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REPORT TO CONGRESS

Health-Related Research and Development Strategy

2011–2015



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U.S. Agency for International Development (USAID)

Report to Congress

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Foreword

The U.S. Agency for International Development (USAID) is pleased to present its new multiyear health-related research strategy. This report details the Agency's ongoing commitment to addressing some of the world's most challenging health and development issues through technology development, research and evaluation, and introduction and scale-up of real world, evidence-based solutions.

Since its creation in 1961, USAID has invested in the development and introduction of simple, innovative, evidence-based, and cost-effective solutions that save millions of lives. After over half a century of effort, USAID continues to encourage the widespread use of bold scientific and technological innovations to reduce poverty and improve livelihoods around the world. As a leader in the application of science, technology, and innovation to achieve development objectives, USAID has supported health research efforts that span the needs of the developing world. These efforts include investments in activities that range from product development to the evaluation of proven interventions. USAID recognizes that a foundation in technology development, and research and evaluation combined with a commitment to introduce and scale up evidence-based approaches, is vital to bringing game-changing innovations into use.

Through the USAID Forward reform agenda, and to address development challenges, the Agency is strengthening its support for pioneering scientific, technological, and innovative approaches. Illustrative of this, the Agency's new evaluation policy renews our commitment to implementation research and the development of "best practices" around priority health interventions. Evidence Summits, concentrating on areas of critical global health importance, provide a mechanism for the U.S. Government and other stakeholders to synthesize best practices and policies, develop a focused research agenda to address critical gaps in understanding, and inform future health research studies. Through the Global Health Initiative, Grand Challenges for Development, Development Innovation Ventures, and the Higher Education Science Network, the Agency will continue to drive breakthroughs in science and technology that can transform development challenges into solvable problems.

The 2012 Child Survival Call to Action brought together governments, civil society, the United Nations, and the private sector to highlight innovative and proven strategies to speed up reductions in child mortality. Looking forward, and working in partnership with stakeholder countries, USAID will work to strengthen the monitoring and reporting of progress in child survival and will implement high-impact solutions to best address the leading causes of child mortality.

We welcome this opportunity to inform you of the Agency's health-related research strategy and look forward to its implementation during the upcoming years. We thank Congress for its continued support of USAID and its health-related research agenda.

Ariel Pablos-Méndez, Assistant Administrator for Global Health
U.S. Agency for International Development

Table of Contents

Overview 1

Maternal and Newborn Health..... 4

Child Health..... 7

Nutrition..... 9

Family Planning and Reproductive Health..... 11

HIV/AIDS..... 13

Malaria..... 15

Tuberculosis 17

Pandemic Influenza and Other Emerging Threats..... 19

Health Systems Strengthening 20

Addendum: Core Funding for Health Research Goals..... 22

Acronyms and Abbreviations..... 23

Acknowledgments.....24

OVERVIEW

The U.S. Agency for International Development (USAID) has a strong history of transforming development through science and technology. In 2006, USAID outlined for Congress its 5-year health research strategy. From 2006 to 2010, USAID proactively sought to accelerate the development and introduction of research products that, when implemented in programs, can improve the health status of infants, children, women of reproductive age, and families. The 2008, 2009, and 2010 Reports to Congress: Health-Related Research and Development Activities at USAID provide updates on the Agency's strategy for using research funds to stimulate the development, introduction, and scale-up of key products and interventions to address diseases affecting the developing world.

From 2006 to 2010, USAID-funded research led to key successes, including global recommendations for newborn survival and child health, the development and adoption of strategies to prevent maternal mortality, innovations in contraceptive methods, and new drug formulations for malaria. The Agency demonstrated that topical cleansing of the umbilical cord using a 4-percent chlorhexidine solution, a low-cost, readily available antiseptic drug, reduces the risk of neonatal death from infections. USAID-supported studies on the effectiveness of community-based treatment for severe pneumonia provided the evidence base for the establishment of new World Health Organization (WHO) guidelines for outpatient management of this childhood illness. In addition, the Centre for the AIDS Programme of Research in South Africa (CAPRISA) 004 trial led to progress in the development of microbicide products to prevent HIV transmission.

This 2012 Report to Congress: Health-Related Research and Development Strategy provides an overview of the Agency's new multiyear strategy on health-related research and development as directed in the joint explanatory statement of the conference report accompanying P.L. 112-74. USAID supports research and introduction activities along a research-to-use continuum from assessment and development to introduction and field implementation. This includes evidence reviews and health assessments in developing countries and the development, testing, adaptation, and introduction of appropriate products and interventions within the context of strengthening health systems. Table I provides a summary of the 2011–2015 strategic areas of focus, which are further detailed in this report.

To accelerate the uptake of global health products and interventions, USAID is seeking to overcome existing technical, supply, and policy hurdles. The 2011–2015 strategy reflects increased investments in implementation science and in operational and evaluative research, so as to advance and guide the adoption and integration of evidence-based interventions that will change practice and accelerate scale-up. Parallel to these efforts, USAID's Center for Accelerating Innovation and Impact (CII) will promote and reinforce innovative, business, management, finance, and market principles to address key bottlenecks along the research-to-use continuum.

In order to achieve health impact, USAID collaborates with diverse partners to address critical barriers to the development, introduction, and scale-up of priority global health interventions. These partners include the U.S. State Department Office of the Global AIDS Coordinator, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Department of Defense, multilateral health organizations, other donor agencies, foundations, host country governments, academia, nongovernmental organizations,

PROMOTING INNOVATION AND SCALING FOR IMPACT

There are a myriad of lifesaving health technologies readily available in the 21st century. However, too few are accessible and take years to reach populations in disease-burdened, low-income countries. Because successful product development and introduction requires viable public and private markets with clear pathways to achieve scale, the Agency is applying cutting-edge thinking to push boundaries and address formidable barriers to adoption – from regulatory inefficiencies and market failures to limited user demand and supply chain hurdles.

To tackle these barriers, USAID established the CII to promote and reinforce innovative, business-minded approaches and solutions toward accelerating impact against some of the world's most important health challenges. By applying forward-looking practices, the Agency will invest in the most promising innovations in health research and cut the time it takes to transform “discoveries in the lab” to “impact on the ground.”

The center will focus on three key areas to promote innovation and impact:

- 1. Identifying State-of-the-Art Practices:** The center will engage with key experts to identify state-of-the-art practices in innovation, introduction, and scale-up across different sectors. The center will identify portfolio management and product launch tools to support investments in research and innovation as well as develop new tools to enable the shaping and enhancement of markets, including market incentives, demand subsidies, robust demand forecasts, and evidence-based business cases for improved product adoption.
- 2. Catalyzing Innovation and Partnerships:** With widespread access to technology virtually anyone can be an agent of change. USAID is harnessing the power of these innovators as the Agency creatively thinks of better ways to do business. Through partnerships such as Saving Lives at Birth: A Grand Challenge for Development, USAID is supporting the development of groundbreaking solutions with the potential for transformational change in the hardest-to-reach parts of the world.
- 3. Scaling for Impact:** Optimizing the use of market mechanisms and strategic partnerships with the private sector can help drive increased access to lifesaving technologies for underserved populations. The center will design and implement accelerated development and introduction plans for priority products and interventions to support their rapid deployment and adoption in target communities, countries, and regions; develop and evaluate innovative financing mechanisms to accelerate product development or access for high-priority health innovations; and support last mile research to improve child health through partnerships with NIH.

and private sector. Building on its relationships with these partners, USAID is looking at the future direction of science and technology, bringing new solutions to existing challenges and applying novel technical tools to advance development.

