledge, efficient dissemination, and protection of data privacy. A fair and effective data sharing policy could maximize the use of data created through PEPFAR and spur innovation and discovery.

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Conclusion: As PEPFAR evolved, leadership increasingly recognized the importance of maximizing the impact of knowledge acquired and created through PEPFAR by disseminating it widely beyond PEPFAR. Headquarters and country-level stakeholders have developed mechanisms and taken steps to share PEPFAR knowledge with Congress, other partners and funders in the HIV/AIDS response, partner country governments, and the public. Additionally, PEPFAR implementing agencies and partners have contributed evidence and vast amounts of publications to the global knowledge base on effective HIV/AIDS interventions and program implementation. Despite these successes, more progress is needed for disseminating knowledge external to PEPFAR, particularly in: sharing knowledge with partner country governments and other partners involved in the HIV/AIDS response, increasing the amount PEPFAR data (routinely collected program monitoring data, evaluation outcomes, and research results) publically available for use by researchers and evaluators, as well as tracking and measuring PEPFAR's contribution to the global knowledge base.

SUMMATION

As described throughout this chapter, PEPFAR has made significant strides in knowledge management—acquiring, creating, capturing, sharing and using knowledge. However, there are many areas where more progress is needed to address limitations in PEPFAR's current knowledge management approaches in order to (1) ensure successful monitoring and evaluation of PEPFAR goals and activities, especially as the model of implementation shifts; (2) continually improve programs; and (3) maximize the impact of knowledge created in PEPFAR to contribute to sustainable, country-owned HIV/AIDS responses.

PEPFAR has developed and contributed to systems to acquire and generate knowledge including: creating a PEPFAR-specific program monitoring data collection system to track activities and program results, supporting epidemiologic and surveillance activities in partner countries, strengthening partner country health information systems, implementing various program evaluation approaches, and supporting research across a wide range of technical areas. As a result, OGAC, implementing agencies, and implementing partners have successfully acquired and created vast amounts of knowledge, often at a scale not seen in other development programs. This includes program monitoring, epidemiological, and surveillance data; evaluation outcomes and research results; and best practices, lessons learned, successes, challenges, and innovation.

At the headquarters level, PEPFAR has utilized knowledge (program monitoring data, epidemiologic data, normative guidance, and intervention effectiveness data) to drive program activities and inform efforts, and at the partner country level, there are good examples of data use by PEPFAR stakeholders. Additionally, PEPFAR has carried out initiatives to build capacity and increase data use among partner country governments and PEPFAR implementing partners contributing to fostering a culture of evidence use among partner countries.

OGAC and PEPFAR stakeholders have developed and utilized a wide variety of formal and informal mechanisms to transfer knowledge within PEPFAR including reporting, intermediaries, meetings, conferences, published guidelines, online technology, study tours, and staff rotation. In addition to internal knowledge transfer and use, PEPFAR leadership has

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increasingly recognized the importance of knowledge dissemination beyond PEPFAR. Some dissemination mechanisms are in place to share knowledge with Congress, other global HIV/AIDS partners, partner country governments, and the public including online technology, publications, reports, technical guidance, tools/training materials, and participation in meetings and conferences. As a result of PEPFAR's dissemination efforts, vast amounts of evidence have been contributed to the global knowledge base on effective HIV/AIDS interventions and program implementation. PEPFAR program data, publications, research results, evaluation outcomes, surveys and surveillance results have, in some cases, been used to influence country-level policies, modify HIV/AIDS interventions and program implementation, and contribute to national and global level reports.

Despite the success and progress described above, significant gaps remain in PEPFAR's knowledge management approaches and more progress is needed to address challenges in the areas of knowledge use, knowledge transfer within PEPFAR, and knowledge dissemination external to PEPFAR, as much of the knowledge acquired and created in PEPFAR does not seem to be routinely disseminated and used. A fundamental gap identified by the committee is that PEPFAR lacks a conceptual framework for knowledge management that articulates the vision, goals, and role of knowledge within PEPFAR and that details what knowledge will be needed in the short and long term; how knowledge acquired and created in PEPFAR will be transferred internal to PEPFAR; how the knowledge should be used, how it will be disseminated beyond PEPFAR, and how the different activities of program monitoring, evaluation, and research will be used in a complementary manner to achieve goals. Articulating this comprehensive framework will require addressing current challenges related to program monitoring, research and evaluation, and knowledge transfer and knowledge dissemination but will lead to a more strategic and efficient approach moving forward. PEPFAR's largest and most sustained effort for generating data is the PEPFAR-specific program monitoring data collection system. The need to quickly measure results at the outset of PEPFAR contributed to this system developing in parallel to partner country M&E systems, but over time, OGAC has modified the system, working closely with global partners in the HIV/AIDS response and partner country governments to increasingly harmonize indicators and alignment with partner country HIV/AIDS monitoring and evaluation systems. However, the system requires the collection and reporting of a large amount of program monitoring data, the preponderance does not seem to be routinely utilized.

Use of the program monitoring data is limited by lack of utility of some of the PEPFAR indicators, technological challenges, reporting burden, and lack of indicator harmonization. Additionally, for a period of time, PEPFAR lacked a central database from which to report, manage, and disseminate program monitoring data, which limited access to and utilization of the data. Finally, PEPFAR reporting requirements place a large administrative burden on implementing partners and mission teams which detracts from their ability to analyze and use data. Further modifications are needed to improve harmonization with global indicators and better align with partner country systems to further reduce the number of PEPFAR-specific indicators, reduce reporting burden, increase data use by PEPFAR partner countries, and ultimately contribute to country-owned HIV/AIDS responses.

PEPFAR indicators also do not capture sufficient information on all of PEPFAR's stated priorities, goals and activities. PEPFAR's indicators, like many program monitoring systems, are focused primarily on outputs, which serve an important function to monitor implementation of activities but do not reflect quality, efficiency, and effectiveness. Measuring program progress

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and effectiveness in achieving desired outcomes is not always best achieved through program monitoring systems; this is also largely true for areas of increasing emphasis in PEPFAR, such as technical assistance, capacity building, systems strengthening, sustainability, and country ownership, that are currently not well-captured in existing knowledge management efforts. Therefore, strategically targeted and well-coordinated evaluation and research are critical complementary activities for assessing meaningful outcomes and for continual improvement to maximize the effectiveness and impact of PEPFAR investments. Despite recent efforts to strengthen PEPFAR research and evaluation activities and develop mechanisms for internal knowledge transfer, challenges remain. Defining appropriate and allowable research activities remains a challenge; research gaps exist both across the whole of PEPFAR-supported programs and in some PEPFAR-supported countries. In addition, establishing formal mechanisms to transfer experiences (lessons learned, best practices, innovations, and models) across countries, implementing partners, and implementing sites would make it more possible to systematically synthesize and capitalize on best practices and internal lessons learned.

PEPFAR has made progress in disseminating knowledge external to PEPFAR, but more progress is needed to maximize the impact of knowledge created in PEPFAR; particularly by sharing knowledge with partner country governments and other partners involved in the HIV/AIDS response; tracking and measuring PEPFAR's contribution to the global knowledge base; as well as increasing the availability of data collected with PEPFAR funds (routinely collected and reported program monitoring and other data from implementing partners and contractors, evaluation outcomes, and research results) for use by external researchers, evaluators, and other interested parties. Challenges identified in PEPFAR's sharing of information with partner country governments included a lack of financial transparency, different fiscal years, a lack of harmonization between PEPFAR and partner country reporting systems, and a lack of routine systems for sharing. A lack of formal mechanisms for sharing limits knowledge exchange between PEPFAR and other partners in the HIV/AIDS response.

Additionally, PEPFAR lacks a comprehensive central repository or tool to track and make available PEPFAR-funded research and evaluation activities, reports, and other dissemination products (publications, abstracts, tools, and guidelines) to both internal stakeholders and the international HIV/AIDS community. The absence of a centralized system makes it difficult to assess PEPFAR's contribution to the global knowledge base and for the knowledge to be fully utilized for maximum impact. Finally, PEPFAR does not have a data sharing policy in place that promotes access to data collected by implementing partners, mission teams, and contractors with PEPFAR support. As a result, PEPFAR stakeholders collect an immense amount of data with PEPFAR funds that are not readily available to outside researchers, evaluators, and the global HIV/AIDS community.

It will be critical for PEPFAR to evolve its knowledge management approaches and systems so that knowledge acquired and created through PEPFAR is useful, accessible, and used by PEPFAR stakeholders to monitor, inform, and improve the performance, effectiveness, and efficiency of efforts supported by PEPFAR. The need to adapt to changing circumstances and requirements with a new knowledge management framework is particularly important as the model for PEPFAR implementation is evolving towards supporting country-led responses in partner countries, with a transition to less emphasis on direct support for delivery of services and programs and more support and technical assistance for systems strengthening, capacity building, and sustainable management of the response by partner country stakeholders. With this transition, PEPFAR's approach to knowledge management must also be transformed in order to

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assess its own efforts going forward. PEPFAR needs to invest now in developing reliable, credible approaches to assessing the effectiveness of efforts beyond support for service delivery. Importantly, with this shift, the ability to attribute results by counting the services provided or beneficiaries reached will be diminished and direct attribution will in fact no longer be an appropriate expectation for accountability. Instead, PEPFAR can seize this opportunity to be forward-looking and to work with others in the global health and development assistance communities to develop appropriate and credible ways to assess contribution to the improved performance and effectiveness of national efforts. Support for epidemiological data collection through surveillance and special studies in partner countries has been a cornerstone of PEPFAR's contribution and should continue to be a critical component of knowledge management activities to support joint planning with partner countries.

Additionally, as one of the largest funders addressing the global HIV/AIDS epidemic, PEPFAR has both the capacity and responsibility to play a significant leadership role in ensuring that knowledge created through the HIV/AIDS response is widely disseminated and available to outside partners, researchers, evaluators and the public to spur innovation, accelerate the pace of knowledge creation, and maximize the public health impact of interventions.

> **Overall Conclusion:** PEPFAR has made progress in managing knowledge and learning by developing systems for data creation and collection, streamlining program monitoring data collection, advancing PEPFAR's role and approach to evaluation and research, and utilizing a wide variety of mechanisms to transfer knowledge. Yet, like other entities involved in the global HIV/AIDS response, it struggles with creating, acquiring, and transferring the right knowledge, at the appropriate scale, and in a manner that facilitates use. PEPFAR has the potential to lead the global HIV/AIDS community in knowledge management by creating and following a conceptual framework that articulates the vision, purposes, intended audiences, and goals of knowledge; how knowledge will be acquired, created, transferred, used, and disseminated to achieve these goals; and the complementary roles of program monitoring, evaluation, and research in achieving these goals. PEPFAR has the opportunity to optimize program efficiency and effectiveness through an improved strategy that (1) streamlines and focuses knowledge creation within PEPFAR,(2) increases acquisition of knowledge external to PEPFAR, (3) improves the efficiency and effectiveness of knowledge transfer within and external to PEPFAR, and (4) institutionalizes the use of knowledge to improve the way work is accomplished.

A more clear conceptual framework that incorporates the core elements of knowledge management (illustrated in Figure 11-9) combined with purposeful planning and implementation of PEPFAR's monitoring, evaluation, research, and dissemination efforts would allow for strategic allocation of limited personnel, time, and financial resources while reducing the burden of collecting and reporting data and other information that is not useful. Achieving a comprehensive strategy will require:

1) identifying what knowledge PEPFAR needs, in the short and long term, to inform, plan, monitor, evaluate, and improve efforts;

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2) determining which internal and external stakeholders need to know what information, at what level of the PEPFAR operational infrastructure, covering what scope of PEPFAR's efforts, and with what frequency;
3) planning which knowledge will be acquired from outside PEPFAR and which knowledge will be created though PEPFAR, mapping these knowledge needs to appropriately matched monitoring, evaluation, or research efforts;
4) establishing mechanisms to transfer and disseminate knowledge; and
5) determining the appropriate amount of personnel, time, and financial resources to devote to knowledge management, in the context of the strategic use of the overall PEPFAR investment, and how best to allocate these resources to find an appropriate balance among generation, use, and dissemination of knowledge.

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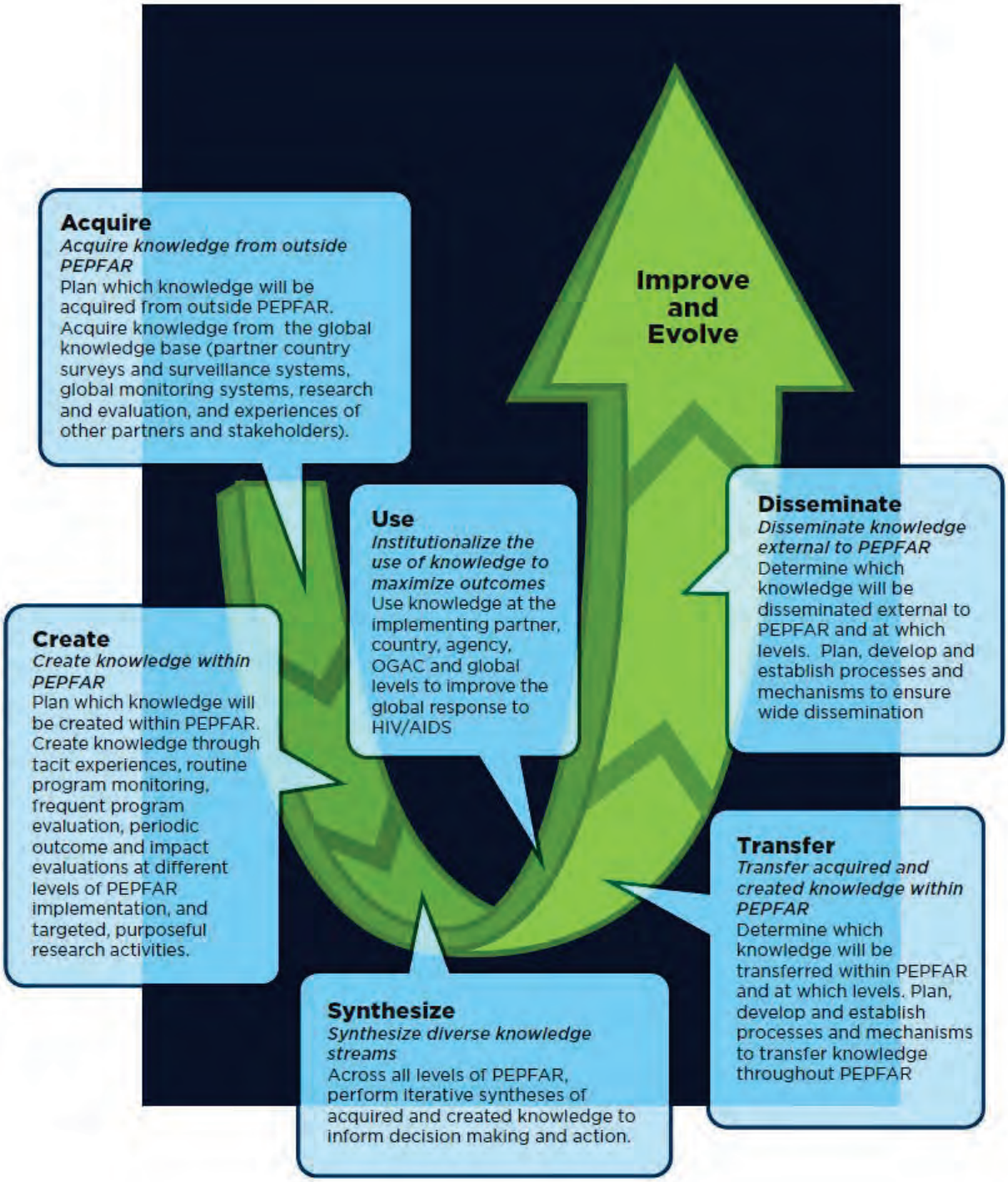

FIGURE 11-9 Elements of Knowledge Management for PEPFAR

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RECOMMENDATIONS

Recommendation 11-1: OGAC should develop a comprehensive knowledge management framework, including a program monitoring and evaluation strategy, a prioritized and targeted research portfolio, and systems for knowledge dissemination. This framework should adapt to emerging needs to assess PEPFAR's models of implementation and contribution to sustainable management of the HIV response in partner countries. This knowledge management framework will require that PEPFAR implement and strategically allocate resources for the following:

A. To better document PEPFAR's progress and effectiveness, OGAC should refine its program monitoring & evaluation strategy to streamline reporting and to strategically coordinate a complementary portfolio of evaluation activities to assess outcomes and effects that are not captured well by program monitoring indicators. Efforts should support innovation in methodologies and measures where needed. Both monitoring and evaluation should be specifically matched to clearly articulated data sources, methods, and uses at each level of PEPFAR's implementation and oversight.

B. To contribute to filling critical knowledge gaps that impede effective and sustainable HIV programs, OGAC should continue to redefine permitted research within PEPFAR by developing a prioritized portfolio with articulated activities and methods. The planning and implementation process at the country and program level should inform and be informed by the research portfolio, which should focus on research that will optimize the effectiveness, quality, and efficiency of PEPFAR-supported activities and will also contribute to the global knowledge base on implementation of HIV/AIDS programs.

C. To maximize the use of knowledge created within PEPFAR, OGAC should develop systems and processes for routine, active transfer and dissemination of knowledge both within and external to PEPFAR. As one component, OGAC should institute a data sharing policy developed through a consultative process. The policy should identify the data to be included and ensure that these stipulated data and results generated by PEPFAR or through PEPFAR-supported activities are made available in a timely manner to PEPFAR stakeholders, external evaluators, the research community, and other interested parties.

The following sections describe additional considerations for implementing each of the components of this recommendation.

<u>Further considerations for implementation of Recommendation 11-1A (Program monitoring and evaluation):</u>

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- OGAC's current tiered program monitoring indicator reporting structure (illustrated in Figure 11-10) should be further streamlined to report upward only those indicators essential at each PEPFAR level:
  - Tier 1: A small set of core indicators, fewer than the current 25, to be reported to central HQ level. These data should be used to monitor performance across PEPFAR as a whole, for congressional reporting, and to document trends; as such these indicators should remain consistent over time. Whenever possible and appropriate, these indicators should be harmonized with existing global indicators and/or national indicators; therefore some centrally reported indicators will reflect PEPFAR's contribution rather than aiming to measure direct attribution.
  - Tier 2: A larger menu of indicators defined in OGAC guidance, from which a subset are selected for their applicability to country programs to be reported by implementing partners to the U.S. mission teams but not routinely reported to HQ. These data should be used to monitor the effectiveness of the in-country response and support mutual accountability with partner countries and their citizens. These data could be considered for occasional centralized use to inform special studies or respond to congressional requests but aggregation and comparability across countries may be limited in this tier as all mission teams may not collect the same data.
  - Tier 3: Indicators selected by implementing partners to monitor and manage program implementation and effectiveness that are not routinely reported to mission teams. Implementing partners should select appropriate indicators defined in OGAC guidance and augment this with other indicators as needed for their programs. Implementing partners should work with mission teams in developing their program monitoring plans with selected indicators. Mission teams should provide oversight and technical assistance to ensure implementation of these plans and to promote local quality data collection, use, and mutual accountability. Although not routinely reported, some of these data could be considered for occasional country-level and centralized use.
  - OGAC should create mechanisms for implementing partners, mission teams, and agency headquarters to mutually contribute to a periodic review across all tiers of indicator development, applicability, and utility and to make modifications if necessary.
  - Tier 1 indicators should be harmonized whenever possible and appropriate with existing global indicators and/or national indicators. For indicators that are not routinely reported centrally (Tiers 2 and 3), country program planning should facilitate alignment of indicator selection and data collection with partner country HIV monitoring and health information systems.

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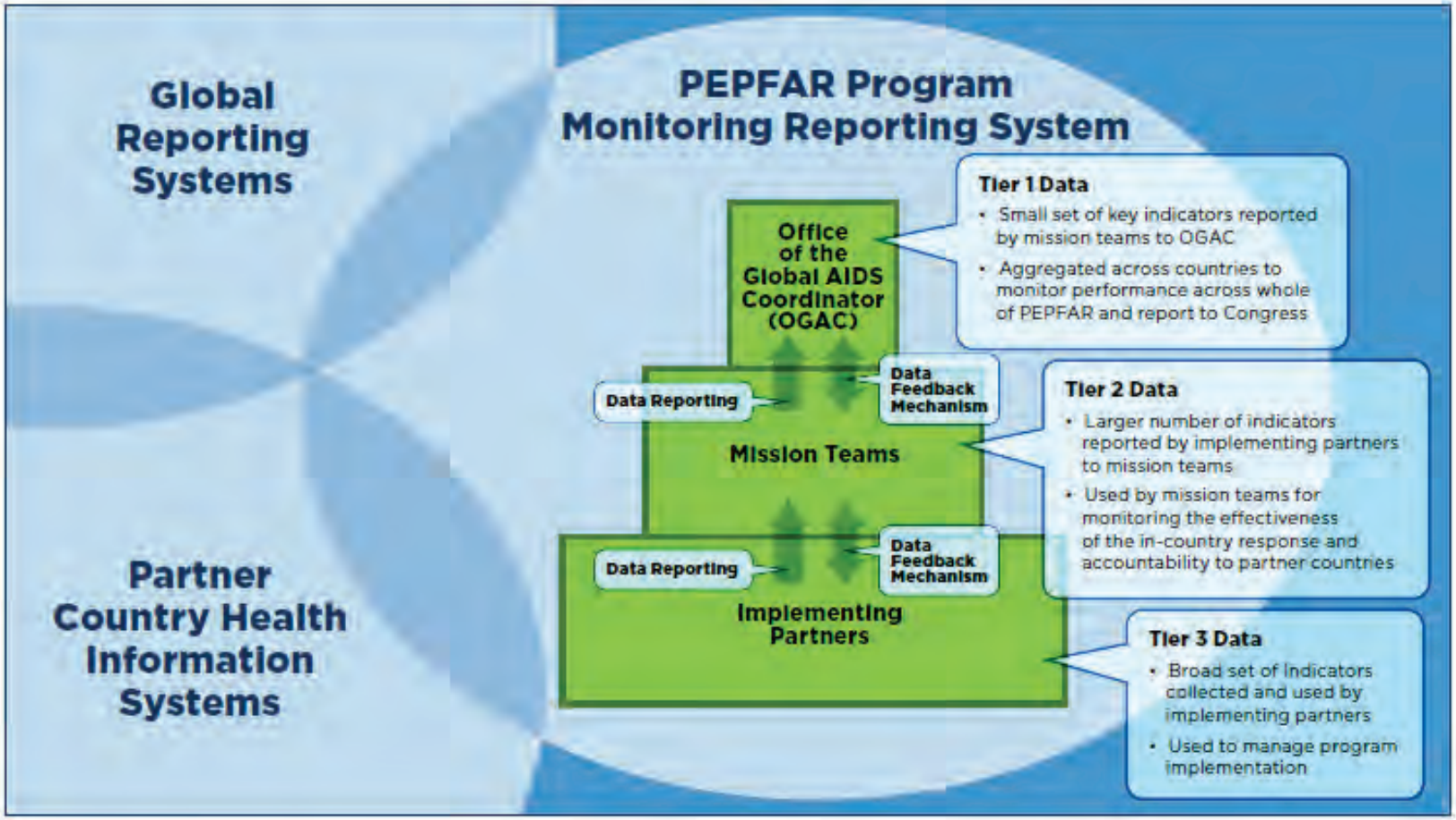

FIGURE 11-10 Recommended PEPFAR Tiered Reporting in the Context of Partner Country and Global Reporting Systems.

