



GUIDANCE ON THE DEFINITION AND USE OF THE GLOBAL HEALTH AND CHILD SURVIVAL ACCOUNT

UPDATE

JANUARY 2009

The guidance contained within this document—including legal requirements, policy requirements, Congressional directives, and USAID guidance—is subject to change. Updates and revisions will be published as addenda.

Please make sure that the correct version of the guidance is being followed.

Questions should be directed to USAID’s Bureau for Global Health, Office of Strategic Planning, Budgeting and Operations (GH/SPBO).

GUIDANCE ON THE DEFINITION AND USE OF THE GLOBAL HEALTH AND CHILD SURVIVAL (GH/CS) ACCOUNT

TABLE OF CONTENTS

I. SUMMARY	8
A. Purpose of the Guidance	8
B. Modifications to the 2004 Guidance and Highlights of the Guidance	9
C. Structure of the Guidance	13
D. Points of Contact	13
II. RELATIONSHIP BETWEEN PROGRAM ELEMENTS AND BUDGET CATEGORIES	15
A. Appropriate Elements under the Foreign Assistance Framework	15
B. Budget Categories	15
III. ALLOWABLE USES OF FUNDS FOR AGENCY PROGRAMMING PURPOSES	18
1. General	18
A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES	18
a. Statutory Authorities	18
b. Nonproject Assistance	20
B. USAID GUIDANCE	20
2. HIV/AIDS	22
A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES	23
a. Prostitution and Sex Trafficking	23
b. Condoms	24
c. Conscience Clause	24
d. Military, Police, Prisons or other Law Enforcement Agencies	24
e. Earmarks and Directives	27
B. USAID GUIDANCE	28
a. Prevention of Sexual Transmission	28
b. Biomedical Prevention	29
c. Prevention of Mother-to-Child HIV Transmission (PMTCT)	31
d. Orphans and Vulnerable Children Affected by HIV/AIDS	31
e. HIV/TB	32
f. Counseling and Testing	33
g. Human Resources for Health	34
h. Microbicide Research and Development for HIV/AIDS Prevention	35
i. Vaccine Research for HIV/AIDS	36
j. Commodity Fund (CF)	36
k. Commodities	37
l. Partnership for Supply Chain Management System (SCMS)	38
m. Working Capital Fund	38
n. Adult and Pediatric Care and Treatment	39
o. Injection Safety	40
p. Health Systems Strengthening	40
q. Gender	41
r. Support to the Global Fund to Fight AIDS, Tuberculosis and Malaria	42

s.	Integrated Family Planning and HIV/AIDS Activities _____	43
3.	Tuberculosis _____	43
A.	LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES _____	44
a.	TB in Prisons _____	44
B.	USAID GUIDANCE _____	45
4.	Malaria _____	48
A.	USAID GUIDANCE _____	48
5.	Avian Influenza _____	50
A.	USAID GUIDANCE _____	50
6.	Other Public Health Threats _____	52
A.	LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES _____	53
B.	USAID GUIDANCE _____	53
a.	Neglected tropical diseases and other infectious diseases of major public health importance _____	53
b.	Antimicrobial Resistance (AMR) Containment _____	53
c.	Surveillance _____	54
d.	Non-communicable public health threats _____	55
7.	Maternal and Child Health _____	55
A.	LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES _____	55
B.	USAID GUIDANCE _____	55
a.	Allowable Uses of Funds for Maternal Health _____	55
b.	Allowable Uses of Funds for Child Survival _____	57
c.	Special Considerations for Maternal and Child Health: Other Funding Considerations _____	57
i.	Polio Eradication Activities _____	57
ii.	Micronutrient Activities _____	58
iii.	GAVI _____	59
iv.	Prohibition on Purchase of Contraceptives _____	59
v.	Child Survival Grant Program _____	59
8.	Family Planning and Reproductive Health (FP/RH) _____	59
A.	LEGAL REQUIREMENTS, POLICY REQUIREMENTS, AND CONGRESSIONAL DIRECTIVES _____	61
a.	Authority _____	61
b.	Legislative Requirements on the Use of FP/RH Funds _____	61
c.	Policy Requirements on the Use of FP/RH Funds _____	63
B.	USAID GUIDANCE _____	64
a.	Allowable Uses of FP/RH Funds for Family Planning Activities _____	64
b.	Allowable Uses of FP/RH Funds for FP/RH System Strengthening Activities _____	66
c.	Allowable Uses of FP/RH Funds for Integrated Family Planning Activities _____	66
i.	Intra-sectoral Family Planning/Reproductive Health Activities _____	67
ii.	Multi-sectoral Family Planning/Reproductive Health Activities _____	68
9.	Water Supply, Sanitation, and Hygiene _____	70
A.	USAID GUIDANCE _____	70
10.	Vulnerable Children _____	73
A.	LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES _____	73
B.	USAID GUIDANCE _____	73
a.	Vulnerable Children _____	73
b.	Displaced Children and Orphans _____	74
c.	Other Vulnerable Children Activities _____	74
11.	Other: Health Systems and Capacity Strengthening _____	75
A.	USAID GUIDANCE _____	75
a.	Construction _____	75
b.	Health Systems/Systems Strengthening _____	76