TABLE: 2011–2015 HEALTH RESEARCH GOALS

<p>Maternal and Newborn Health</p>	<ul style="list-style-type: none"> ■ Develop and introduce new and improved evidence-based interventions for care during pregnancy and at birth. ■ Strengthen and standardize high-quality obstetric care for the prevention, management, and treatment of fistula. ■ Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia. ■ Develop, test, and introduce community-based health interventions to treat and prevent newborn infections. ■ Develop scalable, cost-effective approaches for integrating maternal and neonatal health services. ■ Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions. ■ Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.
<p>Child Health</p>	<ul style="list-style-type: none"> ■ Support implementation research to inform the uptake of integrated Community Case Management. ■ Develop and test cost-effective approaches to decrease the incidence of acute lower respiratory infections due to household air pollution. ■ Evaluate interventions to increase the use of efficacious diarrhea treatments. ■ Develop and test scalable approaches to improve drinking water quality, access, use of sanitation, and hygiene behaviors.
<p>Nutrition</p>	<ul style="list-style-type: none"> ■ Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia. ■ Support implementation research for improved diet diversity and quality. ■ Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.
<p>Family Planning and Reproductive Health</p>	<ul style="list-style-type: none"> ■ Refine, develop, and introduce new contraceptive methods. ■ Improve and expand the use of family planning methods in developing countries. ■ Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies.
<p>HIV/AIDS</p>	<ul style="list-style-type: none"> ■ Develop and introduce microbicides for women to reduce their risk of HIV infection. ■ Accelerate the development and clinical testing of novel HIV vaccine candidates. ■ Strengthen the evidence base to improve HIV/AIDS prevention, care, and treatment programs.
<p>Malaria</p>	<ul style="list-style-type: none"> ■ Develop safe and effective vaccines to reduce morbidity and mortality due to <i>Plasmodium falciparum</i>. ■ Develop effective and affordable medicines for the treatment and prevention of malaria. ■ Improve malaria control program implementation and impact.
<p>Tuberculosis</p>	<ul style="list-style-type: none"> ■ Develop diagnostic tools to more effectively detect TB in individuals with and without HIV. ■ Develop shorter TB regimens that are effective against all forms of TB, can be used with antiretroviral therapy, are suitable for children, affordable, and easily managed in resource-limited settings. ■ Conduct operations research for improving TB program performance and management of TB-HIV.
<p>Pandemic Influenza and Other Emerging Threats</p>	<ul style="list-style-type: none"> ■ Develop and introduce surveillance models to increase pathogen detection. ■ Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.
<p>Health Systems Strengthening</p>	<ul style="list-style-type: none"> ■ Strengthen and improve health systems performance and contribute to more sustainable programmatic outcomes. ■ Advance methodologies to measure health systems strengthening and performance. ■ Strengthen evidence-based practices for the uptake and use of proven approaches to improve health systems performance at the country level.

MATERNAL AND NEWBORN HEALTH

Background

Each year, an estimated 287,000 women die from complications during pregnancy and childbirth that can be prevented. Eighty-seven percent of maternal deaths take place in sub-Saharan Africa and South Asia. Postpartum hemorrhage continues to be the leading direct cause of maternal mortality in developing countries, followed by pre-eclampsia and eclampsia, and sepsis.

Despite the steady decline in child mortality rates worldwide, approximately 6.9 million children under 5 years of age die annually. Of these deaths, an estimated 2.9 million are

newborns in their first month of life. The main causes of newborn mortality are severe infection (sepsis or pneumonia, diarrhea, and tetanus), preterm births, asphyxia, and congenital abnormalities. Low birth weight is the most important indirect cause of neonatal mortality.

USAID-supported research has contributed to the development and adoption of strategies for maternal mortality reduction. The Agency has also been a key player in bringing global attention to newborn survival as well as in investing in research on commu-

nity-based management of sick newborns, which is forming the basis of global recommendations and action. With the existence of new evidence-based maternal and newborn interventions, more focus is needed on approaches to translate them into sustainable and scalable programs. Challenges in access to skilled care at birth, the implementation of a defined integrated postnatal care package, and a lack of an integrated community-to-facility maternal and newborn health service delivery system point to the need for evaluation and implementation research to reduce mortality.

MATERNAL HEALTH RESEARCH GOALS

1 *Develop and introduce new and improved evidence-based interventions for care during pregnancy and at birth.*

Rationale: Postpartum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E) account for 35 percent and 18 percent of maternal deaths, respectively. Active Management of the Third Stage of Labor (AMTSL) is a feasible, low-cost intervention that can prevent 60 percent of uterine atony (poor contraction) that leads to hemorrhage and maternal death. Uterotonics (medications used to cause the uterus to contract and reduce PPH) are a key component of AMTSL, but they are not yet widely sanctioned by ministries of health for use at the community level, including first-level health facilities. Though the provision of calcium and aspirin during pregnancy has been shown to improve PE/E outcomes, gaps in uptake remain. There is a need to develop intervention packages that may be used to prevent and manage PPH and PE/E in low-resource settings and to identify operational factors that will facilitate program implementation.

An estimated two-thirds of maternal deaths occur during labor and the 24 hours following birth. Though the majority of complications are preventable, or can be appropriately managed by a skilled birth attendant (SBA) during delivery, an SBA is present at only an estimated 46 percent of deliveries in low-income countries compared to 58 percent in lower middle-income countries and 99 percent in upper middle-income countries. A lack of respectful and nonabusive care at birth may contribute to the limited use of SBAs at the facility level.

2011–2015 Expected Results:

- Develop and introduce approaches that lower the cost of delivery, eliminate usage barriers, and expand the availability and appropriate use of uterotonics at the community level for the prevention and management of PPH in low-resource settings.
- Identify and test simple, low-cost technologies and innovations for the diagnosis and treatment of PE/E at different levels of the health system.
- Identify barriers to access and demand for SBAs, current and future needs, as well as potential financing options to support their sustained use in both private and public health care settings.
- Identify contributors to the mistreatment of women around the time of labor and delivery in facilities and address its impact on the utilization of facility care at birth.

2 *Strengthen and standardize high-quality obstetric care for the prevention, management, and treatment of fistula.*

Rationale: Obstetric fistula, a condition in which an abnormal opening (or fistula) in the birth canal forms, is a debilitating condition most often caused by prolonged, obstructed labor and lack of emergency obstetric care. As a result of obstructed labor, between 50,000 and 100,000 women encounter fistula each year, and more than 2 million women live with untreated fistula in Asia and sub-Saharan Africa. An untreated fistula can cause severe, lifelong complications and disability. Provision of safe and timely Cesarean sections is a key prevention strategy.

2011–2015 Expected Results:

- Determine the efficacy, safety, and related costs of short-term catheterization after fistula repair as compared to longer-term catheterization for increased access to treatment and care for women with fistula.
- Identify the indications for Cesarean delivery in health facilities as related to the incidence of fistula.
- Identify and address the factors that contribute to negative postoperative outcomes of fistula repair surgery.

1 *Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia.*

Rationale: Birth asphyxia is the second leading cause of newborn mortality, accounting for approximately 759,000 neonatal deaths annually. Reducing these deaths requires availability of the appropriate technologies for low-resource settings and training on their use. The Helping Babies Breathe (HBB) Global Development Alliance (a USAID-supported public-private partnership) evidence-based program to train birth attendants in neonatal resuscitation techniques has been found to reduce asphyxia-related deaths by 50 percent. Evidence-based approaches are needed to inform the continued introduction and scale-up of HBB at the country level.

2011–2015 Expected Results:

- Identify promising low-cost simplified neonatal resuscitator technologies for ventilatory performance and operational and user feasibility for use in resource-limited settings.
- Evaluate the quality, coverage, and impact of the HBB program at the community and facility levels and its relation to health systems performance, provider competence, quality of care, and key outcomes.

2 *Develop, test, and introduce community-based health interventions to treat and prevent newborn infections.*

Rationale: Newborns are vulnerable to infections that account for approximately one-third of the estimated 2.9 million child deaths that occur each year. Improvements in hygiene, reductions in exposure to life-threatening bacterial infections, and the availability of antibiotics can substantially prevent death and treat severe illness in low-resource settings with limited access to quality facility-based care. USAID-supported research has demonstrated that topical cleansing of the umbilical cord using a 4-percent chlorhexidine solution, a low-cost, readily available antiseptic, reduces the risk of neonatal death from infections in research settings. There is a continued need for the development and scale-up of simplified, cost-effective community-based regimens that can treat newborn sepsis in resource-limited settings.

2011–2015 Expected Results:

- Develop and introduce low-cost, scalable approaches, including marketing strategies, for the introduction of chlorhexidine for umbilical cord care at the community and facility levels.
- Determine the efficacy of two alternative, simplified antibiotic regimens for community-based management of neonates with suspected severe infection.