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- OGAC should complement program monitoring with a unified evaluation portfolio that includes periodic program evaluation at the PEPFAR country program and implementing partner levels to assess process, progress, and outcomes as well as periodic impact evaluations at the country, multi-country, and headquarters levels.
    - OGAC evaluation guidance should provide information about prioritizing areas for evaluation, the types of evaluation questions, methodologies guidance, potential study designs, template evaluation plans, examples of key outcomes, and how evaluation results should be used and disseminated. PEPFAR should support a range of appropriate methodologies for program evaluation, including mixed qualitative and quantitative methods, and should shift emphasis from probability designs to plausibility designs that provide valid evidence of impact.
    - To allow for some comparability across countries and programs, OGAC and HQ technical working groups should, with input from country teams, strategically plan and coordinate a subset of evaluations within programmatic areas that include (but are not limited to) a minimum of centrally-identified and -defined outcome measures and methodologies.
    - Within PEPFAR-supported evaluation activities there should be an emphasis on the use of in-country local expertise to enhance capacity building for program evaluation and contribute to country ownership.
- For both program monitoring and evaluation OGAC should continue its work on defining and developing measures to assess progress in the currently under-measured areas of country ownership, sustainability, gender, policy, capacity building, and technical assistance.

<u>Further considerations for implementation of Recommendation 11-1B (Research):</u>

- OGAC should clearly define what activities and methodologies will be included under the umbrella of PEPFAR-supported research as distinguished from program evaluation.
- OGAC should draw on input from implementing agencies, mission teams, partner countries, implementing partners, the Scientific Advisory Board, and other expert consultations to identify and articulate research priorities and appropriate research methodologies. The research proposals and funding mechanisms should be designed to ensure that these priorities are met and methodologies are applied through RFAs and other investigator-driven research proposals as well as through targeted solicitations of research in gap areas not met through open requests.
- Given PEPFAR's legislative and programmatic objectives to support research that assesses program quality, effectiveness, and population-based impact; optimizes service delivery; and contributes to the global evidence base on HIV/AIDS interventions and program implementation, at the time of this evaluation the committee identified the following gaps in PEPFAR's research activities:
    - Behavioral and structural interventions, especially in areas such as prevention, gender, nonclinical and OVC care and support, and treatment retention and adherence. These research activities should employ appropriate methodologies

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and study designs without being unduly limited to random assignment designs.
  - Costs, benefits, and feasibility of integrating gender-focused programs with clinical and community-based activities.
  - Health systems strengthening interventions across the WHO building blocks, with a prioritized goal of determining setting- and system-specific feasibility, effectiveness, quality of services, and costs for innovative models.
- To contribute to country ownership, PEPFAR should facilitate in-country local participation and research capacity building through simplified, streamlined, and transparent application and review processes that encourage submissions from country-based implementing partners and researchers.

Further considerations for implementation of Recommendation 11-1C (Knowledge transfer and dissemination):

- The knowledge created within PEPFAR that should be more widely documented and disseminated includes program monitoring data, financial data, research results, evaluation outcomes, best practices, and informal knowledge such as implementation experience, lessons learned, and other information.
- To institutionalize internal and external knowledge transfer and learning, PEPFAR should develop appropriate systems and processes for the most needed types and scale of knowledge transfer. To achieve this, PEPFAR should draw on broad stakeholder input to assess the strengths and weaknesses in current processes and to identify needs and opportunities for improved knowledge transfer.
- PEPFAR should invest in innovative mechanisms and technology to facilitate knowledge transfer across partner countries and implementing partners. Mechanisms currently used successfully on a small scale and an ad hoc basis could be more formally scaled up across PEPFAR. OGAC should also look to other organizations with wide geographic reach and organizational complexity, such as multi-country PEPFAR implementing partners, other large global health initiatives, and global corporations, for models of successful knowledge transfer systems.
- OGAC should develop a policy for data sharing and transparency that facilitates timely access to PEPFAR-created knowledge for analysis and evaluation. The purpose of this policy would be to ensure that, within a purposefully and reasonably defined scope, specified program monitoring data and financial data, evaluation outcomes, and research data and results generated with PEPFAR support by contractors, grantees, mission teams, and USG agencies be made available to the public, research community, and other external stakeholders. OGAC and the PEPFAR implementing agencies should consult with both internal and external parties who would be affected by this policy to help identify the data that are most critical for external access and that can be reasonably subject to data sharing requirements, as well as to help develop feasible mechanisms to implement a data sharing policy.

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- For routinely collected financial and program monitoring data, a limited set of essential data should be identified and made available for external use in a timely way.
- Evaluation and research reports and publications using data collected through PEPFAR-supported programs should be tracked and made available in a publically accessible central repository. U.S. government agencies with similar repositories can be considered as models.
- For research data and other information that is expressly generated for new knowledge, the policy should respect time-bound exclusivity for the right to engage in the publication process, yet also ensure the timely availability of data, regardless of publication, for access and use by external evaluators and researchers. OGAC should look to U.S. government agencies with similar research data policies as models.
- In developing the policy and specifying the scope of data to be included, several key factors and potential constraints that can affect the implementation of the policy will need to be addressed. In particular, these include patient and client information confidentiality; the financial resources, personnel, and time needed to make data available; and issues of data ownership, especially in the context of increasing responsibility in partner countries and provision of PEPFAR support through country systems or through activities and programs supported by multiple funding streams.

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Appendix A

Statement of Task

In a two-phased process, an ad hoc committee will undertake the second phase to conduct the assessment/evaluation of HIV/AIDS programs implemented under the Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 and issue a report to the U.S. Congress on the committee's findings and recommendations in 2012. In conducting the evaluation, the committee will follow the approach developed in the first phase, described in the IOM/NRC report, *Strategic Approach to the Evaluation of Programs Implemented Under the Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.*

The congressionally-mandated tasks are an assessment of the performance of United States-assisted global HIV/AIDS programs and an evaluation of the impact on health of prevention, treatment, and care efforts that are supported by United States funding, including multilateral and bilateral programs involving joint operations.[1]

Further, Congress asked that the IOM study include the following as part of its evaluation:

(i) an assessment of progress toward prevention, treatment, and care targets;
(ii) an assessment of the effects on health systems, including on the financing and management of health systems and the quality of service delivery and staffing;
(iii) an assessment of efforts to address gender-specific aspects of HIV/AIDS, including gender-related constraints to accessing services and addressing underlying social and economic vulnerabilities of women and men;
(iv) an evaluation of the impact of treatment and care programs on 5-year survival rates, drug adherence, and the emergence of drug resistance;
(v) an evaluation of the impact of prevention programs on HIV incidence in relevant population groups;
(vi) an evaluation of the impact on child health and welfare of interventions authorized under the Act on behalf of orphans and vulnerable children;
(vii) an evaluation of the impact of programs and activities authorized in the Act on child mortality; and
(viii) recommendations for improving the HIV/AIDS programs implemented under the US Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

Sponsor: U.S. Department of State

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[1] Note: "Joint operations" has been interpreted as per instruction from Senate Foreign Relations and OGAC headquarters staff as limiting multilateral program evaluations to only those in which the multilateral programs are actually jointly executed with bilateral programs; other multilateral programs will be excluded.

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Appendix B

Recommendations[1]

PREVENTION

Recommendation 5-1: To contribute to sustainable management of the HIV epidemic in partner countries, PEPFAR should support a stronger emphasis on prevention. The prevention response should prioritize reduction of sexual transmission, which is the primary driver of most HIV infections, while maintaining support for interventions targeted at other modes of transmission. The response should incorporate an approach balanced among biomedical, behavioral, and structural interventions that is informed by epidemiological data and intervention effectiveness evidence. PEPFAR should support advances in prevention science to expand the availability of effective interventions where knowledge is lacking.

Further considerations for implementation of this recommendation:

- PEPFAR has made a commitment to overarching goals for prevention and for achieving an AIDS-Free Generation, but this does not constitute a long-term prevention strategy that clearly states prevention objectives and the pathways to achieving them. The following elements will be critical for a more comprehensive strategy to achieve successful execution of prevention programs:
    - PEPFAR should continue to enhance its efforts to involve partner country stakeholders and incorporate country-specific epidemiology, context, and priorities in planning appropriately-matched prevention programs that achieve a balanced approach to HIV prevention across the available modalities. To provide greater technical and operational clarity, OGAC[2] should provide mechanisms to support the development, implementation, and monitoring of comprehensive prevention portfolios; including how to determine what populations need which directed prevention activities in which settings. Areas of prevention where current interventions are successful and effective, such as PMTCT, should be continued and scaled up to ensure access, coverage, and quality. As new PEPFAR-supported

[1] The recommendation numbers represent the chapters in which the recommendations appear and their order within each chapter.

[2] It is the committee's intent that actions recommended to be taken by OGAC should be carried out through PEPFAR's interagency coordination mechanism, which involves not only the OGAC staff but also the leadership and technical staff of the U.S. government implementing agencies.

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prevention activities are adopted, OGAC should communicate their objectives and the methods for introducing or scaling up with specified populations.

- OGAC should improve mechanisms to collect and incorporate evidence on the effectiveness of prevention activities implemented in partner countries. The key components for future assessment and evaluation of HIV prevention should include need, coverage of need, quality of services provided, and behavioral and epidemiological outcomes. OGAC should provide clearly defined process and outcome measures as well as impact assessment methods to evaluate progress.
- PEPFAR's prevention strategy should include balanced support for innovation, research, and evaluation to contribute to the evolving evidence base and advance understanding of the effectiveness of interventions within all prevention modalities. To define and ensure this balance, OGAC should, through its existing mechanisms, convene and use expertise spanning behavioral, structural, and biomedical prevention intervention approaches. PEPFAR-supported research and evaluation activities should employ appropriate methodologies and study designs, without unduly emphasizing random assignment designs. PEPFAR should support innovations in prevention science methodologies where needed to achieve its programmatic research aims (see also Recommendation 11-1).

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CARE AND TREATMENT

Recommendation 6-1: To improve the implementation and assessment of non-clinical care and support programs for adults and children, including programs for orphans and vulnerable children,[3] the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.

Further considerations for implementing this recommendation (Chapter 6):

- Outcomes for consideration for OGAC's guidance should reflect the aims of care and support programs, which are to optimize quality of life, promote health, slow the progression of AIDS, and reduce HIV-related complications and mortality.
- To enable this shift to a more outcomes-oriented approach, partner countries will need support and assistance to prioritize outcomes and targeting of services. PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to assess country-specific needs and select a subset of the core key outcomes to focus on when planning, selecting, and developing evidence-informed activities and programs for implementation.
- OGAC should provide general guidance for country programs on continuous program evaluation and quality improvement to measure and monitor achievement of the key outcomes. This may include, for example, template evaluation plans and methodological guidance. To allow for comparability across countries and programs, evaluation plans should include (but not be limited to) the defined indicators or other measures of the core key outcomes. Evaluations should emphasize the use of in-country local expertise (e.g., local implementing partners/subpartners and local academic institutions) to enhance capacity building and contribute to country ownership. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)
- PEPFAR should develop a system for active dissemination and sharing of evaluation outcomes and best practices both within and across countries that is driven as much by country-identified needs for information as by opportunities for exchange of information identified by headquarters-level leadership and Technical Working Groups. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)

Recommendation 6-2: To contribute to sustainable care and treatment programs in partner countries, PEPFAR should build on its experience and support efforts to develop, implement, and scale up more effective and efficient facility- and community-based service delivery models for the continuum of adult and pediatric testing, care, and treatment. These efforts

[3] The discussion of OVC care leading to this aspect of this recommendation can be found in Chapter 7 and the parallel recommendation 7-1.

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should aim to enhance equitable access, improve retention, increase clinical and laboratory monitoring, ensure quality, and implement cost efficiencies.

Further considerations for implementation of this recommendation:

- This recommendation should be implemented in coordination with recommendations and considerations discussed in Chapter 9, Health Systems Strengthening.
- PEPFAR should develop a system for active dissemination and sharing of best practices in service delivery both within and across countries. (See also recommendation for PEPFAR's Knowledge Management in Chapter 11.)

Recommendation 6-3: To assess PEPFAR-supported HIV care and treatment programs and to evaluate new service delivery models, the Office of the U.S. Global AIDS Coordinator should support an enhanced, nested program monitoring effort in which additional longitudinal data on core outcomes for HIV-positive adults and children enrolled in care and treatment are collected and centrally reported from a coordinated representative sample across multiple countries and implementing partners.

Further considerations for implementation of this recommendation:

- This activity would serve as a targeted, nested evaluation within routine program monitoring systems to allow for long-term operational assessment of performance and outcomes for care and treatment, across a representative sample of PEPFAR-supported programs. The aim would be to focus on key areas for evaluation and improvement of programs going forward, including as PEPFAR supports innovations in service delivery and as PEPFAR-supported programs transition to new models of implementation.
- Data collected and reported for this sample should be harmonized with existing data collection whenever possible, including data already collected by implementing partners but not centrally reported (for example, see the discussion of Tier 3 data in the implementation considerations for Recommendation 11-1A). Collaborative opportunities may be feasible with existing or new large-scale national and multicountry samples.
- This data collection effort should be designed by first identifying and prioritizing the key questions that require longitudinal data and then focusing on relevant key outcomes with measures that are standardized across the sample. Priorities should include core outcomes related to clinical care and treatment, including adherence and retention; outcomes related to the reduction of HIV transmission through biomedical and behavioral prevention interventions for people living with HIV; quality measures; and program measures, such as the costs of services, that can help inform strategies for efficiencies, sustainable management, and resource planning for the trajectory of need.
- There may also be opportunities for an established data collection effort of this kind to serve as a synergistic platform for targeted implementation research studies in subset samples to assess innovations and advance best practices with maximal readiness for translation for scale-up.

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- In addition to implementing this approach prospectively, OGAC should explore working with and coordinating Track 1.0 partners to pool data for retrospective outcome analyses.

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CHILDREN AND ADOLESCENTS

Recommendation 7-1: To improve the implementation and assessment of nonclinical care and support programs for adults[4] and children, including programs for orphans and vulnerable children, the Office of the U.S. Global AIDS Coordinator should shift its guidance from specifying allowable activities to instead specifying a limited number of key outcomes. The guidance should permit country programs to select prioritized outcomes to inform the selection, design, and implementation of their activities. The guidance should also specify how to measure and monitor the key outcomes.

Further considerations for implementing this recommendation:

- For orphans and vulnerable children, the new OVC guidance and the ongoing developments for program evaluation already represent advances in addressing some of the challenges identified in this evaluation; this recommendation and considerations are intended to reinforce and further inform and support progress in achieving PEPFAR's goals for children and adolescents.
- Outcomes for consideration should be linked to the aims of OVC programs, and therefore could include, for example, increased rates of staying in school, decreased excessive labor, reduced rates of exposure to further traumas, increased immunization completion, and increased coverage of HIV testing and treatment. In continuing to focus on supporting developmentally-informed programs, consideration should be given to identifying appropriate core outcomes for different age groups and for achieving developmental milestones. The program evaluation indicator development process currently being carried out in PEPFAR already offers a reasonable opportunity to link measures to core target outcomes for OVC programs.
- The core key outcomes should also include quality of services and measures to reflect the potential sustainability of programs.
- To enable a shift to a more outcomes-oriented implementation model, partner countries will need support to define their prioritized outcomes and their target population and then conduct baseline assessments so that progress toward outcomes can be measured.
- PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to assess country-specific needs and select a subset of the core key outcomes to focus on when planning, selecting, and developing evidence-informed activities and programs for implementation
- Prioritization is critical in the context of large need and finite resources. Planning with partner countries, PEPFAR should improve targeted coverage and quality of supported services for affected children and adolescents by not only prioritizing outcomes and activities but also by more explicitly, clearly, and narrowly defining the eligibility for PEPFAR-supported services. This prioritization should be based on an assessment of country-specific needs with a process that consistently applies considerations and criteria across countries and programs. This

[4] The discussion of nonclinical care and support for adults leading to this aspect of this recommendation can be found in Chapter 6 and the parallel Recommendation 6-1.

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prioritization should be done in coordination across program areas that address the needs and vulnerabilities of children and adolescents. These areas, which may target and serve a broader eligible population of children and adolescents than is determined for specific OVC programs, include care and treatment, PMTCT, other prevention services, and gender programs.

- To improve the targeted coverage and sustainability for children and adolescents, PEPFAR and its implementing partners should continue to enhance services through existing systems and infrastructure and support national governments to expand social support services and the workforce to meet the health, education, and psychosocial needs of affected children and adolescents.
- OGAC should provide general guidance for country programs on continuous program evaluation and quality improvement to measure and monitor achievement of the key outcomes. This may include, for example, template evaluation plans and methodological guidance. To allow for comparability across countries and programs, evaluation plans should include (but not be limited to) the defined indicators or other measures of the core key outcomes. Evaluations should emphasize the use of in-country local expertise (e.g., local implementing partners/subpartners and local academic institutions) to enhance capacity building and contribute to country ownership. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)
- PEPFAR should develop a system for active dissemination and sharing of evaluation outcomes and best practices both within and across countries that is driven as much by country-identified needs for information as by opportunities for exchange of information identified by headquarters-level leadership and Technical Working Groups. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)

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GENDER

Recommendation 8-1: To achieve PEPFAR's stated aim of addressing gender norms and inequities as a way to reduce HIV risk and increase access to HIV services, the Office of the U.S. Global AIDS Coordinator (OGAC) should develop and clearly state objectives and desired outcomes for gender-focused efforts. OGAC should issue guidance for how to operationalize, implement, monitor, and evaluate activities and interventions to achieve these objectives.

Further considerations for implementation of this recommendation:

- The objectives and guidance should be informed by the available evidence on how gender dynamics influence both HIV outcomes and the implementation of activities and services, as well as evidence on intervention effectiveness from the existing knowledge base, expert consultation, and experiences from pilot programs in partner countries.
- OGAC's guidance on gender-focused efforts should encompass programs specific to addressing gender norms and inequities and efforts to incorporate gender-focused objectives within prevention, care, and treatment activities.
- The development of guidance for gender-focused efforts should take advantage of lessons learned from the processes used for PEPFAR's recent updates to guidance for prevention and OVC programs.
- PEPFAR U.S. mission teams should work with partner country stakeholders and implementers to strategically plan, select, develop, implement, and measure evidence-informed activities and programs to achieve the gender-focused objectives.
- Strategic implementation of gender-focused efforts will require strong technical leadership, and as such additional capacity in gender expertise will be needed at both the OGAC and U.S. mission team levels. If gender efforts are to be appropriately integrated into all the aspects of service delivery and effectively implemented, this capacity cannot be limited to gender-specific experts but should also be incorporated as part of the core competencies of Mission Team staff across PEPFAR's programmatic areas.
- As an engaged participant with other global and partner country stakeholders, through its implementation PEPFAR should contribute to generating evidence to inform gender-focused efforts through research and evaluation. (See also recommendations for PEPFAR's knowledge management in Chapter 11.)

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STRENGTHENING HEALTH SYSTEMS

Recommendation 9-1: To support the delivery of HIV-related services, make progress toward sustainable management of the HIV response, and contribute to other health needs, PEPFAR should continue to implement and leverage efforts that have had positive effects within partner country health systems. PEPFAR should maintain efforts in all six building blocks but have a concerted focus on areas that will be most critical for sustaining the HIV response, especially workforce, supply chain, and financing.

Further considerations for implementation of this recommendation:

- An important focus for PEPFAR's future activities and policies should be support for partner country capacity to locally produce and retain clinical, nonclinical, and management professionals whose training and scope of practice are appropriate and optimized for the tasks needed. MEPI and NEPI have provided a starting point for the training of physicians and nurses; however the training of associate clinicians and other cadres will also be critical to sustainable management of the response. In addition, PEPFAR needs to augment its efforts to build partner country capacity to track the placement of trained workers, to promote retention, and to develop long term human resources plans. (See also the discussion and recommendation for capacity building in Chapter 10 on Progress Toward a Sustainable Response.)
- Building on the progress made through the public-private partnership with SCMS, PEPFAR should enhance and expand efforts with a greater focus on capacity building for accountable supply chain management in partner countries. The aim of this improved capacity should be to gradually shift to local or regional leadership, coordination, and management to ensure a reliable supply chain for essential medicines and commodities.
- Financing and leadership and governance are particularly critical for sustainable management of the HIV response, and this area is addressed in Recommendation 10-1 (see Chapter 10).
- To contribute to the knowledge base for health systems strengthening, PEPFAR should include this area in its research and evaluation agenda and its knowledge dissemination efforts. (See also recommendations for PEPFAR's Knowledge Management in Chapter 11.)

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TRANSITIONING TO A SUSTAINABLE RESPONSE IN PARTNER COUNTRIES

Recommendation 10-1: To contribute to a country-owned and sustainable HIV response, the Office of the U.S. Global AIDS Coordinator should develop a comprehensive plan for long-term capacity building in partner countries. The plan should target four key areas: service delivery, financial management, program management, and knowledge management.

Further considerations for implementation of this recommendation:

- In all four key areas, OGAC should invest more resources in initiatives for long-term capacity building and infrastructure development such as strengthening in-country academic institutions, degree programs, and long-course trainings, to improve in-country capacity and to accelerate progress toward country ownership and sustainability. These investments should foster the placement and retention of trained personnel in partner countries.
- These initiatives should be monitored routinely at the country level to assess progress and identify necessary modifications. Special periodic multi-country studies could be used to evaluate the outcome and impact of the PEPFAR capacity building initiative. To achieve this, OGAC should, using input from country programs, identify milestones towards achieving specified goals, define core metrics to assess capacity building efforts, encourage innovative approaches through pilot initiatives and develop tools to help country programs monitor and evaluate these efforts, and encourage innovative approaches through pilot initiatives.

Recommendation 10-2: Building on the Partnership Framework implementation process, PEPFAR should continue to work with partner country governments and other stakeholders to plan for sustainable management of the response to HIV. PEPFAR should support and participate in comprehensive country-specific planning that includes the following:

- **Ascertain the trajectory of the epidemic and the need for prevention, care and treatment, and other services.**
- **Identify gaps, unmet needs, and fragilities in the current response.**
- **Estimate costs of the current response and project resource needs for different future response scenarios.**
- **Develop plans for resource mobilization to increase and diversify funding, including internal country-level funding sources.**
- **Encourage and participate in country-led, transparent stakeholder coordination and sharing of information related to funding, activities, and data collection and use.**
- **Establish and clearly articulate priorities, goals, and benchmarks for progress.**

Further considerations for implementing this recommendation:

- PEPFAR is not alone in trying to achieve locally-led, sustainable health and development objectives. Contributing stakeholders, including partner countries, will need mutually-agreed, principle-based resource allocation to achieve a

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strategic and ethical balance among the priorities of maintaining current coverage, expanding to meet existing unmet needs, and increasing coverage eligibility. Having processes in place to support this arduous decision making is a critical part of achieving sustainable HIV programs and sustainable management of the HIV epidemic in partner countries.

- Partners in developing resource mobilization plans and potential sources for more diverse funding and other resources could include national and subnational governments other bilateral donors, multilateral agencies, global and regional development banks, and private sector consultants.
- There may be learning opportunities at both headquarters and country level for PEPFAR and other USG entities involved in development assistance to exchange strategies, best practices, and lessons learned for sustaining development objectives.

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PEPFAR'S KNOWLEDGE MANAGEMENT

Recommendation 11-1: The Office of the U.S. Global AIDS Coordinator (OGAC) should develop a comprehensive knowledge management framework, including a program monitoring and evaluation strategy, a prioritized and targeted research portfolio, and systems for knowledge dissemination. This framework should adapt to emerging needs to assess PEPFAR's models of implementation and contribution to sustainable management of the HIV response in partner countries. This knowledge management framework will require that PEPFAR implement and strategically allocate resources for the following:

A. To better document PEPFAR's progress and effectiveness, OGAC should refine its program monitoring and evaluation strategy to streamline reporting and to strategically coordinate a complementary portfolio of evaluation activities to assess outcomes and effects that are not captured well by program monitoring indicators. Efforts should support innovation in methodologies and measures where needed. Both monitoring and evaluation should be specifically matched to clearly articulated data sources, methods, and uses at each level of PEPFAR's implementation and oversight.

B. To contribute to filling critical knowledge gaps that impede effective and sustainable HIV programs, OGAC should continue to redefine permitted research within PEPFAR by developing a prioritized portfolio with articulated activities and methods. The planning and implementation process at the country and program level should inform and be informed by the research portfolio, which should focus on research that will improve the effectiveness, quality, and efficiency of PEPFAR-supported activities and will also contribute to the global knowledge base on implementation of HIV/AIDS programs.