12. Rebuilding Countries	78
A. USAID GUIDANCE	78
a. Allowable Uses of Funds for Fragile States	79
13. Administrative/Management Costs	81
A. USAID GUIDANCE	81
14. Co-Programming	83
A. USAID GUIDANCE	83
IV. PROCEDURES FOR DEVIATIONS FROM THE GUIDANCE	85

APPENDICES

<i>APPENDIX I: Excerpts from Relevant Legislation and Congressional Reports</i>	<i>A-4</i>
<i>APPENDIX II: HIV/AIDS ABC Guidance</i>	<i>A-24</i>
<i>APPENDIX III: HIV/AIDS Palliative Care Guidance</i>	<i>A-38</i>
<i>APPENDIX IV: Preventive Care Guidance</i>	<i>A-57</i>
<i>APPENDIX V: HIV Prevention among Drug Users Guidance</i>	<i>A-70</i>
<i>APPENDIX VI: Executive Message on President's Malaria Initiative, December 23, 2005</i>	<i>A-73</i>
<i>APPENDIX VII: Executive Message on Avian Influenza, September 26, 2005</i>	<i>A-76</i>
<i>APPENDIX VIII: Executive Message on Avian Influenza, November 3, 2005</i>	<i>A-79</i>
<i>APPENDIX IX: USAID Family Planning Requirements, Statutory and Policy</i>	<i>A-80</i>
<i>APPENDIX X: Sample Template for Documenting Technical Consultations</i>	<i>A84</i>