Saving Lives at Birth: USAID, through the Center for Accelerating Innovation and Impact, is supporting the Saving Lives at Birth: A Grand Challenge for Development program to develop groundbreaking innovations to address maternal and neonatal health in rural settings during the 48 hours surrounding birth. By partnering with the Governments of Norway and the United Kingdom, the Bill & Melinda Gates Foundation, and Grand Challenges Canada, the 5-year, \$50 million program supports proof-of-concept innovations and invests in transformational ideas that have the potential to be scaled up and have sustained impact over time. Saving Lives at Birth features a diverse portfolio of 39 technologies, service delivery models, and ways to stimulate demand for health care services. These include a heat-stable pouch for home delivery of antiretrovirals immediately after birth to reduce mother-to-child transmission of HIV; mobile vouchers to encourage prenatal care and facility births; and a simple, rapid assessment tool for frontline health workers to identify and triage preterm infants.

1 *Develop scalable, cost-effective approaches for integrating maternal and neonatal health services.*

Rationale: The limited implementation of integrated approaches that effectively incorporate services in maternal and newborn health, nutrition, and HIV/AIDS undermines efforts to reduce mortality. Limited information exists on the relative cost-effectiveness of integrated versus nonintegrated services, as well as impact on health outcomes, quality, morbidity, and mortality. There is a need to assess the sustainability of integrated approaches toward informing decision makers on the scale-up and replication of these interventions.

2011–2015 Expected Results:

- Determine and demonstrate optimal strategies for implementation and sustained delivery of evidence-based, cost-effective, and culturally acceptable integrated maternal and newborn health, nutrition, and HIV/AIDS interventions.
- Develop models for evidence-based integrated service packages that include AMTSL, Essential Newborn Care, and/or postpartum family planning delivered by community health workers.

2 *Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions.*

Rationale: Populations who lack access to health services show consistently worse health outcomes and greater mortality. The development of approaches to expand access to services, decrease barriers, and reduce inequities in the provision of essential services provides new opportunities to decrease maternal, neonatal, and child mortalities.

2011–2015 Expected Results:

- Determine the intended and unintended consequences of macro policy interventions on the access, utilization, and quality of essential obstetric and newborn care.
- Develop equity-based tools and approaches to identify high-risk groups and enable targeting of marginalized populations.
- Identify effective strategies to improve the ability of families to recognize maternal-newborn complications and seek appropriate care.
- Assess the barriers to the scale-up and formalization of task-shifting approaches to expand access to essential maternal, newborn, and child health services.
- Develop innovative approaches that address critical bottlenecks in service provision, particularly for vulnerable populations.
- Develop mHealth technologies that can address usage barriers and inequities among underserved populations.

3 *Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.*

Rationale: Monitoring maternal and perinatal mortalities is an integral part of routine health information systems and a critical component to the development and implementation of quality maternal and newborn health interventions. The lack of standardized criteria and effective tools for defining and measuring perinatal morbidity and mortality leads to inconsistencies in the way deaths are classified and reported worldwide. In addition, there is a lack of consensus on the appropriate quality of care indicators for routine program monitoring and quality improvement to enable comparisons at subnational, national, and global levels. Better data and direct measurements will decrease the application of proxy measures that are currently used to assess health interventions, quality improvement efforts, economic impact, and societal outcomes related to maternal and perinatal death.

2011–2015 Expected Results:

- Revise the perinatal death classification system to standardize the cause distribution of perinatal deaths within and across countries.
- Define global quality of care indicators for routine program monitoring and quality improvement of maternal and child health services.

CHILD HEALTH

Background

Every year, approximately 6.9 million children under the age of 5 die; two-thirds of these deaths – most of them preventable – are from pneumonia, diarrhea, and malaria. These health threats account for 1.24 million, 759,000, and 483,000 deaths, respectively. Substantial progress has been made in reducing under-5 mortality; about half of the decline between 2000 and 2011 (from 9.6 million to 6.9 million) can be attributed to improvements in combatting three life-threatening conditions: pneumonia and diarrhea as well as measles. In addition, the dramatic scale-up of malaria prevention and treatment efforts that has taken place over the last 5 to 10 years in sub-Saharan Africa is having a major impact on malaria-related illness. Today, the majority of under

5 deaths occur among populations with limited access to health facilities and can be avoided through improved treatment and prevention approaches, such as integrated Community Case Management (iCCM) – the joint treatment of pneumonia, diarrhea, and malaria (in malaria-endemic areas) – safe water, and sanitation and hygiene.

Identifying high-impact, replicable, and scalable approaches can accelerate progress on child survival and facilitate widespread uptake. USAID-supported studies have demonstrated that nonsevere and severe pneumonia and malaria may be effectively managed by community health workers using appropriate antibiotics, rapid diagnostic tests, and artemisinin-based combination

therapy. Almost 90 percent of diarrhea is caused by unsafe water, lack of access to sanitation services, and poor hygiene. Safe drinking water, proper handwashing at critical times, and correct and consistent use of basic sanitation can reduce diarrhea in children under 5 by 25 percent to over 50 percent, depending on the intervention and the implementation modality. Zinc and oral rehydration therapy, a low-cost, simple treatment for dehydration associated with diarrhea, contributes to the global reduction in childhood diarrhea-related deaths. Current underutilization of these evidence-based interventions undermines under 5 mortality reduction efforts.

CHILD HEALTH RESEARCH GOALS

1 Support implementation research to inform the uptake of integrated Community Case Management.

Rationale: iCCM is a key global strategy to reduce under-5 mortality. The utilization of community health workers to manage cases of pneumonia, diarrhea, and malaria has been shown to be safe, effective, and of similar quality to facility care. Despite this strong evidence-base, there are challenges to the introduction and uptake of iCCM at the country level and among hard-to-reach populations. Additionally, more focus is needed on approaches that promote the improvement of iCCM program acceptance and design, eliminate implementation barriers, inform policy development, and foster sustainability. USAID is working with WHO and UNICEF to evaluate best practices and overcome bottlenecks for the successful scale-up of iCCM.

2011–2015 Expected Results:

- Develop a simple tool to rapidly assess the costs and financing of iCCM introduction and expansion efforts in developing country settings.
- Inform the routine and episodic monitoring of iCCM programming through implementation research on existing platforms.
- Develop policy frameworks that can be applied to countries at various stages of iCCM policy and program development.
- Develop and introduce innovative solutions to maximize available human resources, including approaches that use task shifting and effective teaming among different cadres of health professionals and communities.

Rationale: Nearly half of all pneumonia deaths among children under 5 occur as a result of exposure to indoor smoke from cooking with biomass fuels. Despite continued advancements in cookstove technologies, evidence-based practical approaches to scaling up and sustaining these interventions in developing country settings have been limited. Individual needs, motivation, and stove usage differ across communities, necessitating stove programs to integrate technology and market development strategies within an enabling environment.

2011–2015 Expected Results:

- Develop programmatic models that combine fuel-efficient cooking technologies with behavior change messages and market-based distribution mechanisms to increase the acquisition and sustained correct use of improved cookstoves.

3 Evaluate interventions to increase the use of efficacious diarrhea treatments.

Rationale: Diarrhea is the second leading cause of child deaths worldwide and a substantial contributor to malnutrition despite the availability of effective low-cost therapies. The use of zinc for treatment along with oral rehydration solutions (ORS) in some settings is limited by product availability, particularly in rural areas, as well as lack of knowledge among health care providers and caregivers regarding ORS and zinc. USAID is identifying new interventions to promote ORS and zinc to health professionals and caregivers with the goal of increasing knowledge and use of zinc/ORS in rural settings.

2011–2015 Expected Results:

- Develop approaches to support public and private sector use of diarrhea treatments.
- Determine usage motivators and barriers for diarrhea treatment among caregivers and public (midwives/nurses) and private (pharmacy agents) providers.

4 Develop and test scalable approaches to improve drinking water quality, access, use of sanitation, and hygiene behaviors.

Rationale: Ensuring safe drinking water at the point of use (POU) at the household is possible through existing low-cost technologies. The effectiveness of POU treatment products – both filter- and consumable-based – for preventing diarrhea is well established, and such products remain a cost-effective option for providing drinking water until households have access to a safe piped-water supply. However, there is a need to identify the most effective ways of delivering POU and other water, sanitation, and hygiene products and services to populations at risk in order to increase access, adoption, and consistent use. Basic sanitation is a critical first line of defense for interrupting fecal-oral transmission, along with handwashing and safe drinking water. Children with diarrhea eat less and struggle to absorb the nutrients from their food, while malnourished children are more susceptible to diarrhea when exposed to fecal material from their environment. Beyond access, research is needed to inform the correct, consistent, and sustained use of sanitation programs.