C. To maximize the use of knowledge created within PEPFAR, OGAC should develop systems and processes for routine, active transfer and dissemination of knowledge both within and external to PEPFAR. As one component, OGAC should institute a data-sharing policy, developed through a consultative process. The policy should identify the data to be included and ensure that these stipulated data and results generated by PEPFAR or through PEPFAR-supported activities are made available in a timely manner to PEPFAR stakeholders, external evaluators, the research community, and other interested parties.

<u>Further considerations for implementation of Recommendation 11-1A: Program monitoring and evaluation:</u>

- OGAC's current tiered program monitoring indicator reporting structure should be further streamlined to report upward only those indicators essential at each PEPFAR level:

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    - Tier 1: A small set of core indicators, fewer than the current 25, to be reported to central HQ level. These data should be used to monitor performance across PEPFAR as a whole, for congressional reporting, and to document trends; as such these indicators should remain consistent over time. Whenever possible and appropriate, these indicators should be harmonized with existing global indicators and/or national indicators; therefore some centrally reported indicators will reflect PEPFAR's contribution rather than aiming to measure direct attribution.
    - Tier 2: A larger menu of indicators defined in OGAC guidance, from which a subset are selected for their applicability to country programs to be reported by implementing partners to the U.S. mission teams but not routinely reported to HQ. These data should be used to monitor the effectiveness of the in-country response and support mutual accountability with partner countries and their citizens. These data could be considered for occasional centralized use to inform special studies or respond to congressional requests but aggregation and comparability across countries may be limited in this tier as all mission teams may not collect the same data.
    - Tier 3: Indicators selected by implementing partners to monitor and manage program implementation and effectiveness that are not routinely reported to mission teams. Implementing partners should select appropriate indicators defined in OGAC guidance and augment this with other indicators as needed for their programs. Implementing partners should work with mission teams in developing their program monitoring plans with selected indicators. Mission teams should provide oversight and technical assistance to ensure implementation of these plans and to promote local quality data collection, use, and mutual accountability. Although not routinely reported, some of these data could be considered for occasional country-level and centralized use.
    - OGAC should create mechanisms for implementing partners, mission teams, and agency headquarters to mutually contribute to a periodic review across all tiers of indicator development, applicability, and utility and to make modifications if necessary.
    - Tier 1 indicators should be harmonized whenever possible and appropriate with existing global indicators and/or national indicators. For indicators that are not routinely reported centrally (Tiers 2 and 3), country program planning should facilitate alignment of indicator selection and data collection with partner country HIV monitoring and health information systems.
- OGAC should complement program monitoring with a unified evaluation portfolio that includes periodic program evaluation at the PEPFAR country program and implementing partner levels to assess process, progress, and outcomes as well as periodic impact evaluations at the country, multi-country, and headquarters levels.
    - OGAC evaluation guidance should provide information about prioritizing areas for evaluation, the types of evaluation questions; methodologies

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guidance, potential study designs, template evaluation plans, examples of key outcomes, and how evaluation results should be used and disseminated. PEPFAR should support a range of appropriate methodologies for program evaluation, including mixed qualitative and quantitative methods, and should shift emphasis from probability designs to plausibility designs that provide valid evidence of impact.

- To allow for some comparability across countries and programs, OGAC and HQ technical working groups should, with input from country teams, strategically plan and coordinate a subset evaluations within programmatic areas that include (but are not limited to) a minimum of centrally identified and defined outcome measures and methodologies.
- Within PEPFAR-supported evaluation activities there should be an emphasis on the use of in-country local expertise to enhance capacity building for program evaluation and contribute to country ownership.

- For both program monitoring and evaluation OGAC should continue its work on defining and developing measures to assess progress in the currently under-measured areas of country ownership, sustainability, gender, policy, capacity building and technical assistance.

<u>Further considerations for implementation of Recommendation 11-1B: Research</u>

- OGAC should clearly define what activities and methodologies will be included under the umbrella of PEPFAR-supported research, as distinguished from program evaluation.
- OGAC should draw on input from implementing agencies, mission teams, partner countries, implementing partners, the Scientific Advisory Board, and other expert consultations to identify and articulate research priorities and appropriate research methodologies. The research proposals and funding mechanisms should be designed to ensure that these priorities are met and methodologies are applied through RFAs and other investigator-driven research proposals as well as through targeted solicitations of research in gap areas not met through open requests.
- Given PEPFAR's legislative and programmatic objectives to support research that assesses program quality, effectiveness, and population-based impact; optimizes service delivery; and contributes to the global evidence base on HIV/AIDS interventions and program implementation, at the time of this evaluation the committee identified the following gaps in PEPFAR's research activities:
  - Behavioral and structural interventions, especially in areas such as prevention, gender, nonclinical and OVC care and support, and treatment retention and adherence. These research activities should employ appropriate methodologies and study designs, without being unduly limited to random assignment designs.
  - Costs, benefits, and feasibility of integrating gender-focused programs with clinical and community-based activities.
  - Health systems strengthening interventions across the WHO building blocks, with a prioritized goal of determining setting- and system-specific feasibility, effectiveness, quality of services, and costs for innovative models.

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- To contribute to country ownership, PEPFAR should facilitate in-country local participation and research capacity building through simplified, streamlined, and transparent application and review processes that encourage submissions from country-based implementing partners and researchers.

Further considerations for implementation of Recommendation 11-1C: Knowledge transfer and dissemination

- The knowledge created within PEPFAR that should be more widely documented and disseminated includes program monitoring data, financial data, research results, evaluation outcomes, best practices, and informal knowledge such as implementation experience, lessons learned, and other information.
- To institutionalize internal and external knowledge transfer and learning, PEPFAR should develop appropriate systems and processes for the most needed types and scale of knowledge transfer. To achieve this, PEPFAR should draw on broad stakeholder input to assess the strengths and weaknesses in current processes and to identify needs and opportunities for improved knowledge transfer.
- PEPFAR should invest in innovative mechanisms and technology to facilitate knowledge transfer across partner countries and implementing partners. Mechanisms currently used successfully on a small scale and an ad hoc basis could be more formally scaled up across PEPFAR. OGAC should also look to other organizations with wide geographic reach and organizational complexity, such as multi-country PEPFAR implementing partners, other large global health initiatives, and global corporations, for models of successful knowledge transfer systems.
- OGAC should develop a policy for data sharing and transparency that facilitates timely access to PEPFAR-created knowledge for analysis and evaluation. The purpose of this policy would be to ensure that, within a purposefully and reasonably defined scope, specified program monitoring data and financial data, evaluation outcomes, and research data and results generated with PEPFAR support by contractors, grantees, mission teams, and USG agencies be made available to the public, research community, and other external stakeholders. OGAC and the PEPFAR implementing agencies should consult with both internal and external parties who would be affected by this policy to help identify the data that are most critical for external access and that can be reasonably subject to data sharing requirements, as well as to help develop feasible mechanisms to implement a data sharing policy.
    - For routinely collected financial and program monitoring data, a limited set of essential data should be identified and made available for external use in a timely way.
    - Evaluation and research reports and publications using data collected through PEPFAR-supported programs should be tracked and made available in a publicly accessible central repository. U.S. government agencies with similar repositories can be considered as models.
    - For research data and other information that is expressly generated for new knowledge, the policy should respect time-bound exclusivity for the right to

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engage in the publication process, yet also ensure the timely availability of data, regardless of publication, for access and use by external evaluators and researchers. OGAC should look to U.S. government agencies with similar research data policies as models.

- In developing the policy and specifying the scope of data to be included, several key factors and potential constraints that can affect the implementation of the policy will need to be addressed. In particular, these include patient and client information confidentiality; the financial resources, personnel, and time needed to make data available; and issues of data ownership, especially in the context of increasing responsibility in partner countries and provision of PEPFAR support through country systems or through activities and programs supported by multiple funding streams.

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Appendix C

Evaluation Methods

OVERVIEW

The evaluation employed a mix of methods and layers of investigation and analysis involving a range of primary and secondary data sources, taking into account the methodological design considerations described in Chapter 2. This included mapping of investments using financial data, assessing trends over time using program monitoring indicators and clinical data from OGAC and PEPFAR implementing partners, benchmarking progress against stated programmatic targets and goals, reviewing extensive documents, and analyzing primary data collected through more than 400 semi-structured interviews with a range of stakeholders on visits to 13 PEPFAR partner countries, at the U.S. headquarters of PEPFAR, and at other institutions and multilateral agencies.

Primary and secondary data were analyzed, using appropriate methodologies, by the members of the evaluation committee, the Institute of Medicine (IOM) study staff, and consultants with specialized knowledge in both qualitative and quantitative methodologies. The committee, staff, and consultants took steps to assess and ensure the quality and completeness of the data used for the evaluation, and took these factors into account during data interpretation. The methods used to assure the quality of the primary data collected and the secondary data received through data requests are described in more detail in the sections that follow. When data analyzed externally were used, the committee, staff, and consultants reviewed and assessed the methodology and quality of the data.

The mandate of the committee was to draw conclusions and make recommendations across the whole program. Wherever possible, data were gathered and data analyses and interpretation were conducted and presented across all 31 PEPFAR partner countries defined as the focus of the evaluation; however, only very limited data were comparable and comprehensive across all countries. In order to not limit the committee's findings to data consistently available across the whole of the program and all of these countries, which would have been a significant constraint, the evaluation draws on subsets of countries, programmatic areas, or intervention components implemented within PEPFAR for which sufficient data could be gathered to contribute to the assessment. Therefore, data presentations and analyses representing these subsets were interpreted with care to inform conclusions about the whole of the program. For example, analysis of country visit interview data was limited to the countries selected for visits by the committee. In addition, some analyses drew on existing data sources that are only

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available for some countries, programs, and partners, such as Track 1.0 partner data. Some evaluation questions were most applicable only for a subset of countries, such as countries with concentrated epidemics driven by injecting drug use. Finally, the time and resources available limited the scope of some analyses, such as those involving review of Country Operational Plans for which the sheer volume of the documents over all countries and years limited the feasibility of comprehensive review across all countries. Throughout the report, where data analyses that do not represent the whole of the program are presented, the scope of these data is described. Because the committee was not charged to draw conclusions or make recommendations at the level of specific countries, partners, or programs, analyses of data from subsets of countries or partners are presented in a manner designed to maintain anonymity.

By applying this mix of methods and layers of investigation and analysis using a range of available primary and secondary data sources, the committee arrived at findings that could be triangulated to draw conclusions about the performance and impact of PEPFAR, even when any one data source was not sufficient or any one methodological approach was not feasible. Building on the interpretation of the available data, the conclusions and recommendations presented in this report represent the consensus reached through the deliberations of the evaluation committee. Over the course of the evaluation, the full committee met six times in person, with participation of the staff and consultants. One additional meeting was conducted using Web-based conferencing. In addition, working groups within the committee that were focused on specific content areas held additional meetings by teleconference as needed for ongoing deliberations as well as for data analysis and interpretation. These committee activities were augmented by ongoing communications by telephone and e-mail among the committee members, staff, and consultants.

The following sections describe some of the overarching processes the committee used to frame and shape the evaluation. Subsequent, more detailed sections describe the methods for each of the data sources used in the evaluation.

Development of Evaluation Questions and Mapping of Data Sources

Through working groups comprised of a subset of committee members, the evaluation committee identified proposed evaluation questions based on major content areas, the Statement of Task (see Appendix A), the Program Impact Pathway (PIP) framework (see Chapter 2), and the preliminary work reported in the *Strategic Approach* (IOM and NRC, 2010). Once the working groups established their initial questions and subquestions, IOM staff and consultants developed and provided to the committee the following information pertaining to each of the more than 300 questions:

- The domains of the PIP to which the question belonged (i.e., input, activity, output, outcome, or impact)
- The type of data necessary to answer the question (e.g., financial data; program monitoring, surveillance, and clinical data; interview data; literature and document review)
- A description of potential data sources that had been identified
- Limitations associated with the data sources, such as issues related to availability, feasibility of accessing the data, and any other relevant issues that could inform considerations for formulating data requests and for the utility of the data

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Mapping of Potential Data Sources

The IOM staff and consultants carried out an extensive data-mapping effort, expanding on the preliminary work conducted during the strategic planning and operational planning phases. The data-mapping process relied on document review, stakeholder interviews, information obtained from preliminary data requests, and information gathered during 2 pilot country visits. The data mapping served to assess the feasibility of collecting and using data from each source, taking into consideration the burden that data requests would place on each source's resources and staff time. In addition, this data mapping assessed whether data from each source would require new data analysis in order to answer the evaluation questions posed by the committee.

The categories of available data sources that were mapped and ultimately used for the evaluation included financial data; program monitoring, surveillance, and clinical data; interview data; and literature and document review. The sources included central OGAC data, data from multilateral organizations, data from implementing partners, and data from publicly available documents and other sources. The data sources used for the evaluation are described in more detail in subsequent sections of this appendix.

Priority Evaluation Questions

Committee members then worked with IOM staff and consultants to finalize a set of priority evaluation questions (PEQs) based on relevance to the Statement of Task and related evaluation considerations, relative importance among subquestions, and feasibility of answering each question with the time, resources, and data available. The ultimate relative contribution of data sources to different content areas and evaluation questions, and, ultimately, to the committee's conclusions and recommendations, varied depending on availability and appropriateness.

Overview of Data Collection

A summary of the data request and data collection processes for each major data source is provided in the sections that follow, along with a description of the analyses for which the data were used.

Requests for interviews and requests for secondary data not readily available publicly were made by the IOM independently, with OGAC and in country Mission Teams serving as a liaison only when necessary. Participation in the evaluation was voluntary. Except when reference is made to existing published materials, findings, examples, and comments are not attributed to individuals and the identities of individuals, programs, partners, and countries are protected.

FINANCIAL DATA

Global Financial Data

To contextualize PEPFAR's financial contribution within the broader donor funding landscape for HIV/AIDS, the committee examined disbursement data on official development assistance for HIV/AIDS as reported to the Organization for Economic Cooperation and Development (OECD) Creditor Reporting System. Disbursements represent the sum of two

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OECD sector codes: STD control including HIV/AIDS and Social mitigation of HIV/AIDS. The committee examined data for the 31 PEPFAR countries that were writing COPs when the IOM evaluation study process began in 2009.

PEPFAR Financial Data: Available, Obligated, and Outlaid

On a quarterly basis, OGAC submits summary financial status reports to Congress on "the allocation, obligation and expenditure of funds appropriated for [PEPFAR]" (PEPFAR, 2012). These reports are publicly available. The committee used the fourth-quarter report from each fiscal year to calculate annual appropriations, obligations, and outlays for the PEPFAR program.

PEPFAR Financial Data: Annual Expenditure Data Calculated from Agency Reporting

In May 2012, in response to a committee data request, IOM consultants received from OGAC PEPFAR funding obligations and outlays for fiscal years (FYs) 2004 through 2011 for all countries receiving PEPFAR funding. Upon review of the data and through clarifications with OGAC, IOM staff and consultants realized that these financial data corresponded to the cumulative amount of funding available, obligated, and outlaid from each budget year rather than the actual annual amount of funding available, obligated, and outlaid. Another request was made to OGAC for funding data that would clearly distinguish funding by budget year and reporting year and would represent actual annual expenditures, regardless of the year in which the money was appropriated or obligated. In July and August 2012, IOM consultants received from OGAC cumulative agency-specific funding for each reporting year. Annual expenditures were derived as described below.

Data Description

OGAC sent IOM consultants 78 Excel spreadsheets containing financial data for the 6 agencies that received PEPFAR funding between FY 2004 and FY 2011:

- United States Agency for International Development (USAID)
- Peace Corps (PC)
- Department of Defense (DOD)
- Department of Labor (DOL)
- Department of State (STATE)
- Department of Health and Human Services (HHS)

With the exception of STATE, each agency reported all of its financial information to OGAC in a consolidated format. STATE, however, reported its PEPFAR funding through 5 distinct offices/bureaus:

- Bureau of African Affairs (AF)
- Bureau of East Asian and Pacific Affairs (EAP)
- Office of the Global AIDS Coordinator (OGAC)
- Bureau of Population, Refugees and Migration (PRM)
- Bureau of Western Hemisphere Affairs (WHA)

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Each file contained cumulative available, obligated, and outlay budget information, by country, corresponding to a single fiscal year's budget. As discussed in Chapter 4, most PEPFAR funding does not have an annual use-or-lose requirement (i.e., unspent funding from one fiscal year can often be carried over to be spent in subsequent years). Therefore, the money spent during a particular year had the potential to come from the budgets of multiple, prior fiscal years.

Consolidating Data into Consistent Files

Each agency provided funding to a different group of PEPFAR countries, many of which received funding from more than one agency. Therefore, each agency's set of budgetary files was first consolidated into a single data file for a total of 10 unique datasets—one set per agency or bureau. Each country's annual funding was retained within each data file to enable potential analyses that would require subgroups of PEPFAR countries based on country attributes. Second, these datasets were harmonized into a single dataset to allow for data to be used together to comprehensively represent PEPFAR spending across agencies, in total and by country.

Documenting Discrepancies, Notes, and Comments

The data extraction process revealed embedded comments within spreadsheet cells and footnotes explaining data nuances; this information was recorded in a separate file. Additionally, some funding numbers changed from one reporting year to the next. Increases in funding amounts were expected over time as more of the funding from a particular fiscal year was expected to be obligated or outlaid. Decreases, however, were not expected from one year to the next; i.e., the amount of available funding from a specific fiscal year budget was not expected to decrease in subsequent reporting years. Therefore, these unexpected changes in the funding data were documented.

For all three of these scenarios—embedded comments, footnotes, or unexpected changes in funding—the following information was recorded corresponding to each instance:

- Agency/Bureau—which agency's spreadsheets contained the comment, footnote, or inconsistency
- Country/Region—the country or region affected by the comment, footnote, or inconsistency
- Reporting Year—the reporting year with the observation
- Budget Year—the year during which the budget was issued
- Comment, footnote, or inconsistency—verbatim comments and footnotes from the spreadsheet; inconsistencies were described as clearly as possible
- Detected by agency or IOM—an indicator variable reflecting whether the comment or footnote was already in the spreadsheet or whether the inconsistency was encountered by IOM staff during the data extraction process

To further assess the most notable discrepancies in the available totals by country by year, these were compiled in a separate spreadsheet and compared from their inception year to the proceeding year across annual reports through 2011. In particular, major discrepancies occurred when the dollar amounts reported as available for a given budget year changed (both increases and decreases were observed) in subsequent reporting years, although one would expect the amount to be a fixed constant for a budget year after that year in which it was made

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available. These discrepancies ranged in magnitude with a maximum of a $214 million difference between two reports for one budget year for one agency. As a result, it was difficult to assess the correct figures for the total amounts made available. Overall, the number of discrepancies and magnitude of changes from year to year diminished in later reporting years, and the same degree of discrepancy was not seen in the reporting of outlays.

Calculation of Annual Expenditures

Once the funding data were completely extracted into a single data file, serial subtractions were performed of each reporting year's cumulative outlay data to obtain the amount of money actually spent (outlaid) during each reporting year, regardless of the fiscal year's budget from which the money came. To get the annual expenditure for within a given fiscal year, all prior year outlays were subtracted from the cumulative total outlays reported for that year. Given the data discrepancies described above, for the calculations for annual expenditures the data from the FY 2011 reports were used for the data for all of the fiscal years to have one consistent source that reflected the most recently available data.

Quality Control

When all of the data had been extracted into consistent data files, an IOM consultant compared all the extracted data files against the raw data files sent from OGAC. The validator worked with the original data extractor and reconciled all inconsistencies uncovered within the extracted data files. This independent validator also verified the serial equations used to calculate the amount of funding spent during each reporting year. The validated datasets were not reconfirmed with OGAC.

Data Presentation

Once all of the data had been validated, IOM consultants imported the data into SAS to generate financial presentations of the annual expenditure over time. These presentations were provided by the consultants to the committee in November 2012.

PEPFAR Financial Data—Planned/Approved Funding for All PEPFAR Countries

Planned/approved funding reflects how OGAC and PEPFAR Mission Teams plan to obligate and outlay funds. Each year, OGAC releases an operational plan for PEPFAR that includes summary budget information regarding the planned and approved use of PEPFAR funding, including which activities will be implemented by which agencies, as determined during the interagency planning process. The operational plans report planned/approved funding for four technical areas that correspond to the primary categories of HIV/AIDS services and systems strengthening efforts: Prevention, Care, Treatment, and Other. PEPFAR funding is planned through budget codes which capture funding information about more specific activities within these categories.

Data Extraction Process

The planned/approved funding was extracted by year and by budget code. Planned/approved funding data were extracted independently by two IOM staff into identical spreadsheets. Each staff member extracted data on total PEPFAR funding by implementing agency and year, as well as total PEPFAR funding by budget code and year.

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Data presentations

The data extraction was validated and IOM consultants converted the data into constant 2010 USD to allow for a consistent interpretation of funding over time. The consultants then generated a final dataset to be used for data presentations showing funding by agency, type of program, and budget code.

PEPFAR Financial Data—Planned/Approved Funding for Subset of 31 Countries

Data on planned/approved funding from the subset of 31 countries that were the focus of this evaluation were gathered through a separate data extraction. These data were used for the committee's analysis of funding by country characteristic.

Data Extraction Process

The planned/approved funding was extracted according to the following classifications:

- By country (31 countries in total)
- By year (FY 2005 through FY 2011, for the years during which a country was completing a COP)
- This funding information was extracted from the following publically available data sources, which were determined to be the most comprehensive across the classifications for the data extraction:
  - FY 2005 through FY 2007—Focus countries only: Operational Plans
  - FY 2008—Focus countries: Operational Plan; non-Focus countries: individual Country Operational Plans (COPs)
  - FY 2009—All countries: individual COPs
  - FY 2010 and FY 2011—All countries: Operational Plans

IOM consultants developed specifications corresponding to the variables necessary for the PEPFAR financial data extraction process and developed dataset specifications for two separate extraction processes. The first data extraction compiled annual, country-specific funding by agency; the second data extraction compiled annual, country-specific funding by technical area and budget code. Data were not extracted by both agency and technical area, but rather either by agency *or* technical area. During the extraction process, any funding corresponding to regions was omitted (e.g., Central America, Central Asia, and Caribbean) and the process was limited to the 31 countries that were preparing COPs at the time this evaluation was initiated. Funding amounts were rounded to the nearest whole dollar.

During the extraction by technical area, some budget codes switched from one technical area to another across reporting years; however, these differences were tracked in an effort to make consistent comparisons over time.

Data Extraction Quality Control

Two IOM consultants extracted the data independently into comparably formatted spreadsheets. Each consultant extracted a spreadsheet of funding data by year, country, and agency, as well as a second spreadsheet by year, country, technical area, and budget code. Once all of the data had been extracted across all budget years, one of the consultants developed a tool

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to compare individual records across datasets and flag inconsistent values. This comparison tool flagged every instance of a record with inconsistent information, whether it corresponded to how the extractors recorded a particular budget code or whether the budget amounts differed. Together, the consultants then reconciled the inconsistent records. Once their datasets matched 100 percent, a third, independent consultant imported the data into SAS and used a random number generator to select 50 (about 4 percent) of the 1,302 records that summarized the financial information by agency. The consultant also randomly selected 80 (about 2 percent) of the 4,123 records that summarized the financial information by budget code and crosschecked these 130 values against the information written in the HQ operational plans and COPs. Note that some of these records corresponded to countries/agencies/budget codes that were not specified during a particular year. Therefore, this selection of records also confirmed that particular combinations of years/countries/agencies/budget codes were not inadvertently incorporated into the datasets. All 130 validation records matched the operational plans exactly, thus, confirming the quality of the data extraction process.

Data Presentations

Once the validation process was complete, IOM consultants generated a final dataset to be used, along with publicly available data from global sources, for data presentations showing PEPFAR funding by HIV prevalence, average funding per person living with HIV, and country income level.

Planned/Approved Funding by Prime Partner

The committee examined planned/approved funding extracted from a range of publically available data sources. The process of extracting and compiling these data was time intensive, so to be feasible within the resources and time available for the study, the committee's analysis had to be limited to a subset of partner countries. The committee chose to compile these data for the same 13 countries purposefully selected for country visits, as described later in this Appendix. Within this subset of countries, the committee was able to compare partner data and planned/approved PEPFAR funding for the focus countries for FY 2004 through FY 2010 and for non-focus countries for FY 2008 through FY 2010.

Data Extraction

Data were extracted according to the following characteristics:

- By country (13 countries in total)
- By year (FY 2004 through FY 2011)
- By prime partner

This funding information was extracted from the following data sources, which were determined to be the most comprehensive data available across the classifications for the data extraction. For FY 2004 to FY 2006, the prime partner funding data were extracted from a Center for Global Development (CGD) dataset in order to present the most complete data consistently for those years. The CGD publicly released this dataset that "was originally obtained from the State Department by the Center for Public Integrity through several Freedom of Information Act requests and a lawsuit against the U.S. Government, settled out of court" (CGD,

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2008). This dataset contains PEPFAR data on country funding obligated to prime partners in focus countries in FYs 2004, 2005, and 2006. Before releasing the dataset, CGD added data on central funding that is obligated from OGAC HQ to partners to implement programs in countries. For FY 2004 and FY 2005, CGD obtained central funding information from the Center for Public Integrity; FY 2006 funding was estimated based on previous funding amounts and the total allocation of PEPFAR funding for focus countries in FY 2006. Partner lists that provide the amount of funding obligated to prime partners within a country are also available on PEPFAR's website. For focus countries, these lists are available for FY 2005 to FY 2008; for non-focus countries, these lists are only available for FY 2008. By comparing most of the PEPFAR partner lists and the CGD dataset for FY 2005 and FY 2006, it appears that the PEPFAR partner lists for 2005 include country and central funding, but the PEPFAR partner lists for 2006 include only country funding. Therefore, the CGD dataset was determined to be the most complete data for FY 2004 to FY 2006 and allowed the presentation of both country and central funding consistently for these years.

For FY 2007 and FY 2008, data were extracted from PEPFAR partner lists. PEPFAR partner lists provide funding amounts but do not include information about the type of funding (i.e., central or country funding). There is no equivalent dataset to the CGD dataset for FY 2007 and FY 2008 so the committee was unable to determine whether the FY 2007 and FY 2008 partner lists report country and central funding, or only country funding.

The only source of partner data for FY 2009 and FY 2010 are the COPs; these data are limited to planned partner funding (not obligations). Since not all partners have been chosen by the time the COPs are submitted, these are incomplete sources of partner funding. For example, 2 percent of total funding data extracted from the FY 2009 COPs was labeled as "To Be Determined", which means that a partner had not yet been chosen or contracted with to provide planned activities.

Two IOM staff members extracted the data independently into identical spreadsheets. After the data extraction, staff carried out additional research as needed to determine the type (multilateral, government, nonprofit, for-profit, academia) and origin (U.S.-based, partner country–based, multilateral, other) of each prime partner. The type and origin of each partner was also recorded into the same spreadsheets with the funding information.

Data Extraction Quality Control

After all the data and supplementary information had been extracted, one of the IOM staff developed a tool to compare individual records across spreadsheets and flag inconsistencies. This comparison tool flagged every instance of a record with inconsistent information. Independently, the staff went back to the original sources to confirm or edit the inconsistencies and the spreadsheets were compared again. Any inconsistencies that persisted were reconciled together until all records matched.

Data Limitations

The prime partner data the committee compiled was limited by incomplete data sources, as described above. Overall, the total amount of partner funding compiled for this analysis reflects only 77 percent of the total planned/approved funding for this subset of countries for FY 2005 to FY 2010 (as reported in the operational plans). The gap between the data used for the analysis and the total planned funding represents expenses not expended through the COP prime partner mechanism, To Be Determined (TBD) funding, and any central funding not reported in

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partner lists or COPs. Funding may have been reported as TBD if prime partners had not been identified prior to reporting or in situations where partners had been identified, but contracts had not been finalized. Given the nature of these gaps, the funding not represented in the dataset would be distributed across types of partners, therefore the committee determined that the dataset represented adequate information for a reasonable descriptive analysis to help understand the distribution of prime partner funding.

Data Presentations

Once all of the data were validated, a final Excel dataset was used to produce data presentations showing funding over time by type and origin of prime partner using data aggregated across all 13 countries.

PEPFAR PROGRAMMATIC INDICATOR DATA

Background

PEPFAR indicators are used to monitor and assess progress in the HIV/AIDS response within and across PEPFAR-funded technical areas. Indicators are grouped into two distinct categories: those that were collected by partner countries during FY 2004–FY 2009 and those that are being collected starting in FY 2010, after a revision of the indicators (OGAC, 2009). Prior to FY 2010, there were two reporting levels of PEPFAR indicators. Indicators were either required and reported to OGAC or were recommended but not reported to OGAC. Starting in FY 2010, PEPFAR classified indicators according to three reporting levels: essential reported, essential not reported, and recommended.[1]

During FY 2004–FY 2009, focus countries were required to report to OGAC 47 "essential" country-level and programmatic indicators[2]. Seven of these 47 indicators corresponded to overall country-level indicators (see Table C-1). These seven country-level indicators were comprised of two components, direct and indirect, "where direct results represented counts for PEPFAR prevention, care, or treatment support provided at PEPFAR-supported delivery sites, while indirect results represented PEPFAR contributions to national,

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[1] OGAC defines these 2009 classifications in the NGI guidance as follows (OGAC, 2009):
Essential/Reported to HQ: Indicators that are aggregated and reported to PEPFAR Headquarters.
Essential/Not Reported to HQ: Indicators that do not need to be aggregated and reported to PEPFAR Headquarters; however, partners are required to report applicable indicators to the PEPFAR country teams. In addition, PEPFAR country teams are expected to support and encourage intermittent surveillance required to monitor indicators not routinely captured through programs. The intent of these indicators is to highlight critical program areas that PEPFAR country teams should be monitoring and provide teams increased flexibility to work within the context of the national system.
Recommended: These are additional indicators for partners and program managers who need information for program management beyond the minimum set reported to OGAC Headquarters. The PEPFAR interagency TWGs selected and recommended these indicators as important areas for program managers to monitor, but they are not considered indispensable to program tracking. The intent of these indicators is to encourage comprehensive monitoring of programs, provide additional recommendations on indicators, and give PEPFAR country teams increased flexibility to work within the context of the national system. These indicators are not subject to audit.
[2] Programmatic refers to PEPFAR indicators that only have 'direct' counts. Country-level refers to PEPFAR indicators that have 'direct' and 'indirect' counts. Phase 1 had only seven country-level indicators.

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regional, or local systems strengthening activities, all resulting to the PEPFAR contributions to the national program (total)" (OGAC, 2011). OGAC issued an indicator guidance document for FY 2006 reporting and revised indicator guidance for FY 2008 reporting, which did not change the number of essential indicators reported to OGAC but did include some new and revised indicators. (Note: No indicator guidance was made available for indicators reported during FY 2004 and FY 2005; for this evaluation the FY 2006 guidance definitions were referenced for interpretation of FY 2004 and FY 2005 indicators.)

TABLE C-1 Country-Level Indicators Reported During FY 2004–FY 2009

Indicator Number	Indicator Label
Prevention	
1.2	Number of pregnant women who received HIV counseling and testing for PMTCT and received their test results
1.3	Number of HIV-infected pregnant women who received antiretroviral prophylaxis for PMTCT in a PMTCT setting
Care	
	Total number of people receiving care and support services, during the reporting period (sum of indicators 6.2 and 8.1)
6.2	Total number of individuals provided with HIV-related palliative care (including TB/HIV)
7.2	Number of HIV-infected clients attending HIV care/treatment services that are receiving treatment for TB disease (a subset of indicator 6.2)
8.1	Number of OVC served by OVC programs
9.2	Number of individuals who received counseling and testing for HIV and received their test results (including TB)
Treatment	
11.4	Number of individuals receiving antiretroviral therapy at the end of the reporting period

In 2009, OGAC developed the Next Generation Indicators (NGIs) to reduce the number of PEPFAR-specific reporting requirements and, where possible, to align with globally harmonized and reported indicators in partner countries (OGAC, 2009). The NGIs "reflect PEPFAR's strategy to increase country ownership of HIV/AIDS efforts and ensure that partner countries and regions are at the center of decision-making, leadership, and management of their HIV/AIDS programs" (OGAC, 2011). As a result, the number of "essential reported" indicators decreased, and countries are now only required to report 25 programmatic indicators to OGAC. If a partner country has a signed Partnership Framework, the country is required to report a 26th programmatic indicator to OGAC (H6.1.D). Five additional indicators are routinely reported to OGAC but these are national-level indicators and are not PEPFAR-specific. In addition, many of the indicators corresponding to care and support were redefined to make definitions easier to understand and information easier to collect.

The NGIs consist of eight primary indicators, a subset of the 25 programmatic indicators required to be reported to OGAC (see Table C-2). Table C-3 presents how the overlapping country-level indicators before and after the NGI revision map to one another.

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TABLE C-2 Primary Indicators for PEPFAR Next Generation Indicators (FY 2010-Present)

Indicator Number	Indicator Label
Prevention	
P1.1.D	Number of pregnant women with known HIV status (includes women who were tested for HIV and received their results)
P1.2.D	Number of HIV-positive pregnant women who received antiretrovirals to reduce risk of mother-to-child transmission
P11.1.D	Number of individuals who received Testing and Counseling services for HIV and received their test results
Care	
C1.1.D	Number of eligible adults and children provided with a minimum of one care service By sex: Male and Female By age: <18 and 18+
C2.1.D	Number of HIV-positive adults and children receiving a minimum of one clinical service
C2.5.D	TB/HIV: Percent of HIV-positive patients in HIV care or treatment (pre-ART or ART) who started TB treatment Numerator: Number of HIV-positive patients in HIV care who started TB treatment Denominator: Number of HIV-positive adults and children receiving a minimum of one clinical service
Treatment	
T1.2.D	Number of adults and children with advanced HIV infection receiving antiretroviral therapy (ART) [CURRENT] By sex: Male and Female By age: <1, <15, 15+
Human Resources for Health	
H2.1.D	Number of new health care workers who graduated from a pre-service training institution By Specific Types: Doctors, Nurses, Midwives

TABLE C-3 Overlapping Country-Level Phase 1 and Primary Phase 2 Indicators

Type of indicator	Phase 1 indicator number	Phase 2 indicator number
Prevention	1.3	P1.2.D
Care	7.2	C2.5.D
Care	9.2	P11.1.D
Treatment	11.4	T1.2.D

Because some of the indicators reported to OGAC changed over time, IOM staff and consultants performed a data mapping of the indicators. Staff and consultants grouped the indicators into three distinct categories (FY 2004 through FY 2007, FY 2008 through FY 2009, and from FY 2010 onward), compared the indicator definitions from each indicator guidance

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document, linked indicators that had essentially the same definition across indicator guidance, and recorded whether each indicator was essential reported, essential not reported, or recommended during each of the three time periods. After this mapping was complete, the committee was able to determine which of the indicators had been reported to OGAC each year, as well as how many years' worth of data OGAC obtained for each indicator.

In addition to mapping the alignment over time, the PEPFAR indicators were also mapped to the 25 UNGASS indicators. One notable difference between the two sets of indicators is that UNGASS reports their indicators by calendar year, whereas PEPFAR reports in fiscal years (October through September). Further, UNGASS indicators reflect country-level results, whereas only a select few PEPFAR indicators report on country-level outcomes. These differences limited the feasibility of using the annual reported data for these indicators together in analyses or data presentations.

Requests for Data

In response to a series of formal data requests to OGAC between April 2011 and March 2012, IOM staff and consultants received a subset of the PEPFAR indicator data that had been reported to OGAC between FY 2004 and FY 2010, inclusive. In April 2011, IOM staff and consultants first conducted a phone interview with Dr. Paul Bouey, the Deputy U.S. Global AIDS Coordinator responsible for Strategic Information and Budget and Management, to obtain a preliminary assessment of available PEPFAR indicator data. IOM conducted a follow-up, in-person interview with Dr. Bouey and two other staff members later that month to learn more about OGAC data collection and querying processes. After the phone interview and again at the in-person interview, IOM staff and consultants formally requested from OGAC all centrally reported PEPFAR program monitoring data corresponding to FY 2004 to FY 2010. Data requests were not made for PEPFAR indicators that had not already been reported centrally ("essential not reported" or "recommended" indicators) because these data would not be available consistently across all PEPFAR countries and because, based on the time and burden that would be placed on country programs, it was determined to not be feasible to collect these data for the evaluation.

At the time of the initial data request, OGAC indicated that it would make only the core programmatic indicators (seven from FY 2004-FY 2009 and eight from FY 2010) available to IOM. Additionally, they indicated that the 17 remaining NGI programmatic indicators (FY 2010) were undergoing data querying and OGAC would not be able to share them until October 2011. As a result, the first official data request to OGAC included the seven core FY 2004-FY 2009 programmatic indicators and eight available core FY 2010 programmatic indicators, which OGAC provided. In September 2011, IOM consultants requested the remaining 17 NGI (FY 2010) programmatic indicators, which OGAC provided to IOM consultants in November 2011 following OGAC's internal querying and cleaning processes.

Between this first and second request, IOM consultants sent OGAC a series of questions containing data clarifications related to the first set of indicators received. These questions dealt primarily with the interpretation of country-specific direct and indirect indicators and how they related to the indicator targets OGAC had defined.

After committee members worked with IOM staff and consultants to finalize a set of priority evaluation questions (PEQs) based on relevance to the Statement of Task (SOT) and related evaluation considerations (as described earlier), IOM staff and consultants selected a subset of the centrally reported FY 2004-FY 2009 program monitoring data deemed most

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relevant and useful to answer the PEQs and evaluate PEPFAR. This subset of Phase 1 data was prioritized into three tiers (see below) to alleviate and space out the burden of data requests on OGAC. IOM consultants made the initial three-tiered request to OGAC in November 2011, with a clarification of the request provided in January 2012. At the end of January, IOM consultants also made a fourth request for national-level indicators not explicitly included in previous requests.

- Tier 1 – FY 2004-FY 2009 indicators considered most broadly useful in answering the priority evaluation questions. IOM therefore requested these indicators as early as possible.
- Tier 2 – FY 2004-FY 2009 indicators with linked NGIs and presumed more likely to be queried and available.
- Tier 3 – FY 2004-FY 2009 indicators that do not have corresponding NGIs but are as important for evaluation as the other tiered indicators. The IOM made this a lower-priority request in case these indicators required more time to prepare than the other listed tiers of indicators.
- Tier 4 – NGI (FY 2010) national-level indicators, which had not been included with the initial transfer of NGI programmatic indicators.

Although OGAC readily provided program monitoring data for the core targets and indicators, they did not provide several of the requested FY 2004-FY 2009 indicators because they considered the data too unclean to be useful. Further, several of the FY 2004-FY 2009 indicators that had been reported to OGAC were disaggregated by sex, age, or other pertinent characteristics. IOM requested disaggregated data for all indicators for which it was collected. OGAC did not provide disaggregation for any of the FY 2004-FY 2009 indicators the IOM evaluation team requested but did provide disaggregated information for all NGI indicators.

Data Presentations

Once IOM consultants received PEPFAR indicator data from OGAC, they created tabular and graphical presentations of indicator data over time using SAS (Cary, North Carolina) versions 9.2 and 9.3. Data presentations were provided by the consultants to the committee in June 2011, September 2011, April 2012, and June 2012.

Data Limitations

One of the main limitations of the centrally reported PEPFAR indicator data was a lack of suitable denominators. This made it difficult to assess the coverage achieved with respect to the population being served at PEPFAR sites or programs or with respect to the total population in need at the national level, as a means to determine PEPFAR's contribution to national coverage. In many cases, the most suitable denominators available were the targets set forth by OGAC for each country during each reporting year. OGAC described the target setting process as "complex" (Bouey and De Leon, 2011). Initially countries were assigned 5-year targets based on 50 percent of the country's estimated need. This was later transitioned to a process whereby countries determine their own targets; a process OGAC described as developing more useful and more realistic targets (Bouey and De Leon, 2011). OGAC provided the annual targets for each

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indicator for each country between FY 2004 and FY 2010. PEPFAR target setting is discussed in more depth in Chapter 11.

Additional limitations for specific indicators are presented in the chapters where the data are presented.

TRACK 1.0 PARTNER DATA

When PEPFAR was initiated, some funding for programs was centrally managed through CDC and HRSA via what are known as "Track 1.0" awards. These were one-time, 5-year awards intended to rapidly initiate and scale-up prevention, care, and treatment services in PEPFAR focus countries. These awards were given to organizations with proven track records and existing operations in focus countries, and therefore with the capacity to respond and implement programs quickly. These partners reported to both in-country mission teams and to CDC and HRSA directly (McCullough, 2011; Sessions, 2011). As a result of this implementation design, Track 1.0 partners have been collecting data longer than other implementing partners; these partners also often collect data beyond the indicators that OGAC requires for routine reporting.

Four PEPFAR Track 1.0[3] partners have been involved in the early and ongoing implementation of care and treatment programs, including ART:

- AIDSRelief –a consortium of five organizations:
  - Catholic Relief Services (CRS), as prime grantee
  - University of Maryland (UMD) School of Medicine Institute of Human Virology (IHV), as technical lead for clinical care and treatment
  - Futures Group, as lead agency for strategic information
  - IMA World Health, as an implementing partner
  - Catholic Medical Mission Board (CMMB), as an implementing partner
- Columbia University's International Center for AIDS Care & Treatment Programs (ICAP)
- Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
- Harvard University

Beginning in March 2011, IOM staff and consultants contacted CDC headquarters staff involved in the central management of Track 1.0 partners and each Track 1.0 partner to initiate a discussion about their roles within PEPFAR and to engage them in discussions related to potential sharing of data. IOM staff and consultants also requested lists of indicators collected, corresponding data dictionaries, and associated data collection guidance from each partner. In response to requests for more information, IOM consultants received from each Track 1.0 partner materials pertaining to their work through PEPFAR.

In July 2011, IOM consultants followed up with a more formal query eliciting additional information from each Track 1.0 partner, including a list of the programs they established within each of their partner countries; implementation of public health evaluations (PHEs); challenges and barriers in the field; intended data usage; data quality assessments; employee training; data

[3] Track 1.0 Partners in this report refers to four partners that were the primary large-scale implementers of ART in PEPFAR's centrally funded Track 1.0 program These partners also implemented other HIV services and programs, and there were also other centrally funded Track 1.0 partners in other program areas.

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management, both within and across partner countries; and standardized data reporting across all Track 1.0 partners.

Between September 2011 and February 2012, IOM staff and consultants conducted semi-structured, in-person interviews with each Track 1.0 partner. One purpose of these interviews, which were part of the primary interview data collection process for the evaluation, was to learn more about the data that each Track 1.0 partner had collected and analyzed, as well as to explore the possibility of acquiring data and analyses from the partners.

CDC Track 1.0 Data

Each Track 1.0 partner is required to compile data from quarterly, facility-based reporting forms and report the information to the CDC and HRSA (CDC manages these data for the partners whose grants are administered through both CDC and HRSA). IOM participated in a teleconference with CDC staff in early March 2012 to discuss the possibility of sharing the quarterly data from all Track 1.0 partners. IOM requested to receive these quarterly care and treatment data directly from CDC. CDC indicated they would share a de-identified dataset that did not identify implementing Track 1.0 partners, countries, or facilities. At the time of the request, data were available from 2005 through the end of 2011.

Data Summary

In April 2012, IOM consultants received from CDC an Excel spreadsheet containing seven years' worth of quarterly, facility-level data (Q1 2005 through Q4 2011) from all four Track 1.0 partners. These data address patient care, treatment, and adherence; median CD4 counts at baseline and at 6 and 12 months after treatment initiation; training in ART and HIV care; and patient retention, death, and loss to follow up. The individual records are not identified by facility, Track 1.0 partner, or country.

This dataset contains over 20,000 records, each of which corresponds to a specific facility's data from a single quarter between 2005 and 2011. During some quarters, as many as 1,300 facilities reported information to the CDC. Each facility reported up to 200 different values. Other variables, such as specific ART regimens, had been captured during the earlier years of this program; however, these data were ultimately removed from the quarterly form and were therefore not included in the dataset provided by CDC.

In addition to having several years' worth of data, this dataset also contains disaggregations. All of the data corresponding to patient enrollment into clinical care, initiation of ART treatment, and patient follow-up are disaggregated by sex (male/female) and age (0-14 years and 15+ years). From 2008 onward, the pediatric data are disaggregated by narrower age ranges: 0-1 years, 2-4 years, and 5-14 years; these narrower age ranges are also disaggregated by sex. The training information is disaggregated by type of worker (physician, nurse, or other). Track 1.0 partners also reported the total number (no disaggregation) of people trained in HIV palliative care (now referred to as Care and Support services) within each country.

Relationship of Track 1.0 Data to OGAC indicators

This Track 1.0 dataset contains three variables that are reported to OGAC and ultimately contribute to the following PEPFAR programmatic indicators:

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- C2.1.D – Number of people receiving at least one clinical care service [Care and Support Sub Area, Clinical Indicator]
- T1.1.D – Number of adults and children with advanced HIV infection newly enrolled on ART [Treatment Indicator]
- T1.2.D – Number of adults and children with advanced HIV infection receiving antiretroviral therapy (ART) [CURRENT] [Treatment Indicator]

The Track 1.0 partners reported each of these indicators with sex and age disaggregation. The data in this CDC dataset correspond to quarters, whereas OGAC indicators represent fiscal years.

Data Limitations

CDC de-identified the data provide to the IOM's third-party consultant. Each facility was assigned an arbitrary facility ID number that prevents linking the information to a specific facility name. Further, rather than indicating within which country a facility is located, CDC assigned each of the Track 1.0 countries with an arbitrary number between 1 and 13 and removed any partner-specific identifier from the data. This de-identification prohibited focused analyses from being conducted. Without partner, country, and facility identifiers, these data were not linked to partner-specific or country-specific information that had been acquired through other data sources, such as structured interviews.

Data Quality

Until this data request, CDC had not reviewed the data at the facility level but rather in aggregated forms, and the CDC did not conduct preliminary data checks before providing the dataset. Instead, for time and efficiency, CDC worked closely with the IOM third-party consultant to address issues and inconsistencies that arose during data quality checks conducted after the transfer of data; these were issues in the facility-level dataset that would not have affected prior aggregated data use by CDC.

During a preliminary review of the dataset, IOM consultants discovered various quality issues that were eventually reconciled. For example, some facilities were missing records for some quarters, and other facilities had multiple records for other quarters. Upon closer review, CDC realized that their "matching" program, which matches and links records from the same sites over time, had erroneously matched multiple sites to one another. Considering the sheer magnitude of data—during peak Track 1.0 partner involvement, CDC received quarterly data from approximately 1,300 sites that were reported in a variety of languages—a few inconsistencies like this were expected. The CDC corrected these mismatches and sent IOM consultants a revised dataset in May 2012.

The dataset also contained other occasional erroneous information, which appears to be attributable to data entry errors. For example, the sum of the men and women receiving treatment within a given facility does not always add up to the total number of people receiving treatment at that facility. Such inconsistencies were infrequent, however, and the magnitude of the difference was usually small. Another example corresponds to CD4 data: some records indicate that the number of people whose CD4 counts are included in the calculation of median CD4 count is equal to the median CD4 count (e.g., 15 people are in the cohort, and the reported median CD4 count equals 15). Records with these types of errors were omitted from any analyses conducted by IOM staff and consultants.

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Analyses

IOM's consultants prepared data presentations for the committee of changes over time in enrollment into clinical care services and treatment services, active facilities, and persons trained. The disaggregated nature of the care and treatment data allowed for assessment of potential differences between age groups (e.g., adults versus children, infants versus older children) and between males and females. Data presentations were provided by the consultants to the committee in June 2012.

Individual Track 1.0 Partner Data

As described previously, during semi-structured interviews, teleconferences, and e-mail communication between March 2011 and October 2012, IOM communicated with each Track 1.0 partner individually to learn more about their programs and discuss the feasibility of their sharing data and analyses with IOM.