2011–2015 Expected Results:

- Support the development of a field-based microbiological test for drinking water quality in rural and resource-limited settings.
- Document the linkages between water, sanitation, and hygiene and child nutritional status.
- Determine the effectiveness of sanitation programming on initiating and sustaining use of latrines for the lowest economic quintiles and other at-risk populations.

NUTRITION

Background

Undernutrition affects more than 170 million children worldwide and contributes to approximately 2.6 million child deaths each year. It hampers the control of infectious diseases, contributes to maternal and child mortality, and threatens cognitive development. Without improvement in child nutrition, a country's human capital and economic growth are significantly constrained. Long-term solutions to undernutrition come from comprehensive and cross-sectoral approaches that address the underlying determinants of nutritional status, including poverty, agriculture, policy environment, health care, maternal and child care practices, girls' education, gender, and social equity and protection. Due to the multisectoral nature of

the causes, consequences, and solutions to undernutrition, the Global Health Initiative, Feed the Future, and the U.S. Government's Global Hunger and Food Security Initiative intersect to harmonize the numerous pathways that impact undernutrition.

Over the past 5 years, findings from USAID-supported research activities coupled with global evidence on effective approaches to reduce undernutrition have led the global nutrition community to better understand what works and where gaps in evidence remain. USAID targets its programs on 1) the prevention of undernutrition in the critical 1,000-day window from pregnancy to 24 months and 2) the treatment of undernu-

trition in children under 5 through individual prevention programs, critical nutrition services (including the treatment of severe malnutrition), enhancing nutrition competency, and promoting an enabling policy environment. The nutrition strategy also supports the scale-up of programs in collaboration with development partners working across sectors. Key to the nutrition research strategy is the development of host country human and institutional capacity to conduct research and use the results to formulate policies and design programs. Greater host country capacity serves to improve food and nutrition security programs at the national and local levels in line with country-led strategies through a multisectoral approach.

NUTRITION RESEARCH GOALS

1 *Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia.*

Rationale: Achieving long-term improvements in nutritional status requires a coordinated effort across multiple sectors. Reducing rates of child or maternal anemia, for example, requires country-specific approaches. Such approaches could include the following: improving the health delivery system, so it can better deliver deworming or micronutrient supplementation; improving access and consumption of iron-rich foods; addressing issues of water and sanitation; and reducing the impact of malaria. Additionally, there is recognition of the potential across the agriculture sector for improved nutrition, but the evidence base on this relationship remains incomplete.

2011–2015 Expected Results:

- Strengthen evidence on design, targeting, implementation, and cost of community-based integrated agriculture and nutrition programs.
- Increase knowledge on effective programmatic approaches to reducing maternal and child anemia.

2 *Support implementation research for improved diet diversity and quality.*

Rationale: Though understanding of effective nutrition intervention approaches has increased, knowledge gaps remain. Significant advances have been made in demonstrating the effectiveness of high-quality processed food commodities to prevent and treat undernutrition in children; however, there is still limited evidence on their effectiveness at program scale. Evidence of the effectiveness of the use of these food products in other vulnerable populations is also limited. In addition, while social and behavior change communication (SBCC) strategies are crucial to improve nutrition outcomes, there is a continued need for research on what specific communication strategies work best in various country contexts and how to effectively build country capacity to develop, implement, and evaluate multisectoral, sustainable SBCC programs.

2011–2015 Expected Results:

- Determine the effectiveness of lipid nutrient supplements for improved nutrition outcomes in programmatic settings.
- Document effectiveness of community management of acute malnutrition integration into national health systems.
- Develop, implement, and evaluate appropriate, evidence-based, and sustainable SBCC programs for the prevention and treatment of stunting and anemia.
- Test community-based solutions that integrate homestead food production and agricultural extension with SBCC messaging promoting diet quality and infant and young child feeding.

3 *Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.*

Rationale: USAID has a long history of supporting the development of practical methods and tools to support rigorous measurement, monitoring, and evaluation. As part of prior efforts, the Agency supported the development of new indicators for infant and young child feeding, women's dietary diversity, and household hunger, which are now used broadly throughout the international nutrition community. Effective tools to measure appropriate outcomes and impact must continue to advance as new integrated multidisciplinary nutrition programs emerge. Additionally, while a variety of surveillance systems have been developed, tested, and applied, no single standard model is appropriate for all contexts, and relatively little attention has been given to systems' needs in a development versus an emergency or highly fragile context.

2011–2015 Expected Results:

- Advance the development of metrics and monitoring tools most relevant for nutrition-oriented SBCC and agriculture for nutrition.
- Establish acceptability of simplified admission and discharge criteria for treatment of acute malnutrition across populations.
- Determine effectiveness of noninvasive anemia test in government health services settings.
- Determine the accuracy and reliability of existing surveillance systems that focus on anthropometric indicators (metrics used to measure nutritional status) appropriate for use in a development and/or emergency context.

FAMILY PLANNING AND REPRODUCTIVE HEALTH

Background

Voluntary family planning, respectful of the rights of individuals and couples to freely choose the timing, spacing, and number of children, contributes to the health and well-being of women and their children. Health benefits result directly from fewer unintended pregnancies, fewer abortions, and longer birth intervals. If all women in developing countries who want to avoid pregnancy used an effective contraceptive method, the number of maternal deaths would fall an additional 30 percent from current levels. If all births were spaced at least 2 years apart, the risk of death in infancy would be reduced by 10 percent, and in ages 1 to 4 years by 21 percent. In addition to these health-related benefits, a woman's ability to choose the number, timing, and spacing of her children can have consequences for her educational attainment, labor force participation, and earnings, which in turn affect the well-being of her children, household, and community. However, more than 74 million women in

developing countries who would like to use contraception to postpone pregnancy are not using it, and in sub-Saharan Africa, 75 percent of the population does not have access to a minimal range of contraceptive options.

Among women with an unmet need for family planning, many barriers underlie nonuse of contraception, incorrect use, and discontinuation – all of which can result in an unintended pregnancy. These barriers can include concerns about side effects, misperceptions about the risk of pregnancy, opposition from partners or others, and inadequate knowledge about contraception and fertile periods. Challenges getting supplies due to clinic hours, provider preparation, and distances to service delivery points compound the problem. In addition, women may find methods inconvenient to use, expensive, or inappropriate for their needs. Certain groups, especially young never-

married women, postpartum women, and women living in rural and underserved areas, have a much higher level of unmet need for family planning.

In order to combat the barriers underlying nonuse of contraception among women with an unmet need for family planning, biomedical research is needed to [a] refine existing contraceptive methods to make them more acceptable, affordable, and accessible and [b] develop new contraceptive methods that fill gaps in the existing method mix and better meet the family planning needs of women and their families. Additionally, implementation research is necessary to lead to more efficient and evidence-based family planning programming, reduce barriers to services, and find new ways to expand services to reach underserved women and their families.

FAMILY PLANNING AND REPRODUCTIVE HEALTH RESEARCH GOALS

1 Refine, develop, and introduce new contraceptive methods.

Rationale: Among women with an unmet need for family planning, available technologies often do not fit their needs, leaving them without a suitable family planning method. These women need alternative methods that have fewer side effects, provide protection of appropriate duration, and are low cost and simple to use. Multipurpose prevention technologies that combine contraception and protection from HIV and other diseases and address multiple aspects of women's sexual and reproductive health needs, regardless of current contraceptive use, are also needed. USAID collaborates with U.S. Government agencies and other donor partners to leverage its resources and ensure efforts to develop new and improved contraceptive technologies are complementary.

2011–2015 Expected Results:

- Refine existing contraceptive methods to make them more affordable (by reducing manufacturing and supply costs), more acceptable (by reducing side effects), easier to provide (by reducing the need for skilled providers), and easier to use (by reducing the complexity of technologies and instruction).
- Determine the safety and efficacy of new contraceptive and multipurpose prevention technologies that fill the duration-of-effectiveness gap between the 3-month injectable and the 5-year implant.
- Define regulatory pathways for new product approval at the domestic and international levels.
- Develop and introduce multipurpose prevention technologies that address the simultaneous risks of unintended pregnancy, HIV, and other sexually transmitted infections, particularly herpes simplex virus and human papillomavirus.

2 *Improve and expand the use of family planning methods in developing countries.*

Rationale: To further accelerate progress in reducing unmet need and the number of unintended pregnancies, it is critical to understand and address the reasons why women and couples who wish to delay childbearing or have completed their desired family size do not use modern family planning methods. Interventions must be specifically tailored to target special populations, including youth and women living in rural areas, as well as those women living in poverty who traditionally have the highest levels of unmet need for family planning. USAID's research strategy takes a unified approach that promotes quality, acceptability, and access to family planning along a continuum from the laboratory to the client. Over the 2011–2015 period, research will be geared toward finding practical, scalable, culturally appropriate, and sustainable solutions.

2011–2015 Expected Results:

- Determine the impact of health systems strengthening on family planning use and continuation.
- Understand the influence of social norms on fertility intentions, decision making, and health behaviors and how they affect unmet need for family planning.
- Develop new approaches to reach special populations, such as youth, rural women, and the poorest of the poor, with voluntary family planning information and services (through such means as the use of information technology, community-based service outlets, and service delivery models involving nonmedical providers).
- Determine the conditions under which integrated approaches (family planning/maternal, newborn, and child health and family planning-HIV) produce improved health outcomes.
- Develop approaches to accelerate, monitor, and evaluate the scale-up of proven interventions.
- Improve program approaches to increasing client access to family planning methods.

3 *Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies.*

Rationale: High-risk pregnancies are significantly associated with an increased risk of maternal, newborn, and child mortality and morbidity. Family planning can enable pregnancies to occur at the healthiest times of a woman's life, which reduces fertility-related high-risk pregnancies. Healthy times for a pregnancy are at least 24 months after a live birth (almost a 3-year birth-to-birth interval); the mother is between the ages of 18 and 34; and at least 6 months after a miscarriage. Pregnancy timing and spacing is the outcome of a complex set of behaviors, perceptions, and motivations at the individual, family, community, and sociocultural levels. USAID is working to establish health timing and spacing of pregnancies as a key intervention to improve newborn, child, and maternal health.

2011–2015 Expected Results:

- Determine the health impact of fertility-related high-risk pregnancies and their link to mortality and morbidity.
- Develop evidence-based counseling tools to enable women to make voluntary, informed, and healthy decisions about family planning use.
- Identify effective social and behavioral change communication and service delivery approaches to educate families on the role of family planning in preventing fertility-related high-risk pregnancies.
- Improve family planning continuation rates by developing marketing and communication strategies to increase understanding of the broader health benefits of family planning.

HIV/AIDS

Background

The HIV/AIDS pandemic continues to impose a global burden, especially in developing countries. Worldwide, an estimated 33 million people are living with HIV/AIDS, and 2.7 million new infections occur annually. Women and girls account for more than half of all global cases of HIV/AIDS and 60 percent of the cases in sub-Saharan Africa. No single approach to HIV/AIDS prevention is likely to have a dramatic impact, and integrated approaches to prevention, detection, and management that are tailored to specific populations yield the best results. Reversing the course of the AIDS pandemic requires carefully combined, evidence-based strategies that include behavioral, biomedical, and structural interventions to prevent the further spread of HIV. There is a continued need for the development and evaluation of novel technologies and evidence-based strategies that complement

currently available methods of HIV prevention. Such tools are crucial to reducing the HIV transmission rate. In a constrained-resource environment, USAID is also seeking to improve the quality and effectiveness of HIV/AIDS service delivery programs, including prevention of mother-to-child transmission; and prevention, treatment, and care and support, as well as access to them. Implementation research and evaluations are equally important in identifying and addressing gaps in programming knowledge and increasing the evidence base for scaling up promising approaches.

USAID is supporting innovative biomedical research in the fields of microbicides and vaccines to develop and introduce new products and technologies for the prevention of HIV transmission. Through 2011, USAID continued its collaboration with key partners

dedicated to the development of an HIV/AIDS vaccine and microbicide products as well as the strengthening of the existing evidence base to improve HIV/AIDS programming. Looking forward, USAID will support the approval process for proven microbicides and continue the development of both microbicide products and a preventive HIV vaccine for global use. USAID also plans to further strengthen the evidence base through implementation science and operations research to improve HIV prevention, care, and treatment programs globally. USAID's research agenda contributes to the HIV/AIDS response and continues to harness USAID's extensive health and development expertise to maximize the reach of technically sound, cost-effective, and sustainable HIV/AIDS interventions.

HIV/AIDS RESEARCH GOALS

1 *Develop and introduce microbicides for women to reduce their risk of HIV infection.*

Rationale: Current strategies for preventing HIV infection, such as delay of sexual debut, partner reduction, and use of condoms, are often not possible for many women in developing countries. There is a need for HIV prevention methods that women can use without their partners' active participation. The USAID-supported CAPRISA 004 trial provided the proof of concept that a microbicide, a 1 percent tenofovir vaginal gel, can safely and effectively reduce a woman's risk of HIV infection. With the real and unprecedented opportunity in the next 5 years to obtain regulatory approval from the U.S. Federal Drug Administration for this product, there is a need to prepare for the introduction of this new prevention technology in the countries where it will have the greatest impact. In addition, USAID remains committed to supporting the development of combination, multipurpose, and novel safe, effective, acceptable, and affordable microbicides that may have a greater impact on the prevention of HIV.

2011–2015 Expected Results:

- Advance 1 percent tenofovir gel toward regulatory approval and introduction through the Follow-on African Consortium for Tenofovir Studies (FACTS) 001 confirmatory study in South Africa, which is currently being conducted and expected to be completed in 2014.
- Support the rollout of tenofovir gel and/or other microbicides as soon as they are approved by targeting the highest priority activities that can be designed, implemented, or initiated in the next 2 to 3 years.
- Develop and clinically test the safety and effectiveness of combination, multipurpose, and novel microbicides.
- Enhance the formulations, dosing regimens, and delivery methods for both coitally-associated and coitally-independent methods.
- Improve validation of Phase I and II trial models (as well as preclinical models) that better predict when a particular product lead warrants the investment required for a Phase III trial.

2 Accelerate the development and clinical testing of novel HIV vaccine candidates.

Rationale: Viral infectious diseases are most effectively controlled through prevention programs that include a vaccine. Vaccines work by neutralizing the infectious agent with antibodies, then eliminating the agent and/or infected cells. Innovative approaches to understanding both the viral behavior and the human immune response are necessary to develop a safe, effective, accessible, and preventive HIV vaccine for use throughout the world, a vaccine that may be incorporated as part of a comprehensive global HIV response to drive down new infections and save millions of lives. Since 2001, USAID has funded the International AIDS Vaccine Initiative (IAVI), a public-private product development partnership that acts as a virtual pharmaceutical company to accelerate the development and clinical testing of HIV vaccine candidates.

2011–2015 Expected Results:

- Support IAVI's coordination of a portfolio of vaccine research and development projects in partnership with universities, public institutes, and private biotechnology and pharmaceutical firms.
- Support IAVI's design of new, and potentially more efficacious, novel vaccine candidates using replicating and nonreplicating viral vectors and antigens.
- Support IAVI's immunogen design programs to block HIV infection by eliciting broadly neutralizing antibodies.
- Advance several HIV vaccine candidates through clinical trials, in partnership with a network of collaborating clinical research centers throughout Africa, including multiple Phase I safety and immunogenicity studies.
- Inform vaccine design and development through support to IAVI's epidemiological studies.
- Strengthen the global environment for AIDS vaccine development through sustained clinical and laboratory programs, robust community engagement, and policy work.
- Advocate to retain AIDS prevention and vaccine research and development as important components of the public policy, international health, and development agendas in HIV-endemic countries.

3 Strengthen the evidence base to improve HIV/AIDS prevention, care, and treatment programs.

Rationale: Evidence-based interventions are needed to prevent the transmission of HIV as well as provide care, treatment, and support to individuals affected by the disease. Implementation science, operations research, and program evaluation efforts can strengthen HIV/AIDS prevention, care, and treatment programs and lead to improved program coverage, quality and cost-effective programming, and increased local capacity to conduct and utilize research.

2011–2015 Expected Results:

- Conduct implementation research and program evaluations to improve HIV prevention, care, and treatment programs in countries most affected by the HIV epidemic.
- Conduct research and evaluations of HIV/AIDS treatment, care and support, and prevention of mother-to-child transmission service delivery programs in developing countries.
- Monitor, evaluate, and address gaps in gender-based violence prevention programming.
- Address HIV/AIDS service delivery challenges for programs under the U.S. President's Emergency Plan for AIDS Relief.
- Develop and demonstrate approaches to translate efficacious HIV/AIDS biomedical prevention methods and service delivery practices into real world settings.
- Expand data collection and analysis to improve program implementation.