One partner was willing to share its existing analyses and to conduct some limited additional analyses for the evaluation related to survival, patient retention, health systems, treatment access and coverage, baseline CD4, monitoring for treatment failure, quality of service delivery, program management and capacity building. There was not adequate time to provide data for IOM consultants to do independent analyses, which would have required a time-consuming internal approval process, nor for this partner to conduct extensive new analyses for the evaluation. The partner provided analyses using aggregated data to IOM consultants over several transfers between May and October 2012. Because the scope of this mandated study does not include a country-specific or partner-specific evaluation, prior to sharing these analyses with the committee and to including data presentations in the report, the IOM consultant redacted country names and partner affiliations from all country-specific analyses. The partner worked closely with IOM staff and consultants to resolve any questions or issues with regard to the analyses.

A second Track 1.0 partner was willing to explore sharing existing analyses with IOM and possibly conducting new analyses; however, upon closer consideration, they declined to share any analyses because they determined that sharing these analyses for use and publication in this evaluation might interfere with their ability to subsequently publish results in peer-reviewed journals. A third Track 1.0 partner also declined to share data or analyses. The fourth Track 1.0 partner described limited independently collected data beyond the quarterly data reported to CDC and OGAC, and therefore did not have extensive additional data or analyses to consider sharing for this evaluation.

Track 1.0 Partner Publication Data

To augment the Track 1.0 partner data received, the IOM consultants made a comprehensive request to the partners to identify and collect published results based on their data that could potentially serve to contribute to the committee's findings. Three of the four Track 1.0 partners shared comprehensive publication lists.

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GLOBAL DATA SOURCES

In addition to pursuing PEPFAR-specific data through the centrally reported indicators and the Track 1.0 partner data, IOM staff and consultants reviewed additional potential data sources for global HIV/AIDS data. As the committee finalized their priority evaluation questions (PEQs) for each content area, the committee work groups, staff, and consultants mapped data from these global data sources to the PEQs to determine which data to prioritize. The mapping effort focused on data sources such as UNAIDS, DHS, World Bank, IeDEA, WHO Global Health Observatory, and UNICEF. Information gathered in the data mapping process led to collecting the data from those sources that were deemed to be most relevant, appropriate, available, and feasible to use within the scope, time, and resources of the study. The data ultimately used in the evaluation are described where data are presented in the report chapters. Additional data sources considered for use in impact analyses considered by the committee are described in sections below.

Data Sources for Overall Data Mapping

AIDSinfo, UNAIDS Database (http://www.aidsinfoonline.org)

The UNAIDS Database is an interactive system that allows the end user to query a compilation of national and international data sources including WHO, UNICEF, UNAIDS, and Measure DHS on the topics of demography, development, epidemiology, HIV/TB, law, and spending. Data covering the following topics are available for at least 169 countries, generally between 1990 and 2009:

- UNGASS indicators
- HIV and AIDS prevalence estimates
- Data pertaining to orphans
- Country population data
- Development measures such as life expectancy, infant mortality rate etc.

International Census Data (http://www.census.gov/ipc/www/idb)

This is a searchable database maintained by the U.S. Census Bureau, with population estimates and projections based on census, survey, vital statistics, and other data available by country or area. Data are available for countries and areas with current populations of 5,000 or more from 1950 with projections up to the year 2050. Available estimates and projections include

- Birth, death, and growth rates, migration rates, infant mortality, and life expectancy
- Fertility rates
- Total population and population by age and sex

WHO Communicable Disease Global Health Atlas (http://apps.who.int/globalatlas)

This database contains reports and documents on the major infectious diseases of poverty, but no specific data on HIV. All WHO countries are represented with data available as far back as 1971 corresponding to the health care workforce including community health workers and laboratory health workers.

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WHO Global Health Observatory (http://apps.who.int/ghodata/)

The Global Health Observatory is a statistics repository for the WHO. An end user has the ability to export data by country (for 193 countries) over time (1990-2009) on various health topics, including

- Health-related Millennium Development Goals (poverty and hunger, child mortality, maternal health, HIV/AIDS, malaria, environmental sustainability, and global partnerships for development)
- Mortality and burden of disease by country (life expectancy, morbidity and mortality, DALYs, disease, and injury)
- World health statistics (mortality and burden of disease, cause-specific morbidity and mortality, selected infectious diseases, health services coverage, risk factors, health workforce and infrastructure, health expenditures, health inequities, demographic and socioeconomic statistics)
- Immunization (country and regional data)
- Nutrition (child malnutrition)
- Epidemic-prone diseases (cholera)
- Tobacco Control
- Violence and Injury (road safety)
- Global Health Information Systems on Alcohol and Health (production and availability, levels and patterns of consumption, harms and consequences, economic aspects, alcohol control policies, prevention, research, and treatment)
- HIV/AIDS (data on the size of the epidemic and on the HIV/AIDS response)
- Tuberculosis (cases, diagnosis, drug regimes, and treatment success)
- Public Health and Environment (household and air pollution, outdoor air pollution, water, sanitation and hygiene, lead, second-hand smoke, UV radiation, climate change, occupational risk factors, total environment, and children's environmental health)

International Epidemiologic Database to Evaluate AIDS (www.iedea-hiv.org)

IeDEA is an initiative that establishes regional centers to collect and harmonize data across countries. The centers collect key variables to address "unique and evolving research questions in HIV/AIDS currently unanswerable by single cohorts." IEDEA provides a mechanism to pool data being collected around the world to enhance HIV/AIDS research.

One data center has been funded for each of the seven IeDEA regions (North America, Caribbean and Central and South America, Asia and Australia, West Africa, Central Africa, East Africa, Southern Africa). This program includes data from nearly 525,000 HIV-infected persons from 43 different countries.

World Bank (http://data.worldbank.org, http://databank.worldbank.org/ddp/home.do)

The data catalog of the World Bank and the "World DataBank" provide access to over 2,000 indicators from the World Bank datasets which cover a wide variety of topics and countries. The datasets contain times series data that can be downloaded by country (all data for all years for a single country) by topic (specific indicators for all countries and years) or by individual indicator (all countries for all years.)

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This group of databases covers a variety of topics (economic, health, financial, etc.) for 209 countries. Some of the data goes as far back as 1960. Databases include but are not limited to

- World Development Indicators and Global Development Finance
- Health Nutrition and Population Statistics
- Africa Development Indicators
- Education Statistics

UNICEF (http://www.unicef.org/sowc2011/statistics.php)

Statistics tables that show economic and social statistics with a particular focus on child well-being. End users can choose countries and indicators to view particular data or download data into spreadsheets. This database includes approximately 185 countries. Data, which are generally available from 2003 to 2009, cover the following topics:

- Basic indicators (total population, annual number of deaths and births)
- Adolescents (population, marital status, attitudes toward domestic violence, education, and HIV knowledge)
- Child protection (child labor, child marriage, and attitudes toward domestic violence)
- Demographics (birth rate, crude death rate, population under 18 and under 5)
- Economics (GDP per capita and inflation rates)
- Education (literacy rates, phone use, and enrollment ratios)
- Health (Percent receiving Expanded Program on Immunization vaccinations and individual vaccination rates)
- HIV/AIDS (prevalence in adults, pregnant women, and young adults; condom use; orphaned children, and HIV knowledge)
- Nutrition
- Rate of progress (under 5 mortality rates, fertility rate, and GDP annual growth)
- Women (literacy, maternal mortality, and antenatal care)

DHS HIV/AIDS Survey Indicators Database and STATcompiler (http://www.measuredhs.com/accesssurveys/search/start.cfm#)

Measure DHS is a compilation of data from 207 sample surveys. The indicators included are derived primarily from the UNAIDS National AIDS Programmes: Guide to Monitoring and Evaluation. The main sources of HIV/AIDS indicators in this database are

- Demographic and Health Surveys (DHS)
- Multiple Indicator Cluster Surveys (MICS)
- Reproductive Health Surveys (RHS)
- Sexual Behavior Surveys (SBS)
- Behavioral Surveillance Surveys (BSS)

This database includes approximately 85 countries and goes back as far as 1985. (The earliest date varies greatly across countries.) STATcompiler includes indicators from the

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Reproductive Health Surveys (RHS). Datasets and reports for these surveys include information related to

- Household characteristics
- Fertility
- Family planning
- Other proximate determinants of fertility
- Fertility preferences
- Early childhood mortality
- Maternal and child health
- Maternal and child nutrition
- HIV/AIDS
- Malaria

DOLPHN (http://dolphn.aimglobalhealth.org)

The Data Online for Population, Health, and Nutrition (DOLPHN) database pulls select demographic and health indicator data for various countries directly from multiple data sources including BUCEN, CDC, Census Bureau, DHS, UNAIDS, UNDP, UNDESCO, UNICEF, WHO, and the World Bank. This data repository is a website that allows quick and easy access to several indicators from different data sources at one time.

Exploration of Mortality Data for Impact Analyses

As described in Chapter 6, during its deliberations, the committee explored the possibility of conducting new modeling to evaluate the impact of PEPFAR. Ideally the committee would have liked to design a model to determine if a larger annual investment of PEPFAR funding, as a continuous variable over time, had led to a greater impact on health.

The committee focused on a possible model of impact on adult all-cause mortality with potential outcome and explanatory variables using the country as the unit of analysis. Such an approach would require a simple dataset with time-varying data for country-specific mortality, a measure of PEPFAR expenditure as the independent variable, and a judiciously chosen set of relevant covariates. Some additional variables were considered as baseline covariates (e.g., total country population) rather than time-varying factors to prevent oversaturating the models.

The committee opted not to try to model HIV mortality because cause-specific mortality data is limited in many low- and middle-income countries and even when collected may not include many of HIV-related deaths with a different specific proximal cause (e.g., an opportunistic infection) (IOM and NRC, 2010). The committee also discussed modeling child mortality as a function of PEPFAR funding over time but decided against this due to the small number of countries where HIV is a sizeable contributor to childhood mortality (see Chapter 7 for a more in-depth discussion of child mortality in PEPFAR partner countries).

Mortality data sources and their limitations

IOM staff and consultants reviewed potential sources of mortality data that could be used in longitudinal analyses that would be designed to understand the overall impact of the PEPFAR program. Each of the sources considered is described briefly here. Many low- and middle-

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income countries do not have adequate vital or civil registration systems; where the systems exist, they are usually not comprehensive and the cause of death is misreported or underreported (IOM and NRC, 2010). Several sources produce estimates of mortality using modeling methods; the most common limitation among available estimated mortality data was that explanatory variables planned to be included in this modeling, such as HIV treatment coverage, were used in the calculation of the mortality estimates, thereby creating circularity in the potential modeling.

UNAIDS Spectrum/EPP model This model has been used to produce annual, country-specific estimates of the number of AIDS deaths from 1990 to 2009. According to the UNAIDS website, Spectrum/EPP modeling requires the end user to input country-level data pertaining to HIV prevalence and ART coverage. Using treatment coverage and HIV prevalence as explanatory variables in our analyses would thus have resulted in circularity within the model.

WHO Statistical Information System (WHOSIS) WHOSIS provides estimates of the total number of registered deaths by country and year, beginning with 1979, including cause, sex and age. According to the site, "The data available on the WHOSIS website comprise deaths registered in national vital registration systems, with underlying cause of death as coded by the relevant national authority. These data are official national statistics in the sense that they have been transmitted to the World Health Organization by the competent authorities of the countries concerned."

The site also includes information on estimates of coverage (of all estimated deaths) and estimated completeness of the registered deaths by country (proportion of all deaths which are registered in the population covered by the vital registration system for a country). Although the site has annual mortality estimates for many countries, several PEPFAR countries (e.g., Angola, Botswana) are not represented in the dataset.

United States Census Bureau This database contains annual crude death rates from 1950 and projected out through 2050 (crude death rate: the average annual number of deaths during a year per 1,000 people at midyear). The mortality estimates in this database include the impact of ART for selected countries. The number of adults and children receiving or targeted to receive ART comes from OGAC, WHO, and other sources. ART coverage is projected by assuming a constant yearly percent reduction in the unmet need for ART, with the assumption that 80 percent is considered universal coverage.

CIA World Factbook This website provides annual death rates per 1,000 people (all ages) for all countries from 2000 through 2011. Despite several requests to clarify the sources of these mortality estimates, the CIA never provided this information. Without knowing more about the data sources and how these estimates were calculated, it was not possible to determine whether circularity would arise with the proposed longitudinal modeling.

UN Population Division This site contains estimates of adult mortality rates between ages 15 and 60 years, for both sexes separately and combined. It also provides estimates of the crude death rate (deaths per 1,000 people). Both sets of estimates are provided for 5-year periods rather than the annual estimates needed for the modeling that was considered.

World Bank The World Bank reports crude death rates by country and year. The primary reference listed for these data is the UN Population Division.

Institute for Health Metrics and Evaluation (IHME) This site provides global estimates of adult mortality risk (probability of death between the ages of 15 years and 60 years) between

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1970 and 2010. Unlike the data on the UN Population Division's website, however, the IHME rates are provided annually. Data are disaggregated by sex. These data correspond to the following paper, "Worldwide mortality in men and women aged 15–59 years from 1970 to 2010: a systematic analysis," published online in the *Lancet* on April 30, 2010. According to the abstract of the paper, the authors "compiled a database of 3,889 measurements of adult mortality for 187 countries from 1970 to 2010 using vital registration data and census and survey data for deaths in the household corrected for completeness, and sibling history data from surveys corrected for survival bias. We used Gaussian process regression to generate yearly estimates of the probability of death between the ages of 15 years and 60 years for men and women for every country with uncertainty intervals that indicate sampling and non-sampling error."

Mortality estimates from Bendavid et al. Through phone and in-person meetings in June and July 2012, IOM staff and consultants spoke with Dr. Eran Bendavid, the primary author of two publications evaluating the PEPFAR program, to learn more about the methods used to develop mortality estimates (Bendavid and Bhattacharya, 2009; Bendavid et al., 2012). The mortality rates used in the 2012 published modeling were derived from raw DHS data. Calculating mortality estimates from these raw data eliminates the smoothing of year-to-year variation that results from modeling (although smoothing can also be an advantage because it prevents irregularities in data from creating false impressions of change). The calculated mortality rates also avoid the circularity introduced when potential explanatory variables are incorporated in the mortality estimation. These data were therefore considered promising as a viable option for longitudinal analyses that was newly available as of the 2012 publication.

However, whereas the committee was interested in modeling using annual by-country mortality estimates, Bendavid's dataset included more than 9 million data points corresponding to individual mortality outcomes, and were only calculated for a subset of PEPFAR countries. Although these data could in theory be converted into annual by-country mortality estimates and calculated for additional countries, this process would have required more time than was available before completion of the evaluation.

PEPFAR Financial Data Sources and Their Limitations

Ideally, the model considered by the committee would have used as the independent variable the annual PEPFAR investment by country for all countries, which would allow for a continuous variable for the magnitude of PEPFAR funding rather than the dichotomous use of focus versus nonfocus countries, which was a limitation in prior published longitudinal modeling (se discussion in Chapter 6). However, as described in Chapter 4, PEPFAR funding data is typically reported as cumulative spending by the budget year funding was made available rather than the actual amount expended each year. In addition, it is not available publicly with disaggregation by all countries receiving PEPFAR funding. As described previously, after several iterative funding data requests, IOM's third-party consultants received from OGAC cumulative country-specific and agency-specific funding reports from which annual expenditures by country could be manually derived. However, these data represented only a subset of total PEPFAR funding, and concerns about completeness and accuracy in the data limit their utility for longitudinal modeling.

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Decision to Omit Longitudinal Modeling from the Evaluation

After careful consideration, the evaluation committee determined that, given the limitations of the available mortality and financial data, within the scope, time, and resources of this evaluation, it was not feasible to conduct statistical analyses comparing countries with variable levels of PEPFAR funding over time to correlate changes in key outcome or impact indicators. Ultimately, the limitations were determined to be too great to design and carry out analyses that would meaningfully add to the previously described existing analyses in the published literature (see discussion in Chapter 6).

DOCUMENT REVIEW

The evaluation team conducted targeted and systematic document reviews and also employed a process of appraising purposefully selected documents in an effort to gather facts (Caulley, 1983), particularly those of relevance to countries involved in the evaluation. Data collection associated with the evaluation involved the team reviewing several types of documents: those providing PEPFAR-specific process, policy, and planning guidance documents; PEPFAR operational plans; reports from PEPFAR-supported activities and evaluations; global guidance documents related to HIV; country-specific HIV/AIDS reports; reports from multilateral agencies and other organizations external to PEPFAR, and the peer-reviewed literature.

Guidance from the World Health Organization regarding HIV/AIDs testing, diagnosis, treatment, care, support and prevention exemplified one type of key document. The team also reviewed key country specific reports such as the biannual Country HIV/AIDS Progress Reports to the United Nations Secretariat (United Nations General Assembly Special Session reports), as well as PEPFAR annual reports to Congress, PEPFAR Country Operational Plans (COPs), and multi-years of COP guidance from OGAC to mission teams. Review of multiple years of COPs for a number of countries provided annual country-specific work plans that were developed collectively by USG agencies under the leadership of the U.S. Ambassador for the purpose of determining annual goals, resource plans, planned activities, and implementing partners. Process and planning guidance also included Partnership Frameworks and their Implementation Plans which provided insight into the processes, steps, and measures to support country ownership and the transition to country-led management of sustainable HIV responses. The evaluation team also reviewed the peer-reviewed literature related to HIV/AIDS program research, some of which was PEPFAR-sponsored, directly related to PEPFAR, or related to specific evaluation topics in countries of interest. The review of documents in general was advantageous in gathering credible, accessible information, some of which was unavailable by means of other evaluation methods (Caulley, 1983).

INTERVIEW DATA

Overview

The team was systematic in its implementation of qualitative evaluation processes in an effort to yield an outcome of quality and consistency in cross-country data collection, analysis, and findings. Multiple strategies were utilized to ensure the credibility of the qualitative

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component of the evaluation. These strategies included triangulation, purposeful and snowball sampling, prolonged engagement in the field, attaining data saturation, researcher reflexivity, maintenance of an audit trail, participant validation of data summaries, debriefing and synthesis processes, and ensuring accuracy of the data collected. This section describes how these strategies were applied pragmatically in the evaluation. The process for collection of country visit interview data is summarized at the end of this section in Figure C-1.

Just as triangulation among different yet complementary data sources was an important methodological approach for the mixed methods evaluation overall, the incorporation of triangulation within the qualitative evaluation component provided an opportunity for the research team to explore and gain insight into the PEPFAR program using diverse data sources and types as well as multiple investigators. Triangulation is an often-recommended strategy in to incorporate different elements and viewpoints (Patton, 2002); Merriam, 2002). The evaluation team employed specific types of triangulation as part of the interview data collection and analysis process (Denzin, 1978; Patton, 2002). First, data triangulation was reflected in the involvement of different sources of data through the inclusion of interviews from a range of countries and stakeholders; these are described in more detail below. Methodological triangulation was evidenced in the use of multiple data collection strategies such as in-depth interviews and site visit observations as well as review of documents and quantitative data relevant to each country visit. Finally, investigator triangulation reflected the presence of multiple researchers in the evaluation process, including committee members, IOM staff, and consultants.

Collection of Country Visit Interview Data

Country visit selection From November 2010 to February 2012, the evaluation committee, IOM staff, and consultants conducted 13 country visits (including 2 pilot visits) to collect qualitative interview data. Originally, 14 countries, including the 2 pilot countries, were selected as country visit sites. These countries were selected through purposeful sampling based on committee deliberation during a closed committee meeting. To make country selections, committee members reviewed background data compiled by IOM staff for each of the 31 PEPFAR countries that were the focus of the evaluation. Background data covered a range of variables including country income level, geographical location, HIV epidemic type, HIV prevalence, status as a PEPFAR focus country, population size, PEPFAR funding per capita and per person living with HIV, and relative contribution of PEPFAR to the national response compared to the Global Fund. Committee members eliminated for consideration those countries where the safety of the delegation team would likely be compromised. They then iteratively grouped countries by different variables and ultimately selected a sample of countries representing a cross-section of attributes. In consultation with mission team staff, two originally selected countries were not visited because of security warnings of sufficient magnitude to warrant U.S. diplomatic mission travel restrictions. One additional country with similar characteristics within the original selection criteria was added to minimize the effects of the two cancellations on the selected sample.

Interviewee selection process During each country visit, the evaluation team conducted qualitative interviews with key stakeholders involved in the HIV/AIDS response. During the months leading up to a country visit and during the visit itself, the team used purposeful sampling to initially identify in-country interviewees. To develop a sample of interviewees that represented a range in types and levels of key stakeholders involved in the country's HIV/AIDS

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response, the selection process took into account input from committee members; country background research completed by the IOM staff team; targeted focus areas within the overall evaluation plan; input from the USG PEPFAR country team; country visit timing; and interviewee availability. In deference to cultural norms and with respectful intentions, the team typically initiated the sampling process in a partner country by contacting key leaders associated with the PEPFAR country program and the partner-country HIV response. Sources for such information included the PEPFAR country coordinator or an individual serving in a comparable role and leaders in the partner countries' health sector. In these discussions, the IOM study co-director who was the Team Leader for the country visit, elicited information about the mission team structure, roles, and operation for PEPFAR implementation and, where possible, lists of all implementing partners by program area which were used by the IOM staff to conduct additional research, followed by identification and selection of interview and site visit candidates. Country-specific documents available to the team (e.g., Country Operational Plans, national strategic plans for HIV/AIDS, and many others) served as additional resources to identify service organizations, programs, and individuals relevant to the response within specific countries. IOM staff then initiated contact with these resources in an effort to further identify individuals with direct experience related to various elements of the HIV response in a given country and to schedule interviews and site visits for each country visit, except where protocol required communication and scheduling with partner country government officials through formal communications by the mission teams. In these limited cases, documentation was sent from the IOM to the mission teams to present to officials. In countries where English was not the primary language, all information sent ahead about the study and requests for interviews and site visits by the IOM study co-directors were translated by language professionals hired by the IOM team, and when needed professional interpreters were hired to accompany the evaluation team on interviews and site visits.

Once the country visit teams were in-country, the team incorporated an additional process of snowball sampling during interviews with stakeholders to identify other information-rich individuals associated with the HIV response in the country for consideration to either fill interview or site visit slots that were intentionally left available for such interviews or that could be replacements if originally scheduled interviews were cancelled by the interviewees for conflicts in scheduling that arose either after the interview or site visit had been confirmed. One example of such sampling efforts was the query, "Can you share with us the names of individuals, programs, or services that you think might contribute interesting or valuable information (sometimes on a particular issues to replace previously scheduled interviewees) regarding PEPFAR or the HIV response in (name of country)?" Another example of a typical query was, "We are interested in learning more about successes and challenges related to the HIV response in (name of country). Are there others involved in (a particular focus of the evaluation—e.g., HIV prevention efforts) who you think we should talk to or who might be helpful to us?" An evaluation team member then contacted each potential interviewee to ascertain her or his availability during the time frame of the planned country visit and willingness to be interviewed and to schedule a possible interview time and date. Unless these were replacement interviewees, these interviews were then added to the number that had been scheduled before arriving in the country

Although the interviews conducted in each country were tailored to the particular county and its unique HIV-response strengths, challenges and attributes, the evaluation team aimed to

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systematically interview stakeholders serving in particular roles in every country visited. The roles of these individuals or groups of individuals included

- U.S. Country Mission leader(s)
- PEPFAR all-staff mission team members
- PEPFAR country coordinator or equivalent
- PEPFAR technical staff/ work group members (with varying numbers of staff and kinds of workgroups depending on the country)
- Partner country stakeholders including, at minimum, health- and HIV-related government or government agency personnel, partner country HIV-related NGO directors, staff, volunteers, and others.
- U.S.-based stakeholders including, at minimum, HIV-related NGO directors/chiefs of party, staff, or volunteers, and others
- HIV-related civil society organization leaders or members, including faith-based programs, human rights programs, and other organizations that provided programs and services for populations at elevated risk or other vulnerable populations
- Personnel having direct experience with a particular focus for data collection within a given country (e.g., services for populations at elevated risk, services for orphans and vulnerable children, the health care system, PMTCT, or others). Such personnel might be from different levels of a partner country government, NGO, and U.S.-based NGOs or other organizations.

In any case, interviewee selection was based on those who had the most direct experience with the area of focus and who were voluntarily willing to be interviewed. For example, interviewees who directed or provided services or programs that addressed the needs of HIV-related vulnerable children were sought in countries designated as target countries for such information.