MALARIA

Background

According to WHO, the estimated number of global malaria deaths fell from about 985,000 in 2000 to about 655,000 in 2010. In spite of this progress, more than 261 million cases occur each year. Malaria remains one of the major public health problems in Africa, with about 80 percent of malaria deaths occurring in African children under 5 years of age. It places a heavy burden on individual families and national health systems. In many African countries, 30 percent or more of outpatient visits and hospital admissions in children under 5 are reported to be caused

by malaria. Because most malaria transmission occurs in rural areas, the greatest burden of the disease usually falls on families with lower incomes and whose access to health care is most limited. Children under 5 and pregnant women are especially at risk.

While current interventions (e.g., insecticide-treated nets (ITNs), indoor residual spraying (IRS), intermittent preventive treatment for pregnant women, and prompt diagnosis and treatment with artemisinin-based combination therapy) are highly effective, challenges

such as insecticide and drug resistance have emerged. New tools, including a highly effective vaccine and novel antimalarial drugs, are needed to further support malaria prevention and control efforts over the coming years. USAID is committed to supporting research on these new tools by partnering with governmental agencies, such as the CDC, NIH, the Department of Defense, and the Department of Health and Human Services, and research partners around the globe.

MALARIA RESEARCH GOALS

1 Develop safe and effective vaccines to reduce morbidity and mortality due to *Plasmodium falciparum*.

Rationale: *Plasmodium falciparum* is the most virulent malaria parasite. Though no commercially available malaria vaccine exists, experimental vaccines have been shown to be capable of protecting against the disease. Rapidly accumulating new knowledge on the parasite continues to inform vaccine development efforts. USAID support contributed to the most advanced malaria vaccine, RTS,S/AS01b, which is on track for licensure as early as 2015. However, it has a limited efficacy: about 50 percent against clinical disease and 60 percent against severe disease. Because this leaves a significant number of children vulnerable to malaria, vaccines with greater efficacy are needed. The USAID Malaria Vaccine Development Program (MVDP) aims to develop a vaccine with an efficacy against clinical disease of 80 percent or more, a duration of at least a full year, and an indefinite durability with annual booster immunizations.

2011–2015 Expected Results:

- Identify promising approaches and design vaccines based on state-of-the-art knowledge derived from MVDP strategic research and the global research community.
- Develop processes to enable production and produce investigational vaccines based on the new designs.
- Evaluate resulting investigational vaccines preclinically, clinically, and in field trials.

2 Develop effective and affordable medicines for the treatment and prevention of malaria.

Rationale: Antimalarial drug resistance remains a global concern. Though resistance to artemisinin drugs has not yet been documented in sub-Saharan Africa, if this were to occur, as it has with the importation of chloroquine-resistant parasites from Southeast Asia, it would represent a major setback for malaria control efforts on the continent. The Medicines for Malaria Venture (MMV) is a nonprofit, public-private partnership established to catalyze antimalarial drug development by supporting development of effective and affordable medicines for the treatment and prevention of malaria. The emphasis of MMV's work is on developing drugs that are effective against drug-resistant strains of *Plasmodium falciparum* and are safe for use in young children and pregnant women – the groups most vulnerable to malaria. MMV's research and development activities are carried out by more than 200 partners in 49 countries, and the organization is supported by 13 major donors, including the Bill & Melinda Gates Foundation and USAID.

2011–2015 Expected Results:

- Support research and development activities on the more than 50 unique compounds that are at various stages of development, from drug discovery to Phase III human field testing.
- Support the development and testing of synthetic peroxides, a new class of antimalarial drugs that can provide an alternative to the current artemisinin treatment. Synthetic peroxides have completed Phase II trials and will enter Phase III trials in 2012 for the treatment of drug-resistant uncomplicated malaria.
- Lay the ground work for the safe and effective use of existing and new antimalarial drugs and drug combinations by national malaria control programs.

3 Improve malaria control program implementation and impact.

Rationale: Evidence-based interventions such as IRS and ITNs have been shown to be highly effective as malaria control measures. However, insecticide resistance is emerging as a major threat to both IRS and ITNs, particularly across Africa. In order to combat resistance proactively, operations research is needed to evaluate new approaches to mitigate its development. In addition, logistical and operational challenges to effectively delivering interventions remain. USAID is focused on the practical operational challenges related to the rollout of malaria interventions and is implementing operations research studies through the President's Malaria Initiative.

2011–2015 Expected Results:

- Assess the use of insecticides in rotation or together to increase the effectiveness of IRS campaigns and help mitigate resistance development.
- Determine the effectiveness of sulfadoxine-pyrimethamine for intermittent preventive treatment in light of growing parasite resistance.
- Assess the physical and insecticidal longevity of ITNs and develop methods to extend their useful lifetime through net care and repair interventions.
- Evaluate new approaches to the use of insecticides for the control of malaria vector mosquitoes, such as insecticide-treated wall linings.
- Assess the best use of IRS and ITNs separately and in combination to control malaria in different settings.
- Develop new approaches to malaria surveillance, especially in areas where malaria transmission has fallen dramatically.

TUBERCULOSIS

Background

Tuberculosis (TB) continues to be a global public health threat; an estimated 8.7 million new cases of TB and 1.4 million deaths occur annually. After HIV, TB is the leading cause of death by an infectious disease among adults worldwide. While TB is found in almost every country in the world, it disproportionately affects poor and marginalized populations living in low- and middle-income countries where transmission and degeneration to active disease is enabled by poor nutritional status, concomitant disease, and overcrowded living conditions. In recent years, TB incidence has declined by about 1 percent per year, but this is insufficient to reach the global target of elimination of TB, defined as less than or equal to one TB case per million population per year, by 2050.

Despite advances in TB prevention and treatment, multidrug-resistant TB (MDR-TB), extensively drug-resistant TB (XDR-TB), and the global HIV pandemic threaten to undermine recent progress in controlling this disease. Moreover, despite the rapid rollout of GeneXpert, TB control continues to be hampered by the unavailability of point-of-care diagnosis tools that can accelerate the detection of TB; more effective drugs that can shorten treatment, improve outcomes, and prevent the development of drug resistance; and a vaccine that can prevent new cases.

USAID will continue to invest in research activities that improve the performance and impact of country-level TB programs

while preventing ongoing TB transmission and mitigating the risks of drug resistance through increased access to early TB diagnosis and effective treatment. USAID's TB research strategy is to invest in new tools and approaches that are less labor intensive, more cost-effective, and can be delivered close to patients to minimize the health workforce burden and improve patient access, thereby improving disease detection and prevention and treatment success rates. In addition, the Agency is committed to providing support to promising vaccines that may have the greatest impact on TB control and will support field trials of clinical vaccine candidates that emerge.

TUBERCULOSIS RESEARCH GOALS

1 *Develop diagnostic tools to more effectively detect TB in individuals with and without HIV.*

Rationale: Each year about 30 percent of new TB cases go undetected and continue to contribute to the transmission of tuberculosis; this compromises efforts to control and prevent active disease. In 2011, of the 8.7 million new TB cases that developed into active tuberculosis, only 5.8 million (67 percent) were detected and initiated on treatment. In most countries, the diagnosis of TB still relies on sputum smear microscopy, which is less sensitive for detecting TB, especially in children and people living with HIV/AIDS. Additionally, smear microscopy does not provide information on drug resistance. There is a need to develop new TB diagnostic tools that can be used at point-of-care and have greater accuracy (high sensitivity, specificity, and predictive value) for the detection of TB in all populations, including children and people living with HIV/AIDS.

2011–2015 Expected Results:

- Determine the accuracy, feasibility, impact, and cost-effectiveness of new diagnostic technologies in different populations, including children and people living with HIV.
- Develop different models for making TB diagnosis, combining new and existing TB diagnostic tools.
- Develop mathematical models to determine the health system requirements for effective implementation of new diagnostic tools.
- Develop and evaluate strategies and/or models for scaling up new TB diagnostic technologies.

2 *Develop shorter TB regimens that are effective against all forms of TB, can be used with antiretroviral therapy, are suitable for children, affordable, and easily managed in resource-limited settings.*

Rationale: Although the current 6-month treatment regimen for drug-susceptible TB has been proven to be efficacious, it is still lengthy, ineffective against resistant forms of TB, and poses problems of interactions with commonly used antiretroviral therapies (ARTs). Additionally, poor treatment adherence leads to drug resistance. The regimens currently used for the treatment of MDR-TB and XDR-TB are long, toxic, poorly tolerated, expensive, and of limited efficacy. More effective, better tolerated, shortened regimens can dramatically improve patient outcomes, slow the development of MDR-TB, and decrease the strain of TB treatment on health systems.

2011–2015 Expected Results:

- Evaluate shorter TB regimens of promising new compound(s) and/or drug combination therapy(ies) for all forms of TB that are compatible with ART.
- Determine the efficacy and effectiveness of short-course MDR-TB treatment regimens using existing MDR-TB drugs.
- Develop and evaluate evidence-based models for the introduction and scale-up of new TB treatment regimens.
- Assess the health system implications for introducing new treatment regimens and determine the cost-effectiveness and impact on the health system.

3 Conduct operations research for improving TB program performance and management of TB-HIV.

Rationale: Country-level operational research is central to the improved performance of TB programs. Despite progress that has been made in USAID-supported countries, the percentage of TB cases detected and treated was 60 percent and 85 percent, respectively, in 2011. There is a need to optimize all elements of TB control across various health system challenges, including efficient case finding, accurate diagnosis, and effective treatment of the disease. Additionally, as people living with HIV are more likely to develop TB disease because of their immunodeficiency and HIV is one of the most important risk factors for the progression of TB infection to disease, there is an urgent need for novel approaches for the diagnosis, treatment, and prevention of both HIV and TB to turn the tide on the TB-HIV syndemic.

2011–2015 Expected Results:

- Develop scalable, cost-effective strategies for optimizing existing diagnostic technologies and case finding approaches for the detection of all forms of TB in different population settings, including people living with HIV as well as children who are not infected with HIV.
- Develop and evaluate models for combining existing TB diagnostic tools with new approaches to case identification, including community-based active case finding, house-to-house TB screening, and intensified TB screening in high-risk populations.
- Develop scalable, cost-effective, and culturally sensitive strategies for improving retention and adherence to TB treatment.
- Identify and evaluate models for involving communities and the private sector in the management of TB.
- Develop scalable, cost-effective models to optimize TB service delivery and prevention of nosocomial infections (infections acquired in hospitals/treatment facilities).
- Design, implement, and evaluate scalable, cost-effective models for increasing access to HIV prevention interventions among individuals with TB symptoms or confirmed tuberculosis.
- Develop scalable and cost-effective models to increase access to TB and HIV diagnosis and treatment interventions among individuals with TB symptoms and those with confirmed tuberculosis.

PANDEMIC INFLUENZA AND OTHER EMERGING THREATS

Background

Nearly 75 percent of all new diseases affecting humans at the beginning of the 21st century have originated in animals. In recent decades, HIV/AIDS, severe respiratory syndrome (SARS), H5N1 avian influenza, and the pandemic 2009 H1N1 influenza virus have been reminders of how vulnerable the increasingly interconnected world is to emerging diseases. The speed with which these diseases can surface and spread presents serious public health, economic, and de-

velopment concerns. It also underscores the need for the development of comprehensive disease detection and response capacities, particularly in locations where disease threats are likely to emerge.

Recognizing this need, in 2009, the USAID launched the Emerging Pandemic Threats (EPT) program that seeks to aggressively preempt and combat diseases that could spark future pandemics. Limited surveillance

data exist to preempt diseases that have the potential to spark pandemics. Pathogen detection and identification prior to a disease spread is critical to pandemic prevention. The EPT program targets geographic “hot spots” where new disease threats have emerged in the past. Additionally, it seeks to identify human behaviors that increase the risk of disease transmission from animals to humans.

PANDEMIC INFLUENZA AND OTHER EMERGING THREATS RESEARCH GOALS

1 *Develop and introduce surveillance methods to increase pathogen detection.*

Rationale: Generating new surveillance data – in a field in which very little exists – will allow for a better understanding of pathogen diversity, both in animals of concern (e.g., rodents, bats, nonhuman primates) and in human populations with high rates of exposure to such animals, and more efficiently targeted surveillance. It will also raise awareness of risks and engage governments in hotspot countries to expand partnership in surveillance, prevention, and early response.

2011–2015 Expected Results:

- Detect known and new viral pathogens of human health importance by sampling high-priority wildlife (including bats, rodents, and primates) and humans at high-risk human-animal interfaces in hotspots around the world.
- Detect known and new variants of influenza viruses that may be of human health importance by sampling high-priority farmed animals – including poultry, swine, and farmed wild birds – at high-risk human-animal interfaces in hotspots in Bangladesh, China, Thailand, and Vietnam.
- Refine current risk modeling for disease emergence to add greater specificity on geographic risk associated with animal-human interactions.
- Develop a “predictive” surveillance method that considers environmental factors, potential points of disease transmission from animals to humans, and advances in genomics and informatics to classify new organisms on the basis of their risk of causing new disease in humans.

2 *Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.*

Rationale: New diseases spill over from animals to humans primarily through individual behavior. Changing the practices of communities and industries such as extractive industries, including the oil, gas, and mining sectors, is paramount to preventing new diseases in wildlife from spilling over to humans and leading to potential public health emergencies. High-risk practices and behaviors must be systematically identified, and mitigating practices must be developed and adopted to preemptively combat potential pandemic-level diseases.

2011–2015 Expected Results:

- Characterize behaviors and practices related to human exposure to high-risk wildlife, wildlife products, and farmed animals from the individual to the market value chain to the industrial sector.
- Identify disease-causing agents among livestock farmers and wildlife hunters/butchers and quantify the risk factors of these workers in association with infection in source animals and/or meat.
- Evaluate current theories on high-risk interfaces and drivers of disease spill over/spread and rank potential interface risks (by type of interface, geographic hotspot, animal species, and/or viral family).
- Develop a method to better link modeling, surveillance, and risk determination data, particularly to (1) update modeling using new surveillance and behavior data and (2) update surveillance strategies based on modeling results and risk determination data.
- Develop models that help depict viral movements among farmed animal populations to understand geographic locations that present greater opportunities for virus mutation and spill over/spread into human populations.
- Develop models that help predict where new variants of influenza viruses, which may be of human health importance, may arise in farmed animal populations in order to focus surveillance and response investments.
- Refine and test geographical and temporal hotspot models building upon existing global infectious disease hotspots models.

HEALTH SYSTEMS STRENGTHENING

Background

USAID views a health system as consisting of all organizations and people in both formal and informal sectors whose primary intent is to promote, restore, or maintain health. The quality, equity, and efficiency of a health system are essential to ensuring the health and well-being of individuals, families, communities, and nations. Achieving progress and impact in family planning, maternal and child health, nutrition, infectious diseases, and HIV/AIDS remains challenging in developing countries with poorly functioning health systems. As such, USAID remains committed to health systems strengthening (HSS), which involves the application of evidence-based approaches to enhance the provision of quality and cost-effective services, protect against financial risk, and better enable access to health care, particularly among the poor and underserved. Significant USAID support for lifesaving interventions and disease-specific programs

has greatly improved health outcomes, but weak health systems present a key barrier to continued progress and ensuring sustainability. Well-designed, evidence-based HSS programming can complement other health program investments and accelerate country ownership of well-functioning national health systems.

More rigorous evidence is still needed on how to best design and implement HSS interventions, and to advance development and uptake of effective tools and approaches for strengthened core system functions and improved system performance. This includes research and evaluation for developing and implementing effective finance schemes and financial protection packages; improving quality and coverage of services; increasing density, retention, and quality of the health workforce; strengthening health information systems and data availability; boosting uptake

of new technologies; ensuring availability, quality, and cost-effective procurement of medicines; advancing health-promoting behavior change at the household and community levels; and increasing efficiency, accountability, and system responsiveness.

Supporting the development and application of sound metrics is essential for measuring progress of HSS investments and standardizing performance indicators across countries. As a recognized leader in HSS, USAID is supporting the development of global evaluation frameworks and informing strategies for greater health impact with systems strengthening through technical coordination with other donors and partner countries. Improved metrics and evaluation methodologies also serve to help assess the value of investing in HSS as a significant component of global health efforts to improve health outcomes.