Based on an IOM Institutional Review Board review and exemption, for the protection of their personal health information, individual beneficiaries were not included in the interview sample, except when individuals serving in one of the roles described above were also beneficiaries of PEPFAR-supported programs (for example, some peer educators were also patients or clients of PEPFAR-supported programs).

During the process of sampling and consequent data collection, team members assiduously protected individual's confidentiality and anonymity. At no time did the evaluation team share with others external to the team the identity of anyone contacted by team members, scheduled for an interview, or interviewed. Team members provided no feedback to individuals who proffered the names of potential interviewees and, with the exception of drivers and interpreters hired by the team, divulged no information of any kind to anyone external to the team. Thus, the team kept the identity of interviewees confidential during all country visits.

Over the 13 country visits, the IOM delegations conducted a total of 383 interviews; 68 of these included a visit to a service delivery facility or program site. The interviewees included individuals or groups representing partner country government, U.S. government mission staff including the Department of State and the PEPFAR implementing agencies, multilateral organizations, nongovernmental organizations (NGOs), academia, and the private sector. Table C-4 summarizes the number of total interviews completed by stakeholder type and subtype.

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TABLE C-4 Country Visit Interviews by Stakeholder Type

Stakeholder Type and Sub-Type		Number of Interviews
U.S. Government Stakeholders		**147**
Mission Leadership In-Briefings and Exit Meetings	26	
PEPFAR All-Staff Mission Team Briefings	16	
PEPFAR Country Coordinator	13	
Agency Leadership	25	
Technical Staff and Working Groups	67	
U.S.-Based Stakeholders with Operations in Partner Country		**62**
NGO	41	
Academia	11	
Private Sector (for-Profit)	10	
Partner Country Stakeholders		**156**
Government, National	53	
Government, Subnational (Province, District, Facility)	40	
NGO	51	
Academia	6	
Global Fund CCM	4	
Private Sector (for-Profit)	2	
Other Stakeholders		**16**
NGO (Other Country-Based)	4	
Other Bilateral Government Donors	1	
Multilateral	11	
Mixed (Stakeholders from USG, Mutilateral Organizations, Other Bilateral Donors, Partner Country Government, US Private Sector)		**2**
TOTAL	**383**	

NOTE: This does not represent the total number of interviewees, as the majority of interviews were with groups of interviewees. In some cases, the same interviewees participated in multiple interviews. For example, there was usually participant duplication between the PEPFAR all-hands interview and subsequent USG interviews. Repeat participation also happened occasionally across multiple interviews with partner country governments.

In-country data collection As advocated in the conduct of credible qualitative studies (Creswall, 2007; Merriam, 2002; Patton, 2002), this evaluation involved the investigators in extended time in the field, which enabled in-depth data collection opportunities that extended well beyond a "snapshot view" (Rossman and Rallis, 2012) of the PEPFAR program. Prolonged engagement afforded the evaluation team an opportunity to gain an in-depth understanding of the PEPFAR program in the context of each country visited.

Country visits typically spanned two weeks, and qualitative data collection encompassed an average of 25 in-depth interviews with key stakeholders as well as several site visits in each of the selected countries. Qualitative data collection during country visits involved the active participation of committee members. Each committee member actively participated in data collection and preliminary analysis processes for at least one visit to a partner country, with the majority engaging in 1-week data collection and analysis efforts while some participated in a full 2 weeks and a few participated in two country visits. At least one and sometimes both IOM study directors led the collection of data and data analysis processes during each country visit. Other

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IOM research staff members also participated as delegation team members in collecting data and engaging in preliminary analysis during typically the full 2-week visit. Consultants participated in the data collection and analysis process for either 1 or 2 weeks during visits to 7 countries.

Data collection toolkits were developed and provided for use by IOM evaluation teams on country visits. Additional preparation was provided through staff trainings, an initial briefing on methods and processes at a committee meeting, and an in-country orientation briefing at the beginning of each country visit. For each country visit delegation, briefing materials were prepared that included background information on the country, the national HIV response, and the PEPFAR country program, as well as basic financial, program monitoring, and surveillance data.

A subset of evaluation team members was present and engaged in qualitative data collection typically for a period of 12-14 days during each visit to a partner country, with a total in-country visit time across the selected countries of about 180 days. Thus, the team had a total of approximately 6 months residence (or approximately 140 person-weeks for all of the committee, IOM staff, and committee consultants) in a total of 13 partner countries from the initiation of onsite data collection in November 2010 to its completion in February 2012. Each day in-country involved the evaluation team in some aspect of the evaluation process, including logistical planning for collecting data, as well as data collection, transcription of notes, team debriefings, and data analysis and interpretation.

Through semi-structured interviews, delegation team members learned about the national HIV/AIDS response, interviewees' experiences with PEPFAR, and the role of PEPFAR in the national response currently and over time. These interviews were conducted using interview guides tailored for each interview. Development of each guide was informed by interviewee role and level, agency type, and program area. Guides were developed by selecting and tailoring a subset of interview questions and follow-up prompts from a pre-established set of key country visit interview questions. Development of these pre-established questions was based on the *Strategic Approach to the Evaluation* (IOM and NRC, 2010) and the evaluation committee's priority evaluation questions. The questions covered eight primary evaluation areas: Knowledge Management, Resource Flow, PEPFAR Implementation, Programmatic Context, PEPFAR Effects, Health System Strengthening, and PEPFAR Transition to Sustainability and Country Ownership, as well as opening and final questions. In addition to the questions, follow-up prompts were developed both within these evaluation areas and for the following programmatic areas: Prevention, Treatment, Care and Support, Laboratory, Children and Adolescents, and Gender.

Interviews were conducted by an interview team generally comprised of a lead facilitator, co-facilitator, and note taker. The typical duration of an interview was 60-90 minutes. During the interview, the facilitator's role was to build rapport and facilitate the interview using the semi-structured guide and the co-facilitator's role was to ask follow-up or clarifying questions, serve as time keeper, write notes, and provide an end-of-interview review of the main points heard during the interview. The purpose of the co-facilitator's summary of main points was to provide an opportunity for participant validation which is discussed below. Additionally, the review of main points served as a starting point for the peer debriefings described below. The note-taker's role was to capture and record the data by means of handwritten or typed field notes as well as electronically, via an audio recorder, with interviewee consent. Additional team members who were present during an interview served as additional note takers; if fewer team members were present, one individual served as both note taker and either facilitator or co-facilitator.

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The evaluation delegation team participated in 68 field visits to a variety of sites in the 13 partner countries visited. The purpose of the site visits was to gain a contextual understanding of PEPFAR programs and resources. Each site visit included an interview, some of which were in-depth open-ended interviews while others were informal interviews conducted during walking tours of the sites. At least one designated delegate team member visiting the site took handwritten field notes during the visit; these were reviewed and reconciled by team members using the same procedures as interview notes.

The team conducted the majority of interviews in English. In the case of interviewees who preferred conducting the interview in a language other than English, the delegation team hired professional interpreters from the partner country and oriented them to the purpose and process of qualitative data collection and their role in the process.

Participant validation of data summaries A commitment to anonymity and confidentiality and a focus on cross-country data reporting precluded the sharing of country-specific findings with interviewees and their agencies or organizations during or after individual partner country visits. Interviewees were able to assess the scope and content of their key messages, however, in response to an end-of-interview summary of key messages that the co-facilitator offered at the conclusion of every interview. Following the summary of key points or messages, co-facilitators explicitly invited interviewees to convey any additions, corrections, or additional information that they wished to offer. Thus, all interviewees had an opportunity to affirm, modify, or extend their key messages, a process that not only affirmed that their viewpoints had been clearly understood and documented by the interview team, but also verified the accuracy and completeness of key messages shared with the team.

Researcher reflexivity Because delegation team members served as "instruments" of qualitative data collection, they were aware of a need to be reflexive or "simultaneously aware of self and other and of the interplay between the two" (Rossman and Rallis, 2012). In other words, engagement in reflexivity facilitated individuals' emergent self-awareness of personal predilections, assumptions, biases and beliefs so that each individual could potentially recognize and thus minimize her or his impact on interviewees and the research environment as well as the impact of the research environment on them (Patton, 2002). Team leaders and consultants urged all team members to engage in reflection and reflexivity throughout the evaluation by using at least one of two primary strategies: maintaining a private reflective and reflexivity journal or engaging in verbal reflexivity during any of the interview or team debriefings. Members of the evaluation team frequently, openly, and voluntarily shared their self-awareness of personal assumptions, biases, and beliefs verbally during one or more of the multiple peer debriefings and synthesis processes associated with data collection. At times, peers encouraged a team member to be reflexive when that individual's personal assumptions or biases emerged during discussions and debriefings related to the evaluation. During discussions, it was not unusual for team members to reference a personal need for self-reflexivity regarding some topic. Thus, the need for all investigators to become increasingly self-aware about their personal beliefs, assumptions, values, and biases that could impact the research or the research environment and vice versa was frequently reinforced during every country visit.

Audit trail The maintenance of an audit trail served as a means by which the evaluation team sought to establish study credibility and confirmability (Wolf, 2003). Evaluation team members

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were charged with organizing and maintaining various electronic and hardcopy audit trail evidence related to the evaluation. Evidentiary documents related to the process of the evaluation included the following:

- An ***agenda log*** maintained electronically for each country visit chronicled interview scheduling and contact information, evaluation-related contacts, and information on the participants and questions covered in completed interviews.
- An ***activity log*** maintained electronically throughout the evaluation process chronicled process and methodological decisions and action items both within and across country visits.
- ***Analysis and interpretation notations*** were indicated on flip chart paper and electronic notes during facilitated team debriefings and the mid-week and exit synthesis process. When evaluation team members recounted interviewees' viewpoints and experiences related to evaluation topics, they not only reported the content of interviewees' perspectives ("what they said") gleaned during interviews, but also differentiated interviewees' narratives from how they as team members interpreted what interviewees shared with them. Team members also discussed emerging linkages among participants' interview data and other data such as documents and observations.
- A ***codebook*** was initially developed and then revised based on evaluation topics and, to a lesser degree, data that emerged from the interviews and site visits. The codebook fostered team members' ability to consistently label or code segments of the narrative data.

Evaluation team debriefings The evaluation team engaged in a multistage process of data debriefings that were instrumental in verifying and communicating interview content, facilitating reflection and personal reflexivity, and synthesizing data findings according to evaluation topic. The types and content of the peer debriefings are outlined below:

- ***Individual Interview Debriefings***
  - Using the co-facilitator's end-of-interview summary as a basis, interview team members' documented interviewees' key points or messages, reflected on the interview process, engaged in and acknowledged personal reflexivity, and participated in a preliminary analysis and interpretation of the data collected during the given individual in-depth interview or group interview.
- ***Daily or Every-Two-Day Interview Debriefings***
  - All team members convened to share key points that emerged from the interviews of which they were a part, their perspectives about and interpretations regarding the data, and their personal reflections/reflexivity.
- ***Synthesis (End of Week 1)***
  - All team members engaged in a midpoint synthesis of interview findings, the process of which was facilitated by the team leader and structured according to evaluation topic.
  - Committee members often participated during the first week of the 2-week country visits. The end-of-week 1 synthesis process was thus critical in

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eliciting committee member insights into country visit data and interpretation before they exited the country.

- ***Exit Synthesis (End of Week 2)***
  - All team members engaged in an 8 to 10 hour process of verbally synthesizing the findings associated with data collection prior to exiting the country. Each team member received a copy of the interview debriefings that had been conducted. Similar to the end-of-week 1 synthesis process, the team leader facilitated the exit synthesis process that was structured according to evaluation topics and that included data documentation, reflection and reflexivity regarding the data collected, and verbal analysis and interpretation notations.
- ***Across country debriefings and discussions***
  - Periodically in between clusters of country visits, IOM study staff participated in a discussion and synthesis of the qualitative findings according to evaluation topic and identified consonance or differences in these findings across a number of countries.
  - At committee meetings that occurred periodically in between clusters of country visits, committee members, either as a whole committee or in working groups focused on specific content areas, participated in discussions of the analysis and interpretation of interview data, including review of draft data presentations.

Accuracy of data collection Critical in this evaluation was accuracy in documenting the data collected. With participants' permission, interviews were digitally recorded in conjunction with handwritten notes taken by members of the interview team. Professional transcriptionists ultimately transcribed the digitally recorded interviews, but the need for timeliness, efficiency, ease of comprehension, and engagement in data analysis from the onset of data collection led the evaluation team to rely on their own typed transcription of handwritten interview notes as the primary source of interview data for analysis. Interview team members later engaged in an independent, detailed review and edification of the note-taker's transcribed handwritten notes to ensure completeness and accuracy which involved an initial round by the assigned note taker, a second round by another team member who participated in the interview, and a final resolution round by the original note taker.

During the end-of-interview summary provided by the co-facilitator (or the facilitator when there was no co-facilitator), interviewees addressed the accuracy of main end-of interview points that co-facilitators shared with them by affirming, correcting, or adding to the end-of-interview summary. In addition, the interview team debriefed each interview shortly after it occurred to affirm the accurate documentation of main points using the co-facilitators' potentially revised summary as a foundation and contributing additional details. An additional accuracy check was afforded team members who could reference the digital recording of the interview when clarifying segments of narrative or resolving issues of disagreement regarding the content of a particular interview.

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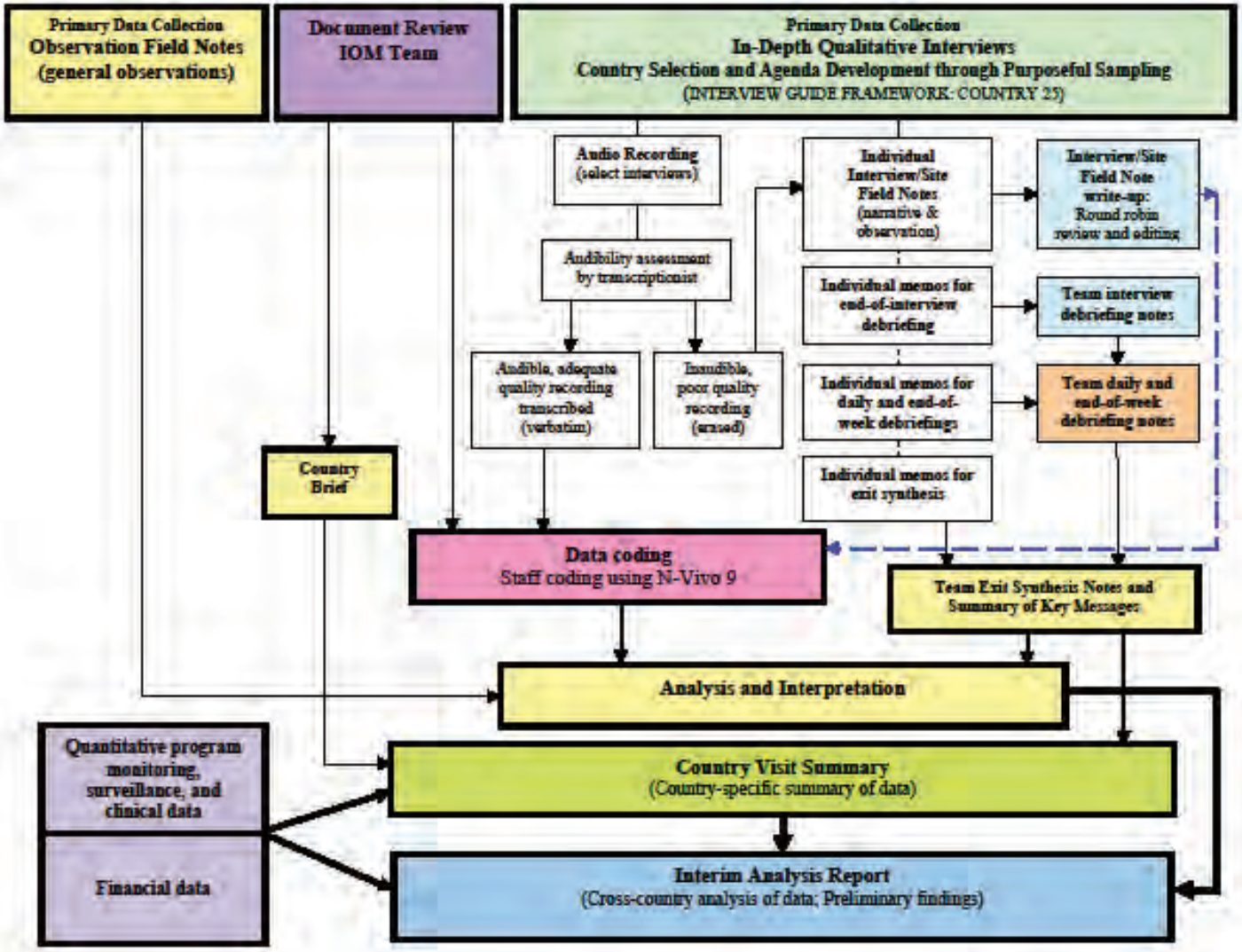

FIGURE C-1 Country visit qualitative data collection process

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Collection of Non-Country Visit Interview Data

As part of the data collection effort for the evaluation, IOM staff and consultants also conducted a series of 32 non-country visit interviews with key stakeholders. These interviewees included the U.S. government at PEPFAR headquarters level (including OGAC, CDC, and USAID) and U.S.-based implementing partners at headquarters level, as well as other organizations who work in the global response to HIV, including multilateral organizations, nongovernmental organizations, and another bilateral donor. As with the country visit interviews, non-country visit interviewees were selected through purposeful sampling, prioritized on the basis of targeted focus areas within the evaluation, and on the process of mapping data sources for evaluation questions. Semi-structured interviews were conducted using the same methodology as the country visit interviews, using interview guides with questions and prompts adapted as appropriate for each interview.

Analyses of Qualitative Data

In-country data analysis process In-country data review and preliminary analysis occurred at various levels and several times during country visits. As soon as possible after each interview, team members conducted a post-interview debriefing to discuss and document the main points shared by the interviewee(s). Delegation members also convened routinely as an entire team during the country visit to engage in debriefings to share with each other the main points from the data across all the interviews that were conducted.

At the close of the first week of each 2-week country visit and again at the close of the country visit, the team conducted an end-of-week debriefing and exit synthesis debriefing (respectively) that utilized an inductive analysis approach for the purpose of identifying dominant themes that emerged from the data. Both of these processes began with delegation members individually reading the debriefing notes from interviews conducted during the week to review key data from the interviews and to identify concepts and themes emerging from the data. Delegation members then collectively discussed the data and dominant themes that arose from the interviews, systematically using categories that were pre-selected based on the evaluation objectives. The delegation team differentiated between evidence (E), the responses heard during the interviews, and analysis and interpretation (A&I), which reflected the delegation's interpretations of what the evidence meant, focusing on the meaning in relation to the evaluation objectives. The output from these processes was an Exit Synthesis document capturing the key evidence and analysis and interpretation from the interviews grouped by evaluation category, and a Key Messages document capturing the main themes that emerged across the interviews.

These documents were then included as part of the country visit summary, which was reviewed by the members of the trip delegation and then posted on the committee portal. The country visit summary also includes other information provided to the delegation in advance of the trip in the form of a country brief, including background research on the country context and PEPFAR program as well as basic financial data and OGAC and other programmatic or indicator data (including UNAIDS data). The country visit summary is a compilation of the data from these multiple sources, not a triangulated analysis of the data and evidence available for each country. The goal was to provide a "snapshot" overview to inform the rest of the committee about the visit and the country and provide a centralized source for country data.

Synthesis of exit syntheses To provide the committee with a sense of the overall current findings emerging from the interview data, for some of the evaluation categories the IOM staff

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and consultant conducted a synthesis to identify and present the dominant themes that emerged in the exit syntheses across countries. This synthesis was conducted and presented in a variety of ways, ranging from analytical synthesis presented in narrative form to data grouped in bulleted form by sub-themes, which offers less synthesis and analysis but is closer to the "raw" data.

Additional analysis of interview data Additional data summaries, syntheses, and analyses from both the country visit and non-country visit interview data were generated using methods detailed below.

Members of the IOM staff used NVivo software (version 9.0) to conduct macro-level coding of the data using detailed interview notes generated by IOM staff and consultants or transcripts generated by contracted professional transcriptionists using audio recordings of interviews. The subset of data coded in NVivo comprised more than half of the interviews, purposefully selected for representation across countries and stakeholder types. This coding was based on a standardized project code book with each code reflecting important data concepts with inclusion and exclusion criteria. The data concepts represented in the code book were based on the *Strategic Approach* (IOM and NRC, 2010), the evaluation committee's development of priority evaluation questions, and the exit synthesis process and review of initial data collected from the pilot country visits and other early country visits. For synthesis and analysis, these coded data were separated and extracted by querying for a single code or combinations of the macro-level codes across interviews. In some cases, data were also extracted from the NVivo dataset using targeted word search queries.

Building on this initial thematic identification, IOM staff or consultants then conducted a more in-depth and refined analysis through repeated reading, reflection, and continued micro-level coding of the data for narrower subconcepts. This led to inductive identification of themes, patterns, and categories that emerged as findings from the data. This was followed by deductive confirmation and disconfirmation of those findings and determinations of data saturation for topics and themes (i.e., whether any new data has emerged). Prolonged engagement in data collection also led team members to affirm data saturation. Delegation evaluation teams recognized data saturation, through multiple iterations of individual and group analyses and discussions described below, as the repetition of information to the point of redundancy (Merriam, 2002; Patton, 2002), which thus indicated that data collection could be reasonably concluded (Lincoln and Guba, 1985).

As the next iteration of the analytical process, drafts of data analysis outputs were read for discussion and revision by members of the project staff, consultants, and evaluation committee members who were familiar with the interview data and had participated in data collection and in-country data analyses. In addition, interview debriefing and exit synthesis documents from all interviews, including those not in the initial coded dataset, were used to carry out supplementary deductive confirmation and disconfirmation of findings that emerged from the coded data, and to identify specific additional interview notes and transcripts for enrichment of the analysis of coded data.

These interview data findings and analyses were presented in a number of ways, including in narrative form with accompanying illustrative quotations, in summary tables, or in bulleted groupings by subconcepts. The presentation of quotes was used when one person's words provided a memorable description of an issue that was resonant with multiple interviewees or perspectives, or in some cases when one person's words represent a meaningful disconfirming perspective. Single quotations denote an interviewee's perspective with wording

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extracted from transcribed notes written during the interview. Double quotations denote an exact quote from an interviewee either confirmed by listening to the audio-recording of the interview or extracted from a full transcript of the audio-recording.

Interview data presented in the report are accompanied by a citation key. Typically interviews in qualitative research are cited with a brief descriptive demographic phrase; however, this was not feasible for an evaluation of this scope, with more than 400 interviews and the frequent citations for multiple interviews. Therefore, a citation tag was developed to allow the reader to identify the key characteristics relevant for the analysis and interpretation of the data for this evaluation, including the range of countries and interviews represented and the stakeholder type. The interview citation key is shown in Box C-1.

BOX C–1
Interview Citation Key

Country Visit Exit Synthesis Key: Country # + ES
Country Visit Interview Citation Key: Country # + Interview # + Organization Type
Non-country Visit Interview Citation Key: "NCV" + Interview # + Organization Type
Organization Types:
United States: **USG** = US Government; **USNGO** = US Nongovernmental Organization; **USPS** = US Private Sector; **USACA** = US Academia
Partner Country: **PCGOV** = Partner Country Government; **PCNGO** = Partner Country NGO; **PCPS** = Partner Country Private Sector; **PCACA** = Partner Country Academia
Other: CCM = Country Coordinating Mechanism; **ML** = Multilateral Organization; **OBL** = Other (non-US and non-Partner Country) Bilateral; **OGOV** = Other Government**;** **ONGO** = Other Country NGO

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Appendix D

Committee, Consultant, and Staff Biographies

COMMITTEE MEMBERS

Dr. Robert E. Black (Chair) is the chair of the Department of International Health and the Edgar Berman Professor in International Health, as well as the director of the Institute for International Programs at the Johns Hopkins Bloomberg School of Public Health. Dr. Black is trained in medicine, infectious diseases and epidemiology. He has served as a medical epidemiologist at the U.S. Centers for Disease Control and Prevention and worked at institutions in Bangladesh and Peru on research related to childhood infectious diseases and nutritional problems. Dr. Black's current research includes field trials of vaccines, micronutrients, and other nutritional interventions; effectiveness studies of health programs; and the evaluation of preventive and curative health service programs in low- and middle-income countries. His other interests are related to the use of evidence in policy and programs, including estimates of the burden of disease, and the development of research capacity. As a member of the Institute of Medicine and advisory bodies of the World Health Organization, the International Vaccine Institute, and other international organizations, he assists with the development of policies intended to improve children's health. He chairs the Child Health Epidemiology Reference Group and the Child Health and Nutrition Research Initiative. He currently has projects in Bangladesh, Ghana, India, Malawi, Mali, Peru, Tanzania, and Zanzibar. He has more than 500 scientific journal publications and is co-editor of the textbook *Global Health*. Dr. Black has served on four committees and the Board on International Health (now Global Health) of the Institute of Medicine.