HEALTH SYSTEMS STRENGTHENING RESEARCH GOALS

1 *Strengthen and improve health systems performance and contribute to more sustainable programmatic outcomes.*

Rationale: Ensuring equitable access to high-quality essential health services requires an increase in the evidence base on how to best implement HSS interventions and promote uptake of best practices. Research and evaluation of core health systems functions will help strengthen and improve systems performance and contribute to more sustainable programmatic outcomes. Core functions include finance, human resources for health, medicines and logistics, health information systems, health promotion, governance and leadership, and innovation and uptake of new technologies.

2011–2015 Expected Results:

- Evaluate the impact of integrated health service platforms for maternal, newborn, and child health; family planning; malaria; and HIV/AIDS on accessibility, affordability, and quality of care.
- Develop new methodologies and evaluate the impact of task shifting, franchising for social gain, and contracting out to strengthen providers' ability to deliver quality and cost-effective essential health services.
- Identify effective approaches to scaling up evidence-based health insurance schemes for essential health services.
- Develop and test financing schemes to reduce out-of-pocket health care expenditures.
- Develop approaches to improve the density, distribution, retention, and quality of the health workforce in resource-limited settings.
- Develop and test innovative quality improvement approaches, including the application of mobile technologies and health workforce team-based approaches.
- Identify effective approaches to improve the availability, quality, and cost-effective procurement of essential medicines.
- Develop accurate and efficient platforms for detecting counterfeit and substandard medicines.
- Develop methodologies for systematic assessments of national pharmaceutical financing schemes, including cost savings for essential medicines and improved procurement efficiencies.

2 Advance methodologies to measure health systems strengthening and performance.

Rationale: Rigorous methodologies are needed to measure both proximal and long-term program successes, set performance standards across countries, and identify strategies for greater effectiveness, efficiency, and equity. Methodological approaches for assessing systems interactions are also needed as health systems grow and mature to deliver better services for greater health impact. Strengthened evaluation practices can better inform the value of investing in HSS.

2011–2015 Expected Results:

- Develop standardized indicators and tools for measuring HSS progress over time, such as pharmaceutical systems strengthening.
- Improve methods and indicators for evaluating service coverage, financial protection, and population coverage.
- Develop evaluation methodologies for linking changes in health policies to improved health outcomes.
- Develop new survey tools for measuring household health expenditures and for assessing financial risk protection, access to services, and population coverage.
- Strengthen evaluation measures for assessing impacts of performance-based incentive schemes on service access and health outcomes.

3 Strengthen evidence-based practices for the uptake and use of proven approaches to improve health systems performance at the country level.

Rationale: Despite significant generation of data, research, and evidence-informed approaches, uptake and use at the country level of interventions to improve health systems performance often remains limited. Evaluation of knowledge transfer and utilization is needed for the development of effective strategies to standardize practices and support institutionalized capacity for knowledge translation. Research supporting innovations for the use of electronic information and communication technologies can reduce operational barriers, enhance data collection and utilization, and strengthen practices for information management and dissemination.

2011–2015 Expected Results:

- Develop, test, and introduce new approaches to increasing health systems data use and improving knowledge management, including the advancement of innovative information and communication technologies.
- Develop innovative methods for advancing uptake of effective HSS interventions for priority health services.

ADDENDUM: CORE FUNDING FOR HEALTH RESEARCH GOALS¹

Health Issue	Research and Introduction Goals	FY 2011 Obligated Funds	FY 2012 Expected Funds
Maternal and Newborn Health	Develop and introduce new and improved evidence-based interventions for care during pregnancy and at birth.	2,272,700	2,925,197
	Strengthen and standardize high-quality obstetric care for the prevention, management, and treatment of fistula.	630,000	730,000
	Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia.	197,914	239,020
	Develop, test, and introduce community-based health interventions to treat and prevent newborn infections.	1,530,080	1,699,435
	Develop scalable, cost-effective approaches for integrating maternal and neonatal health services.	1,527,700	1,473,330
	Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions.	1,179,304	2,325,262
	Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.	755,000	370,000
	Total	8,092,768	9,726,244
Child Health	Support implementation research to inform the uptake of integrated Community Case Management.	535,351	813,085
	Develop and test cost-effective approaches to decrease the incidence of acute lower respiratory infections due to household air pollution.	550,000	427,125
	Evaluate interventions to increase the use of efficacious diarrhea treatments.	400,000	25,000
	Develop and test scalable approaches to improve drinking water quality, access, use of sanitation, and hygiene behaviors.	0	269,026
	Total	1,485,351	1,534,236
Nutrition	Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia.	2,200,000	2,200,000
	Support implementation research for improved diet diversity and quality.	2,000,000	2,000,000
	Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.	1,300,000	1,300,000
	Total	5,500,000	5,500,000
Family Planning and Reproductive Health	Refine, develop, and introduce new contraceptive methods.	10,680,000	10,350,000
	Improve and expand the use of family planning methods in developing countries.	16,455,000	14,425,000
	Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies.	440,000	379,000
	Total	27,575,000	25,154,000
HIV/AIDS	Develop and introduce microbicides for women to reduce their risk of HIV infection.	45,000,000	45,000,000
	Accelerate the development and clinical testing of novel HIV vaccine candidates.	28,710,000	28,710,000
	Strengthen the evidence base to improve HIV/AIDS prevention, care, and treatment programs.	26,379,411	20,000,000
	Total	100,089,411	93,710,000
Malaria	Develop safe and effective vaccines to reduce morbidity and mortality due to <i>Plasmodium falciparum</i> .	7,100,000	7,100,000
	Develop effective and affordable medicines for the treatment and prevention of malaria.	3,000,000	4,000,000
	Improve malaria control program implementation and impact.	1,300,000	2,000,000
	Total	11,400,000	13,100,000
Tuberculosis	Develop diagnostic tools to more effectively detect TB in individuals with and without HIV.	3,035,971	3,184,395
	Develop shorter TB regimens that are effective against all forms of TB, can be used with antiretroviral therapy, are suitable for children, affordable, and easily managed in resource-limited settings.	5,000,000	6,000,000
	Conduct operations research for improving TB program performance and management of TB-HIV.	11,667,181	11,815,605
	Total	19,703,152	21,000,000
Pandemic Influenza and Other Emerging Threats	Develop and introduce surveillance methods to increase pathogen detection.	7,000,000	7,000,000
	Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.	2,325,000	2,325,000
	Total	9,325,000	9,325,000
Health Systems Strengthening ²	Strengthen and improve health systems performance and contribute to more sustainable programmatic outcomes.	2,158,442	3,055,261
	Advance methodologies to measure health systems strengthening and performance.	6,802,510	6,220,307
	Strengthen evidence-based practices for the uptake and use of proven approaches to improve health systems performance at the country level.	1,273,840	1,012,456
	Total	10,204,792	10,288,024
TOTAL FUNDING		192,379,324³	188,209,504

¹ This report highlights approximately 80 percent of the total health-related research at USAID.

² This reflects a recategorization of the health systems strengthening research goals to more appropriately reflect funding across the six core functions of a health system.

³ The total health research funding for FY 2011 reflects a substantial increase in HIV implementation science and the inclusion of funding for tuberculosis operational research, which was not captured in the 2006–2010 strategy.

ACRONYMS AND ABBREVIATIONS

AMTSL	Active Management of the Third Stage of Labor
ART	Antiretroviral therapy
CAPRISA	Centre for the AIDS Programme of Research in South Africa
CII	Center for Accelerating Innovation and Impact
EPT	Emerging pandemic threats
HBB	Helping Babies Breathe
HSS	Health systems strengthening
IAVI	International AIDS Vaccine Initiative
iCCM	Integrated Community Case Management
IRS	Indoor residual spraying
ITN	Insecticide-treated net
MDR-TB	Multidrug-resistant TB
MMV	Medicines for Malaria Venture
MVDP	Malaria Vaccine Development Program
ORS	Oral rehydration solution
PE/E	Pre-eclampsia/eclampsia
POU	Point of use
PPH	Postpartum hemorrhage
SBA	Skilled birth attendant
SBCC	Social and behavior change communication
TB	Tuberculosis
USAID	U.S. Agency for International Development
XDR-TB	Extensively drug-resistant TB

Acknowledgments

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U.S. Agency for International Development

1300 Pennsylvania Avenue, NW

Washington, DC 20523

Tel: (202) 712-0000

Fax: (202) 216-3524

www.usaid.gov