Dr. Judith Auerbach is a sociologist and independent science and policy consultant who most recently served as vice president of Research and Evaluation at the San Francisco AIDS Foundation. Her previous positions include vice president of Public Policy and Program Development at amfAR, (The Foundation for AIDS Research); the director of the Behavioral and Social Science Program and the HIV prevention science coordinator in the Office of AIDS Research at the U.S. National Institutes of Health (NIH); assistant director for Social and Behavioral Sciences in the White House Office of Science and Technology Policy, and senior program officer at the Institute of Medicine. Dr. Auerbach received her Ph.D. in sociology from the University of California, Berkeley, and has taught, presented, and published in the areas of

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HIV/AIDS, social science and public policy, and sex and gender, with articles appearing in such journals as *Global Public Health, American Journal of Public Health*, *Science*, *Health Affairs*, and the *Journal of Health and Social Behavior*. She serves on a number of commissions and advisory and editorial boards, including for the International AIDS Society Governing Council, the Global HIV Prevention Working Group, the NIH Office of AIDS Research Advisory Council, and the *Journal of the International AIDS Society*. Dr. Auerbach has received a number of awards, including the 2004 Feminist Activist Award from Sociologists for Women in Society, the 2006 Research in Action Award from the Treatment Action Group, the 2008 Career Award from the Sociologists AIDS Network, and the 2010 Thomas M. Kelly Leadership Award from Project Inform.

Dr. Mary T. Bassett joined the Doris Duke Charitable Foundation in 2009 as director for its African Health Initiative, an effort that focuses on strengthening health systems in projects underway in Ghana, Mozambique, Rwanda, Tanzania, and Zambia. In late 2011, she additionally assumed leadership for the Child Abuse Prevention Program, which for 10 years has made grants aimed at preventing child maltreatment. Previously, she was a deputy commissioner at the New York City Health Department, where she oversaw programs that addressed noncommunicable disease and maternal and child health, as well as district public health offices based in Harlem, Central Brooklyn, and the Bronx. Between 1985 and 2002, she lived in Harare, Zimbabwe, where she was a member of the medical faculty at the University of Zimbabwe. She has also served for many years as an associate editor of the *American Journal of Public Health*.

Dr. Ronald Brookmeyer is a professor of biostatistics at the University of California, Los Angeles School of Public Health. Dr. Brookmeyer's research is at the interface of biostatistics and public health. A main theme of Dr. Brookmeyer's work is the use of statistical and quantitative approaches to measure the health of populations. Dr. Brookmeyer develops statistical methods and models for tracking and forecasting health and disease. He has worked extensively on the development of methods for tracking the course of the global HIV/AIDS epidemic. Dr. Brookmeyer developed the back-calculation method for disease forecasting and developed statistical approaches for biomarker-based methods for ascertaining HIV incidence rates in populations. He has also worked on issues of biosecurity, including the development of epidemic models. His research interests in biostatistics include survival analysis, clinical trial design and analyses, and epidemiological and statistical methods for disease surveillance. Dr. Brookmeyer has served as chair of the Statistics in Epidemiology Section of the American Statistical Association (ASA) and of the Statistics Section of American Association for the Advancement of Science (AAAS). He is a fellow of both the AAAS and the ASA. A member of the Institute of Medicine, he has served on six prior National Academies committees.

Dr. Lola Dare is the chief executive officer of the Center for Health Sciences Training, Research and Development (CHESTRAD) International and a community physician and epidemiologist. Dr. Dare has been a member of the West African Postgraduate Medical College in the Faculty of Public Health since 1990 and a fellow of the Nigerian National Postgraduate Medical College in the Faculty of Community Medicine since 1992. Dr. Dare also holds a certificate in Advance Management from the European Business School in France (2006) and is a member of the U.K. Faculty of Public Health by distinction. Dr. Dare has been engaged in advocacy for people-centered reform and development in Nigeria and was a member of the

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World Bank Expert Panel for Better Health in Africa (BHA). In 1998, the BHA panel metamorphosed into the African Council for Sustainable Health Development (ACOSHED), and Dr. Dare is currently a member of ACOSHED's Interim Executive Board. Dr. Dare facilitates health leadership development and management programs and serves as a consultant for many regional and global organizations in public health and social development (health, education, and poverty reduction), working at local, national and regional levels to advocate for and support the increased application of management and business tools to improve the performance of African health and social development systems. She graduated with a Bachelor of Medicine and Bachelor of Surgery (M.B.B.S) degree from the College of Medicine at the University of Ibadan in June 1985; obtained an M.Sc. degree in epidemiology from the London School of Hygiene and Tropical Medicine in 1991; and was awarded certificates in population and development and international health as a David E. Bell and Takemi Fellow of the Harvard School of Public Health in 1994 and 2000, respectively.

Dr. Alex C. Ezeh is the executive director of the African Population and Health Research Center (APHRC) and the director of the Consortium for Advanced Research Training and Research in Africa (CARTA). He joined APHRC in 1998 (then a program of the Population Council in Nairobi) as a senior research fellow. In 2000, he was appointed APHRC's interim director and charged with the responsibility of leading its transition to an autonomous institution. Having successfully led this transition, he was appointed APHRC's executive director in 2001 and has since steered the young institution to phenomenal growth. Prior to joining APHRC, he worked at ORC/Macro International, where he provided technical assistance to governmental and nongovernmental institutions in several African countries in the design and conduct of Demographic and Health Surveys. Dr. Ezeh has more than 20 years of experience working in public health and has authored numerous scientific publications covering the issues of population, demographics, health, and health metrics. Currently, he participates on the boards and committees of several international public health organizations, including PATH, the Council of the International Union for the Scientific Study of Population, the Scientific Advisory Group of Doris Duke's Africa Health Initiative, the Consortium for National Health Research in Kenya, the Alliance for Health and Systems at the World Health Organization, the Wittgenstein Centre for Demography and Global Human Capital, and the KEMRI-Wellcome Trust International Scientific Advisory Board. Dr. Ezeh received his Ph.D. in Demography from the University of Pennsylvania in 1993. He is also an honorary professor at University of Witwatersrand, South Africa. He has an M.A. in demography from the same university (1991) and an M.Sc. in sociology from the University of Ibadan, Nigeria (1988). Dr. Alex Ezeh has also been honored by the Obafemi Awolowo University in Ile Ife, Nigeria, for his outstanding contribution to the advancement of academic training in Africa.

Professor Sofia Gruskin directs the Program on Global Health and Human Rights at the Institute for Global Health at the University of Southern California and holds appointments as a professor of Preventive Medicine at the Keck School of Medicine and as a professor of Law and Preventive Medicine at the Gould School of Law. She is adjunct professor of Global Health at the Harvard School of Public Health, where she was previously an associate professor in the Department of Global Health and Population; the director of the Program on International Health and Human Rights; the co-director of the Interdepartmental Program on Women, Gender and Health; and the faculty chair of the Group on Reproductive Health and Rights at the Harvard

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Center for Population and Development Studies. Her work has been instrumental in the conceptual, methodological, policy, and practice development of linking health to human rights, with a focus on HIV/AIDS, sexual and reproductive health, child and adolescent health, gender-based violence, and health systems. She has extensive experience in research, training, and programmatic work with nongovernmental, governmental, and intergovernmental organizations working in the fields of health and human rights around the world. Professor Gruskin is the principal investigator for several projects sponsored by the Joint United Nations Programme on HIV and AIDS (UNAIDS), the World Health Organization, and the United National Population Fund that are intended to strengthen the health and human rights research and policy agenda, particularly in the areas of HIV/AIDS, sexual and reproductive health, child and adolescent health, and gender-based violence. She serves on numerous boards and committees nationally and internationally, including as a member of the technical advisory group of the Global Commission on HIV and the Law and the UNAIDS Monitoring and Evaluation Reference Group. She served as a permanent member of the Behavioral and Social Consequences of HIV/AIDS study section at the U.S. National Institutes of Health (2005–2009) and as chair of the UNAIDS Global Reference Group on HIV/AIDS and Human Rights (2002–2006). Professor Gruskin was editor-in-chief of the international journal *Health and Human Rights* from 1994 to 2006 and is currently an associate editor for the *American Journal of Public Health*, *Global Public Health*, and *Reproductive Health Matters*.

Dr. Angelina Kakooza is a neuropediatrician and lecturer in the Department of Pediatrics and Child Health at the School of Medicine, Makerere University College of Health Sciences. Her major research interests are in the fields of neurology and infectious diseases and she has vast experience in the field of HIV/AIDS among children. The bulk of her educational training has been in Uganda, however, she has also attended several short courses in pediatrics, neurology, and public health in various countries in Africa, Asia, and Europe. She took a course on the Clinical Management of HIV at the Johannesburg Medical School, University of Witwatersrand in South Africa. She has worked as a sessional pediatrician in specialized HIV units in Uganda, including the Mild May International Center, Kajjansi, Uganda (a center for specialist training on HIV/AIDS and the management of HIV/AIDS patients). She also worked at the Baylor College of Medicine Children's Foundation (formerly the Pediatric Infectious Diseases Clinic), which is a Pediatric and Adolescent HIV Center of Excellence. She is an alumna of the African International Brain Research Organization–funded schools. She was a recipient of the International Scholarship Award from the American Epilepsy Society in 2005 which she undertook at Children's Hospital Boston and Harvard Medical School under the supervision of Prof. Frances Jensen, and she was a Mentee Awardee of the Collegium Internationale Neuropsychopharmacologicum Research Mentor Program. She is a co–principal investigator on an U.S. National Institutes of Health grant to study neurodevelopmental disabilities screening and assessment in Uganda, and she has a multisite study on the epidemiology of epilepsy in sub-Saharan Africa. She has published work in general pediatrics, autism, and HIV/AIDS. She is a member of several professional and voluntary bodies and is the president of the Uganda Chapter of the International League Against Epilepsy (ILAE) and treasurer of the Commission on African Affairs of the ILAE. Currently, she is pursuing a Ph.D. in medicine (neurology) jointly at Makerere University in Kampala and the Karolinska Institute in Stockholm, Sweden, and she was a recipient of the African Doctoral Dissertation Research Fellowship in 2011.

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Dr. Jennifer Kates is vice president and director of Global Health & HIV Policy at the Kaiser Family Foundation. She oversees the Foundation's policy analysis and research focused on the U.S. government's role in global health and on the global and domestic HIV epidemics. Widely regarded as an expert in the field, she regularly publishes and presents on global health issues and is particularly known for her work analyzing donor government investments in global health; assessing and mapping the U.S. government's global health architecture, programs, and funding; and tracking key trends in the HIV epidemic, an area she has been working in for more than 20 years. Prior to joining the Foundation in 1998, Dr. Kates was a senior associate with The Lewin Group, a health care consulting firm, where she focused on HIV policy, strategic planning/health systems analysis, and health care for vulnerable populations. Prior to that, she directed the Office of Lesbian, Gay, and Bisexual Concerns at Princeton University. Dr. Kates received her Ph.D. in health policy from The George Washington University, where she is also a lecturer. She holds a bachelor's degree from Dartmouth College, a master's degree in public affairs from Princeton University's Woodrow Wilson School of Public and International Affairs, and a master's degree in political science from the University of Massachusetts.

Dr. Ann Kurth is a professor and founding director of the Global Division, New York University College of Nursing. She maintains affiliate appointments in the University of Washington Department of Global Health and its School of Nursing. As a clinically-trained epidemiologist, Dr. Kurth's work focuses on HIV/sexually transmitted infections/reproductive health prevention, screening, and care, as well as on global health workforce issues. Her research has been funded by the NIH (NIAID, NIDA, NIMH, NICHD), Bill & Melinda Gates Foundation, the Joint United Nations Programme on HIV and AIDS, the U.S. Centers for Disease Control and Prevention, the U.S. Health Resources and Services Administration, and others, for studies conducted in the United States and internationally. She is currently involved in projects in the United States, Uganda, Ghana, Kenya, Tanzania, Rwanda, India, the Republic of Georgia, and Peru. Dr. Kurth has published over 100 peer-reviewed articles, book chapters, and scholarly monographs and edited one of the first books published on women and HIV (*Until the Cure*, Yale Press 1993). She served as president of the Association of Nurses in AIDS Care, which has international affiliates in Canada and Europe and which created credentialing certifications for HIV nurses. Dr. Kurth received a Ph.D. in epidemiology from the University of Washington; a M.S.N., R.N., and C.N.M. in nurse-midwifery from Yale University; and a M.P.H. in population and family health from Columbia University. Her undergraduate work was done at Princeton University (A.B., magna cum laude). Dr. Kurth is a fellow of both the American Academy of Nursing and the New York Academy of Medicine.

Dr. Anne Petersen is the founder and president of Global Philanthropy Alliance, a foundation making grants in Africa. She also is a research professor at the Center for Human Growth and Development at the University of Michigan among other affiliations there. She serves on several voluntary boards and committees for governments, foundations, and scientific or community-based organizations. For example, she is co-chair of the advisory board for CALIT2, an institute created a decade ago to move information technology advances in health and other areas from the University of California system to industry in California and beyond. She also chairs the jury for the million-Swiss Franc research prize given by the Jacobs Foundation. Prior to returning to Michigan, Dr.Petersen was a professor of psychology at Stanford University and the deputy director for the Center for Advanced Study in the Behavioral Sciences, where she instituted new

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practices for fellow selection and fundraising. For a decade, Dr. Petersen was the senior vice president for programs and a corporate officer at the W.K. Kellogg Foundation, among the largest in United States. She was responsible for all Kellogg programs in the United States, Latin America, and Africa. Among her accomplishments there, she established a learning system that would permit the Foundation to capture and track lessons learned from program work. The U.S. president nominated and the Senate confirmed Dr. Petersen as the deputy director and chief operating officer of National Science Foundation (NSF), with responsibilities for all science and engineering research and education programs. She was the first woman to hold either of the top two positions at NSF. Dr. Petersen was the first vice president for research at the University of Minnesota, as well as the graduate dean and a professor at the Institute for Child Development and the Department of Pediatrics. At Penn State University for a decade, Dr. Petersen was the department head and founding dean of the College of Health and Human Development, and professor of health and human development. Prior to Penn State, Dr. Petersen was a faculty member at the University of Chicago and the associate director of the MacArthur Foundation Health Program. Dr. Petersen has authored 12 books and over 230 articles on adolescent and gender issues, including health and development, cognition, evaluation and research methods, and higher education. Her honors include election to the Institute of Medicine and being named a fellow in several scientific societies including the American Association for the Advancement of Science, the American Psychological Association (three divisions), and the Association for Psychological Science, where she was a founding fellow. She co-founded the Society of Research on Adolescence, was the president of several scientific societies, and is the past president of the International Society for the Study of Behavioral Development. Dr. Petersen earned all her degrees at the University of Chicago: a B.A. in mathematics, an M.S. in statistics, and a Ph.D. in measurement, evaluation, and statistical analysis.

Dr. Douglas Richman is a distinguished professor of pathology and medicine at the University of California San Diego (UCSD) and the Florence Seeley Riford Chair in AIDS Research. He is the director of the Center for AIDS Research at UCSD and a staff physician at the Department of Veterans Affairs (VA) San Diego Healthcare System. He trained as an infectious disease physician and medical virologist at Stanford, the National Institutes of Health (NIH), and Harvard before joining the faculty at UCSD in 1976. He has focused his investigation on HIV disease and pathogenesis for the past 30 years. His laboratory was the first to identify HIV drug resistance. His laboratory joined two others in identifying latently infected CD4 cells as the obstacle to eradication of HIV with potent antiretroviral therapy. More recently, his lab described the dynamics of the neutralizing antibody response to HIV and the rapidity of viral escape and evolution in response to this selective pressure. Dr. Richman has authored over 625 scientific publications. He is also a co-editor of *Clinical Virology*, a state-of-the-art reference book, and editor of *Antiviral Drug Resistance*. Dr. Richman has served as a consultant to the NIH, the VA, the World Health Organization, and the State of California and has been honored with an NIH Merit Award and the Howard M. Temin Award for Clinical Science and Clinical Excellence in the Fight Against HIV/AIDS. He served on the Institute of Medicine Committee for Examining the Probable Consequences of Alternative Patterns of Widespread Antiretroviral Drug Use in Resource-Constrained Settings.

Dr. Jennifer Prah Ruger is an associate professor at Yale University at the Schools of Public Health, Medicine, and Graduate School of Arts and Sciences and adjunct faculty at the Law

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School. She is a senior research fellow at the MacMillan Center for International and Area Studies. She is a faculty associate of Yale's Interdisciplinary Center for Bioethics, its Center for Interdisciplinary Research on AIDS, and the Rudd Center for Food Policy and Obesity. Following a postdoctoral fellowship at Harvard's Center for Population and Development Studies, she served on the Health and Development Satellite Secretariat of the World Health Organization Director-General, Dr. Gro Harlem Brundtland's Transition Team. She then worked as a health economist at the World Bank and later served as a speechwriter to President James D. Wolfensohn. Dr. Ruger was a member of the Institute of Medicine's Global Health Governance Working Group, Committee on the U.S. Commitment to Global Health. She is currently a member of the Ethics Subcommittee of the Advisory Committee to the Director at the U.S. Centers for Disease Control and Prevention and is chair of the Ethics Special Primary Interest Group of the American Public Health Association. Her research interests focus on health ethics, economics, and politics on the political economy of health and include health financing and insurance; health, health systems, and economic development; health and social justice; global health justice; and global health governance. These contributions are unified by an overarching interest in disparities and equity in health and health care, focusing on vulnerable and impoverished populations at the national and global level. She has published both theoretical and empirical work on equity and efficiency of health system access, financing, resource allocation, policy reform and the social determinants of health. She received a B.A. in political economy from the University of California-Berkeley, a M.Sc. from Oxford University, a M.A from the Fletcher School of Law and Diplomacy, and a Ph.D. from Harvard University.

Dr. Deborah L. Rugg has more than 30 years of professional international and national evaluation experience and has led international evaluation standards-setting bodies such as the HIV/AIDS Monitoring and Evaluation Reference Group, which she chaired from 2006 to 2011, and the United Nations (UN) Evaluation Group, where she has served as vice chair since 2012. Since August, 2011, Dr. Rugg has served as the director of the Inspection and Evaluation Division in the Office of Inspection and Oversight Services, UN Secretariat in New York City. Previously she served as Chief of the Monitoring and Evaluation Division at the Joint UN Programme on AIDS (UNAIDS) in Geneva, Switzerland. Prior to joining UNAIDS in 2005, Dr. Rugg was the associate director for Monitoring and Evaluation for the Global AIDS Program of the U.S. Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, from 2000 to 2005. While in Atlanta, she also served as an adjunct associate professor at the Emory University School of Public Health. Prior to that, she was an assistant professor of health psychology at the University of California, San Francisco School of Medicine and then at the San Diego State University School of Public Health from 1982 to 1987. She joined the CDC in 1987 as an Epidemic Intelligence Service (EIS) officer in the Division of HIV/STD Prevention. She has authored or coauthored more than 70 peer-reviewed publications and 30 major agency reports and normative guidances, primarily on evaluation methods in HIV, especially in relation to adolescents, risk groups, and HIV counseling and testing. She served on the National Research Council Panel on Data and Research Priorities for Arresting AIDS in Sub-Saharan Africa. She has a B.A. from the University of Wisconsin in physiological psychology and earned her Ph.D. in health psychology from the University of California, San Francisco School of Medicine in 1982.

Dr. Dawn K. Smith is a medical epidemiologist in the Division of HIV/AIDS Prevention

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(DHAP) at the U.S. Centers for Disease Control and Prevention (CDC). As lead for the Biomedical Interventions Activity in the Epidemiology Branch, she coordinates planning for health services and systems research, and development of guidelines and other support tools for the domestic implementation of clinical interventions to reduce HIV acquisition, including non-occupational pre-exposure prophylaxis (nPEP), pre-exposure prophylaxis (PrEP), and potential topical microbicides. Dr. Smith began her career at CDC coordinating the HER Study, a multisite longitudinal study of the effects of HIV infection on women, and collaborating with the National Institute of Allergy and Infectious Diseases (NIAID)-funded women's HIV cohort study, the WIHS. She then led the development of CDC guidelines for the use of nPEP and led the writing of a 5-year microbicide research agenda for the agency. She spent 4 years as the associate director for HIV research at the CDC field station in Botswana, where she established clinical trial infrastructure with integrated sociobehavioral research and initiated PrEP trials and then served for three years as an Associate Chief for Science in the DHAP Epidemiology Branch. She maintains a strong research interest in the intersections of race, ethnicity, social class, injection drug use, and the HIV epidemic. Dr. Smith has served on scientific committees and review panels for NIAID, the Office of AIDS Research, and the National Institute on Drug Abuse. Dr. Smith received her M.D. from the University of Massachusetts Medical School and went on to complete an M.P.H. in public health policy and international health, and a M.S. in clinical research design and statistical analysis at the University of Michigan. A family physician, Dr. Smith has practiced in varied settings, providing medical care in a Native American community, in an urban clinic with Hispanic, Vietnamese, and African American families, and to HIV-infected women at Grady Hospital in Atlanta.

Dr. Papa Salif Sow is a professor of infectious diseases at the University of Dakar in Senegal. He received his medical degree from the Faculty of Medicine of the University of Dakar in 1987. He trained as a physician specializing in infectious and tropical diseases. Dr. Sow completed his training at the Institute of Tropical Medicine of Antwerp in Belgium in 1991 (where he obtained an M.S. degree) and at Nagasaki University in Japan in 1994. In 1990, he was recognized as a World AIDS Foundation International Scholar at the San Francisco General Hospital. Since 1987, Dr. Sow has worked extensively in the field of infectious diseases in general and HIV/AIDS in particular, focusing on the care of patients, teaching, and research. He has focused his research on the development of diagnosis and treatment of opportunistic infections and on first-line antiretroviral therapies and management strategies in resources-limited countries. In 2002, Professor Sow was nominated as the head of the Department of Infectious Diseases of the University of Dakar. Since 1998, he has been the clinical coordinator of the Senegalese Initiative for Access to ARV and has led a multidisciplinary team for scaling up this strategy to the entire country. He has also undertaken several consultancies on HIV/AIDS care and treatment for the Joint United Nations Programme on HIV and AIDS and the World Health Organization (WHO) in Geneva. He is a member of the WHO Writing Guidelines for Access to Care and Treatment in Resource Limited Settings, a member of the Strategic Advisory Committee for HIV/AIDS, and was a member of the Technical Review Panel of the Global Fund to Fight AIDS, Tuberculosis and Malaria during Rounds 4, 5, 6 and 7. He has many research collaborations, mainly with the Agence nationale de recherche sur le sida et les hépatites virales in France and the University of Washington, Seattle, focusing on opportunistic infections and HIV therapies. His current research interests include second-line antiretroviral therapies in resources-limited countries and HPV vaccine trials in young girls. Dr. Sow is the president of the African Network for AIDS

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Physicians and the coordinator of the Regional Centre for Research and Training at Fann Hospital Dakar, Senegal. Since 2008, he has been a member of the Governing Council of the International AIDS Society for Africa.

Dr. Sally K. Stansfield is a physician epidemiologist who works as a health systems technology advisor, focusing on metrics and the development of institutions and policies to deliver better health outcomes. She works with multiple stakeholders, including United Nations member states, technical agencies, donors, and civil society groups that are committed to strengthening country-owned strategies and systems for health. An expert in evaluation and planning for health systems, Dr. Stansfield has worked extensively in Africa, Asia, Central America, South America, and the Middle East. She was the founding director of the Health Metrics Network initiative, an innovative partnership hosted by the World Health Organization (WHO) to strengthen health information systems. For seven years prior to working at WHO, she worked within the newly established Global Health Program for the Bill & Melinda Gates Foundation. There, she was instrumental in shaping strategies and in creating and managing several landmark alliances including the Global Alliance for Vaccines and Immunization; the Global Fund to Fight Tuberculosis, AIDS and Malaria; and the Global Alliance for Improved Nutrition. She has worked in senior positions for Management Sciences for Health in Cambodia, the International Development Research Centre in Ottawa, the U.S. Agency for International Development, and the U.S. Centers for Disease Control and Prevention. Dr. Stansfield has also served in research and teaching roles on the faculties of Addis Ababa University in Ethiopia, McGill University in Montreal, Johns Hopkins University in Baltimore, the University of Washington in Seattle, and the Uniformed Services University of the Health Sciences in Bethesda, Maryland. Dr. Stansfield's awards include the Alpha Omega Alpha medical honorary, the International College of Surgeons Award, the U.S. Public Health Service Distinguished Service Commendation, a Fulbright Fellowship, and the Yale Tercentennial Medal.

Dr. Taha E. Taha is a professor and the co-director of the Infectious Disease Program, Department of Epidemiology, at the Johns Hopkins University Bloomberg School of Public Health. Dr. Taha is also a professor of Population, Family and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health. Dr. Taha is a physician with diverse training and extensive experience in infectious diseases, community medicine, public health, and demography. Dr. Taha is the principal investigator (PI) for the National Institutes of Health (NIH)–funded (2006-2013) Malawi HIV Clinical Trials Unit, a consortium of three institutions including Johns Hopkins University, the Malawi College of Medicine, and the University of North Carolina at Chapel Hill. Previously, Dr. Taha was the PI of two NIH-funded projects in Malawi — the HIV Prevention Trials Network and the HIV Vaccine Trials Network (HVTN). He is also a PI, co–PI or a co-investigator on multiple other cooperative agreements, subcontracts, and investigator-initiated research and training projects in Malawi funded by the NIH, the U.S. Centers for Disease Control and Prevention, and other agencies. For more than 15 years, Dr. Taha has directed several large cohort studies and clinical trials in Malawi. His expertise is in conduct of HIV epidemiologic studies in, sexually transmitted infections, malaria, and other tropical diseases. He has published extensively in the fields of HIV and sexually transmitted diseases and has participated in teaching of graduate medical and public health students and postdoctoral fellows in several countries in Africa.

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Dr. Kathryn Whetten is a professor of public policy and global health at Duke University. She holds joint appointments in community and family medicine and nursing. She is the director of the Center for Health Policy and Health Inequities Research and is the research director for the Hart Fellows Program. Dr. Whetten assisted in the creation of Duke's Global Health Institute, of which she is a member. Dr. Whetten's research focuses on understanding disparities in health and well-being by taking into account characteristics at the individual, family, community, and policy levels. Her research attempts to account for lifecourse events, such as childhood trauma, neglect, and abuse on current beliefs, health-related behaviors, and health outcomes. She then tests interventions designed to mitigate past negative experiences and improve outcomes. The target audience for her research is health policy analysts and decision makers, administrators, and clinicians. Dr. Whetten's area of study involves the identification of barriers to positive health outcomes, the creation of models of care that reduce barriers to care in a changing financial environment, the evaluation of such models, and engaging in the policy debate. Much of Dr. Whetten's current research focuses on two of the most difficult populations to serve: those living with HIV, mental health and/or substance disorders living around the world and children who have been orphaned or abandoned. Dr. Whetten has led more than 20 federally funded research grants and is the author of three books and more than 60 peer-reviewed articles. Currently, Dr. Whetten and her intervention, service, and research team have research projects that address issues surrounding HIV/AIDS, mental health, substance abuse, being orphaned, social justice, and poverty in the U.S. Deep South, Tanzania, Kenya, Ethiopia, India (including Nagaland), Cambodia, Malawi, Cameroon, and Russia. A few of the research projects are "Positive Outcomes for Children Orphaned by AIDS," "Coping with HIV/AIDS in Tanzania," "Integrative Treatment Model for Substance Abusing Women in Russia," and the "North Carolina HIV/AIDS Training Network." Dr. Whetten received her Ph.D. in population health research at the University of North Carolina at Chapel Hill.

Dr. Catherine Wilfert graduated with distinction from Stanford College in 1958 and then attended Harvard Medical School. Her internship was at Boston City Hospital, and her residency was at North Carolina Baptist Hospital and Children's Hospital Medical Center, Boston. In 1964, Dr. Wilfert returned to Boston, where she continued to work in infectious diseases in pediatrics and medicine. In 1971, she went to Duke University School of Medicine, where she achieved the rank of division chief of Pediatric Infectious Diseases and professor in the Department of Pediatrics (1976–1994) and professor in the Department of Microbiology and Immunology. In 1996, she left Duke to become the scientific director of the Elizabeth Glaser Pediatric AIDS Foundation. Dr. Wilfert's work, since the onset of AIDS, has primarily been focused on the eradication of pediatric AIDS and, she is considered a seminal investigator in the field. She guided the National Institutes of Health AIDS Clinical Trials Group when the efficacy of using doses of AZT to reduce the incidence of mother-to-child transmission of HIV was established. Mother-to-child transmission of HIV in the United States is estimated to have been reduced to fewer than 200 cases per year. Dr. Wilfert has worked to reduce mother-to-infant transmission of AIDS in developing countries around the world. She has been on the editorial board of numerous publications and has served as a consultant for private companies, as well as U.S. and state governments. She is the recipient of many awards, including the 1997 Award of Recognition for Outstanding Contributions to Advancing the Prevention of Perinatal Transmission at A Global Strategies Conference for the Prevention of Mothers-to-Infants HIV Transmission. She also received a Lifetime Achievement Award in HIV from the Third International Meeting on HIV in

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India in 2001 and in 2004, was given the Distinguished Award of Honor for Love of Humanity Especially in the Third World from the Cameroon Baptist Convention on Occasion of Its 50th Anniversary Celebration. She was inducted into the Institute of Medicine (IOM) in 1999. Dr. Wilfert has served on five prior IOM committees and on the IOM Roundtable for the Development of Drugs and Vaccines Against AIDS.

CONSULTANTS

Dr. Sharon Knight served as a qualitative research consultant for this evaluation. She is a professor of health education and promotion at East Carolina University and former associate dean of the College of Health and Human Performance. She teaches graduate-level academic courses on qualitative research, including an interdisciplinary qualitative research course in the health sciences, and mentors graduate students in conducting qualitative research. She has had over two decades experience as a qualitative researcher and holds a certificate in qualitative research from the University of North Carolina at Chapel Hill School of Nursing. She most recently served on a Macy Foundation–funded project titled, "The National Initiative on Gender, Culture, and Leadership in Medicine." She has published over 40 refereed journal articles and two books.

Kathryn Tucker is a statistical scientist at Statistics Collaborative, Inc. (SCI), where she has worked since 2001. At SCI, Ms. Tucker has worked with clinical trials in a variety of therapeutic areas, including cardiology, oncology, tropical and infectious diseases, allergies, genetic disorders, radiographic imaging, and pre-clinical studies of decompression sickness. She has served as the independent statistician reporting to data-monitoring committees for several multi-center Phase 1, 2, and 3 trials. In this role, she oversees the preparation of interim statistical analysis plans and interim monitoring reports. As a consulting statistician for clients conducting clinical and pre-clinical studies, she helps design study protocols, determines appropriate sample sizes and power calculations, and writes final statistical reports and clinical study reports. Ms. Tucker manages biostatistical and programming staff on her projects, including their development of analysis datasets and presentations. She has also developed and validated randomization schedules and designed case report forms and databases for several Phase 1, Phase 2, and field trials in malaria. Since 2004, Ms. Tucker has also served as SCI's Director of Quality Assurance, maintaining corporate policies and procedures and overseeing employee training. She received her B.S. magna cum laude in statistics with a minor in mathematics and her M.S. in statistics from Virginia Polytechnic Institute and State University.

Dr. Janet Wittes is President of Statistics Collaborative, Inc. which she founded in 1990. Her previous positions were as a biostatistician in government (National Heart, Lung, and Blood Institute and the Department of Veterans Affairs) and as a faculty member in the Department of Mathematical Sciences at Hunter College of The City University of New York. Her research has focused on randomized clinical trials, capture-recapture methods in epidemiology, sample size recalculation problems in clinical studies, and incorporation of subjective outcomes in clinical trials. She is a member of many advisory committees for government and industry. She has been a statistician for studies of prevention of HIV/AIDS in South Africa and studies of malaria vaccines in Thailand and sub-Saharan Africa. She is a fellow of the American Statistical Association, the Society for Clinical Trials, and the American Association for the Advancement

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of Science and an elected member of the International Statistical Institute. She received her A.B. in mathematics from Radcliffe College (1964) and her M.A. and Ph.D. in statistics from Harvard University (1965, 1970).

IOM STAFF

Kimberly A. Scott joined the Institute of Medicine's Board on Global Health in September, 2005 as a senior program officer. She has directed several studies and activities, including the Committee for the Evaluation of the President's Emergency Plan for AIDS Relief Implementation; the Planning Committee on Preventing Violence in Low- and Middle-Income Countries; the Committee on the Assessment of the Role of Intermittent Preventive Treatment for Malaria in Infants; and the Committee on Achieving Global Sustainable Surveillance for Zoonotic Diseases. She was the support program officer for workshop planning on the Committee on Depression, Parenting Practices, and the Health Development of Children. She is currently the study co-director for the evaluation of U.S. global HIV/AIDS programs. Prior to joining IOM, she was an analyst on the health care team at the U.S. Government Accountability Office. Before her graduate studies at Duke University's Center for Health Policy, Law, and Management, she coordinated programs for integrating mental health services into the continuum of care for people living with and affected by HIV/AIDS in 54 counties in North Carolina, including training of mental health professionals and HIV case managers for the provision of clinical services to people living with HIV/AIDS. For 6 years, she served as the Executive Director of a Ryan White–funded HIV/AIDS consortium, developing a comprehensive ambulatory care system for 21 mostly rural counties in North Carolina. Previous North Carolina health-related committee service includes a number of advisory committees to the governor of North Carolina and to the secretary of the North Carolina Department of Health and Human Services (NC DHHS) for programmatic and policy issues related to HIV care, prevention, and treatment, including the formation of the Title II Ryan White AIDS Care Consortia. She received a Lifetime Achievement Award from the AIDS Care Branch in the NC DHHS. As an Echols Scholar, she received her B.A. in psychology from the University of Virginia. She received an M.S.P.H., with a concentration in health policy analysis, from the University of North Carolina at Chapel Hill.

Dr. Bridget B. Kelly is a senior program officer with the Institute of Medicine's (IOM) Board on Global Health. Prior to co-directing this evaluation of U.S. global HIV/AIDS programs, she was the study director for the report, *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health*, and continues to direct a series of related follow up activities, including the workshop *Country-Level Decision Making for Control of Chronic Diseases*. She serves on the Senior Advisory Council for the journal *Global Heart* and the advisory working group for the National Forum for Heart Disease and Stroke Prevention's *Policy Depot*. Prior to joining the IOM's Board on Global Health in September 2008, she worked in the Board on Children, Youth, and Families for projects on prevention of mental, emotional, and behavioral disorders among children, youth, and young adults; on depression, parenting practices, and child development; and on strengthening benefit-cost methodology for the evaluation of early childhood interventions. She first came to the National Academies in September 2007 as a Christine Mirzayan Science and Technology Policy Graduate Fellow. She holds both an M.D. and a Ph.D. in neurobiology, which she completed as part of the Medical

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Scientist Training Program at Duke University. She received her B.A. in biology and neuroscience from Williams College, where she was also the recipient of the Hubbard Hutchinson Fellowship in fine arts. In addition to her health policy experience and background in science and medicine, she has over 10 years of experience in grassroots nonprofit arts administration.

Margaret Hawthorne is a program officer with the Institute of Medicine's (IOM) Board on Global Health. Prior to joining the IOM, she was an epidemiologist at the Texas Department of State Health Services (DSHS) in the TB/HIV/STD Epidemiology and Surveillance Branch. While at DSHS, she served as the HIV Incidence Surveillance and Viral Resistance Coordinator for the state, overseeing the surveillance systems used to track the leading edge of the HIV epidemic in Texas. She previously worked as a research program manager at the Institute for Global Tobacco Control at the Johns Hopkins School of Public Health. There she developed capacity-building trainings and in-country workshops aimed at building tobacco control leadership globally. Ms. Hawthornes received an M.P.H. in health systems and policy from the Johns Hopkins Bloomberg School of Public Health, and a B.A. in business from Southwestern University.

Livia Navon is a program officer with the Institute of Medicine's (IOM) Board on Global Health. Prior to joining the IOM, she worked as the district epidemiologist for the Alexandria Health Department (AHD), as part of the Virginia Department of Health. While working at the AHD, she worked on emergency preparedness and response activities, including the local response to the 2009 H1N1 pandemic, and investigated communicable disease outbreaks. Previously, she worked at the National Center for Health Statistics on the annual *Health, United States* report and for the Wisconsin Department of Health Services, as an environmental epidemiologist for the Wisconsin Asthma Program. She received her B.S. in biochemistry with a minor in chemistry from the University of Florida and an M.S. in nutrition from Cornell University. She completed her dietetic internship at the University of Wisconsin Hospital and Clinics.

Dr. Carmen Cecilia Mundaca is serving as a postdoctoral fellow with the Institute of Medicine's Board on Global Health. Previously, she served as the Head of the Surveillance Center of the Emerging Infections Program in the U.S. Naval Medical Research Center Detachment in Lima, Peru. In that role, Dr. Mundaca led the successful implementation of a technology-based disease surveillance system (Alerta DISAMAR, a partnership involving the Peruvian Navy and the U.S. Navy) at sites across the nation and initiated its broad adoption in five other countries in South America, and provided the mechanism for reporting of 45 diseases/syndromes via a telephone or a computer with Internet access. She also led the collaborative syndromic surveillance pilot implementation in the Peruvian Ministry of Health. Dr. Mundaca was part of the Early Warning Outbreak Recognition System (EWORS) Working Group and participated in several studies including a field visit to evaluate the performance of the system in Laos PDR. She obtained her M.D. from San Marcos University, Lima, Peru, and her M.P.H. degree from the Uniformed Services University of the Health Sciences in Bethesda, Maryland, where she is currently pursuing her Dr.P.H. degree. Her dissertation work will focus on developing a framework that will serve as a guideline for the implementation of disease

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surveillance systems in developing countries. Dr. Mundaca successfully completed a Certificate in Emerging Infectious Disease Epidemiology at the University of Iowa.

Mila C. González Dávila is a Dr.P.H. candidate in the Department of Epidemiology at Columbia University's Mailman School of Public Health in New York City. Prior to starting her doctoral studies in September 2012, she was an associate program officer with the Institute of Medicine's (IOM) Board on Global Health, having joined as a research assistant in 2007. Starting in 2009, she worked with the Committee for the Outcome and Impact Evaluation of U.S. Global HIV/AIDS Programs Implemented under the Lantos/Hyde Act of 2008. Before working on the IOM evaluation of PEPFAR, she provided research support on two IOM reports, *Assessment of the Role of Intermittent Preventive Treatment for Malaria in Infants* (2008) and *Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin* (2009). Previously, she worked as a clinical research assistant for a study evaluating the effects that exposure to violence has on young mothers with preschool-age children at the Children's Research Institute of the Children's National Medical Center in Washington, D.C. She received her M.P.H. in global health promotion from The George Washington University School of Public Health and her B.S. in physiology and neurobiology from the University of Maryland at College Park.

Kate Meck is a research associate with the Institute of Medicine's Board on Global Health. She previously worked with the Committee on the U.S. Commitment to Global Health, the sequel to *America's Vital Interest in Global Health* (1997). Ms. Meck received her B.A. in international relations, with minors in economics and Spanish & Latin American Studies, from American University in 2007, and her M.P.H. in global health program design, monitoring, and evaluation from The George Washington University School of Public Health and Health Services.

Kristen Danforth is a research associate with the Institute of Medicine's Board on Global Health. Prior to this study she worked on the report *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health* (2010). She received her B.S. in international health from Georgetown University and her M.P.H. from the Bloomberg School of Public Health at Johns Hopkins University.

Rebecca Marksamer is a research associate with the Institute of Medicine's (IOM) Board on Global Health. Prior to joining the IOM, she worked in the international programs department at Africare, a development assistance and humanitarian aid organization for Africa. She received her bachelor's degree in Biological Basis of Behavior from the University of Pennsylvania and her M.P.H. in Global Health Policy from The George Washington University School of Public Health and Health Services.

Collin Weinberger is a research associate at the Institute of Medicine's (IOM) Board on Global Health. In addition to this study, he has served as research staff for the IOM's Forum on Microbial Threats and for the recent report, *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health* (2010). Prior to joining the IOM, he was a communications associate at Global Health Strategies, a communications and advocacy consultancy specializing in diseases of the developing world. He also spent a year as a volunteer with Partners in Health/Socios en Salud in Lima, Peru, where he worked with the organization's

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children's health, multidrug-resistant tuberculosis, and HIV/AIDS programs. He received his bachelors degree in Health and Societies from the University of Pennsylvania and is a 2013 M.P.H. candidate at Johns Hopkins Bloomberg School of Public Health.

Ijeoma Emenanjo spent five years working on the Board on African Science Academy Development, where he primarily mentored the staff at the National Academy of Nigeria on conducting convening activities and consensus studies. Mr. Emenanjo also served with the Institute of Medicine's (IOM) Board on Global Health as a senior program associate for the IOM evaluation of PEPFAR and as a research associate for the Committee on the Assessment of the Role of Intermittent Preventive Treatment for Malaria in Infants. Before coming to the National Academies in 2004, he worked on policy implementation issues such as HIV/AIDS prevention policy and electoral administration in Anglophone and Francophone West Africa. Prior to his transition into international policy work, Mr. Emenanjo was a polymeric materials engineer at the U.S. Army Research Lab in Adelphi, Maryland, and at the National Institutes of Standards and Technology's Building and Fire Research Lab. He received his B.S. in chemical engineering with a minor in economics from Howard University, and his M.P.P. from the University of Maryland, Baltimore County.

Leigh Carroll is a research assistant with the Institute of Medicine's Board (IOM) on Global Health. She is involved in dissemination activities for the 2010 report *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health* as well as in the outcome and impact evaluation of PEPFAR. Before coming to the IOM, she spent 2 years in rural Tanzania teaching high school science through the Peace Corps. She received her B.S. in neuroscience from the University of Rochester.

Tessa Burke worked on the evaluation of PEPFAR as a senior program assistant with the Institute of Medicine's (IOM) Board on Global Health. Prior to joining the IOM, she worked as a senior program coordinator in the technical leadership office of Jhpiego, an international nongovernmental organization affiliated with Johns Hopkins University. She received her bachelor's degree from Georgetown University, graduating with a major in international health and a minor in studio art.

Wendy E. Keenan is a program associate with the Institute of Medicine (IOM)–National Research Council (NRC) Board on Children, Youth, and Families. She helps organize planning meetings and workshops that cover current issues related to children, youth, and families and also provides administrative and research support to the Board's various program committees. Ms. Keenan has been on the National Academies' staff for over 10 years and has worked on studies for both the IOM and the NRC. As a senior program assistant, she worked with the NRC's Board on Behavioral, Cognitive, and Sensory Sciences. Prior to joining the National Academies, she taught English as a second language for Washington, D.C., public schools. She received a B.A. in sociology from Pennsylvania State University and took graduate courses in social and public policy from Georgetown University.

Angela Christian is a program associate with the Institute of Medicine's (IOM) Board on Global Health. She currently serves as the administrative assistant for the Board on Global Health and the administrator for the Board on African Science Academy Development Initiative. Over the past 5 years, Ms. Christian has managed and facilitated international conferences in

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Senegal, the United Kingdom, Ghana, and South Africa while mentoring local administrators. Prior to her current position, she served as a senior program assistant to the PEFAR evaluation and DoD–GEIS Influenza Assessment studies, where she planned and managed logistics for about 19 international site visits to Africa, Asia, and Latin America for committee members from different parts of the world. Prior to joining the IOM, she was a practice manager of a private orthopedic surgery at the Washington Hospital Center. She has over 15 years experience in business and project management, serving as a Small Business Advisor with Empretec Ghana Foundation (a United Nations Project), an administrative assistant at the American College of Cardiology, and a project manager with a private events and project management firm implementing national projects and private initiatives in Ghana. Ms. Christian is currently pursuing a program in Global Business and Public Policy at the University of Maryland and also has a certificate in project management.

Dr. Kimber Bogard is the director of the Board on Children, Youth and Families at the Institute of Medicine and National Research Council. In this role, she directs a range of activities that address emerging and critical issues in the lives of children, youth, and families. She was previously the Associate Director of the Institute of Human Development and Social Change at New York University where she managed a portfolio of grants and contracts that examined child development within a changing global context. A developmental psychologist by training, Dr. Bogard has worked with numerous organizations that support children's cognitive, affective, and behavioral development in early childhood education through the high school years, including the Foundation for Child Development, W.K. Kellogg Foundation, the Center for Children's Initiatives, and Partners for a Bright and Healthy Haiti. In 2006, she received her Ph.D. from Fordham University in applied developmental psychology, and she also holds a master's degree from Columbia University-Teachers College where she studied risk and prevention strategies in adolescents. Dr. Bogard often speaks to various audiences about child development in the context of families and schools, with a keen focus on how policies influence developmental, educational, and health trajectories.

Rosemary Chalk is the former Director of the Board on Children, Youth, and Families, a joint effort of the Institute of Medicine (IOM) and the National Research Council (NRC). She is a policy analyst who had been a study director at the National Academies since 1987. She directed or served as a senior staff member for over a dozen studies in the IOM and the NRC, including studies on vaccine finance, the public health infrastructure for immunization, family violence, child abuse and neglect, research ethics and misconduct in science, and education finance. From 2000 to 2003, she also directed a research project on the development of child well-being indicators for the child welfare system at Child Trends in Washington, DC. She has previously served as a consultant for science and society research projects at the Harvard School of Public Health and was an Exxon research fellow in the Program on Science, Technology, and Society at the Massachusetts Institute of Technology. She was the program head of the Committee on Scientific Freedom and Responsibility of the American Association for the Advancement of Science from 1976 to 1986. She has a B.A. in foreign affairs from the University of Cincinnati.

Dr. Patrick Kelley joined the Institute of Medicine (IOM) in July 2003 as the director of the Board on Global Health. He has subsequently also been appointed the director of the Board on African Science Academy Development. Dr. Kelley has overseen a portfolio of IOM expert

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consensus studies and convening activities on subjects as wide ranging as the U.S. commitment to global health, priorities for building food and drug regulatory capacity in developing countries, sustainable surveillance for zoonotic infections, and promoting cardiovascular health in the developing world. He also directs a unique capacity-building effort, the African Science Academy Development Initiative, which over 11 years aims to strengthen the capacity of African academies to advise their governments on scientific matters. Prior to coming to the National Academies, Dr. Kelley served in the U.S. Army for more than 23 years as a physician, residency director, epidemiologist, and program manager. In his last Department of Defense (DoD) position, Dr. Kelley founded and directed the DoD Global Emerging Infections Surveillance and Response System. This responsibility entailed managing surveillance and capacity-building partnerships with numerous elements of the federal government and with health ministries in more than 45 developing countries. Dr. Kelley is an experienced communicator, having lectured in English or Spanish in more than 20 countries and having published more than 70 scholarly papers, book chapters, and monographs. Dr. Kelley obtained his M.D. from the University of Virginia and his Dr.P.H. in epidemiology from the Johns Hopkins School of Hygiene and Public Health.

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