ACRONYMS

AAPD	Acquisition and Assistance Policy Directive	IDU	Injecting Drug User
AB	Abstinence, Be faithful	IEC	Information, Education, and Communication
ABC	Abstinence, Be faithful, correct and consistent Condom use	IIP	Investing in People
ACI	Andean Counterdrug Initiative	IPA	Inter-Agency Personnel Authority
ADS	Automated Directives System	IRS	Indoor Residual Spraying
AEEB	Assistance for Eastern Europe and the Baltics	JSP	Joint Strategic Plan
AFR	Bureau for Africa	LAC	Bureau for Latin America and the Caribbean
AI	Avian Influenza	M/HR	Bureau for Management/Office of Human Resources
AIDS	Acquired Immunodeficiency Syndrome	MDR	Multi-drug Resistant
AIMEBA	Avian Influenza Monitoring and Evaluation and Budget Analysis	MH	Maternal Health
AMR	Anti-Microbial Resistance	MOH	Ministry of Health
ANE	Bureau for Asia and the Near East	MVA	Manual Vacuum Aspiration
ARV	Anti-retroviral	NCD	Non-Communicable Disease
ART	Anti-retroviral Treatment	NGO	Non-Governmental Organization
CASU	Cooperative Assistance Support Unit	NTD	Neglected Tropical Disease
CCM	Country Coordinating Mechanism	NTP	National TB Program
CDC	Centers for Disease Control and Prevention	OE	Operating Expenses
CF	Commodity Fund	S/GAC	Office of the Global AIDS Coordinator
CIB	Contract Information Bulletin	OHA	Office of HIV/AIDS
COO	Chief Operating Officer	OP	Operational Plan
COP	Country Operational Plan	OPHT	Other Public Health Threats
CS	Child Survival	ORS	Oral Rehydration Salts/Solution
CSH	Child Survival and Health Programs Fund	OU	Operating Unit
CTO	Cognizant Technical Officer	OVC	Orphans and Vulnerable Children
DA	Development Assistance	OVC	Other Vulnerable Children
DCHA	Bureau for Democracy, Conflict, and Humanitarian Assistance	PAPA	Participating Agency Program Agreement
DCOF	Displaced Children and Orphans Fund	PASA	Participating Agency Service Agreement
DOD	Department of Defense	PD-3	Policy Determination 3
DOTS	Directly Observed Therapy – Short Course	PEPFAR	President's Emergency Plan for AIDS Relief
DP	Development Planning Office	PHN	Population, Health, and Nutrition
E&E	Bureau for Europe & Eurasia	PLWHA	People Living with HIV/AIDS
EGAT	Bureau for Economic Growth, Agriculture, and Trade	PMP	Performance Management Plan
ESF	Economic Support Fund	PMTCT	Prevention of Mother-to-Child Transmission
F	Office of the Director of Foreign Assistance	PMI	President's Malaria Initiative
FAA	Foreign Assistance Act	PPC	Bureau for Policy and Program Coordination
FACTS	Foreign Assistance Coordination and Tracking System	PPM	Public Private Mix
FBO	Faith-Based Organization	PR	Principal Recipient
FDA	Food and Drug Administration	PRH	Office of Population and Reproductive Health
FFP	Food for Peace	PSC	Personal Service Contract
FGC	Female Genital Cutting	PSCMS	Partnership for Supply Chain Management
FNGO	Foreign Nongovernmental Organization	PVO	Private Voluntary Organization
FP/RH	Family Planning / Reproductive Health	Q&As	Questions and Answers
FSA	Freedom Support Act	RFP	Request for Proposal
FSL	Foreign Service Limited	STI	Sexually Transmitted Infections
FY	Fiscal Year	SO	Strategic Objective
GC	Office of the General Counsel	SPBO	Office of Strategic Planning, Budgeting and Operations
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria	TAACS	Technical Advisors in AIDS and Child Survival
GH	Bureau for Global Health	TB	Tuberculosis
GHA1	Global HIV/AIDS Initiative	UNICEF	United Nations Children's Fund
GH/CS	Global Health and Child Survival	U.S.	United States
HIDN	Office of Health, Infectious Diseases and Nutrition	USAID	United States Agency for International Development
HIV	Human Immunodeficiency Virus	USAID/W	USAID/Washington
HHS	Department of Health and Human Services	USG	United States Government
IAVI	International AIDS Vaccine Initiative	VCT	Voluntary HIV Counseling and Testing
IDFA	International Disaster and Famine Assistance	WCF	Working Capital Fund
		WHO	World Health Organization
		XDR	Extensively Drug Resistant

GUIDANCE ON THE DEFINITION AND USE OF THE GLOBAL HEALTH AND CHILD SURVIVAL ACCOUNT

I. SUMMARY

A. Purpose of the Guidance

The purpose of the Guidance on the Definition and Use of the Global Health and Child Survival Account (“Guidance”) is to (1) provide comprehensive guidance to USAID operating units on the definition and use of the Global Health and Child Survival Account (“GH/CS Account,” formerly the Child Survival and Health (CSH) Programs Fund and the Global HIV/AIDS Initiative (GHAI) Account); (2) provide reference documents to management, technical, program, and budget officers; and (3) delineate special considerations for programming the GH/CS Account.

Unless otherwise noted, the legislative and policy requirements contained in this guidance apply to the GH/CS Account. As a policy matter, if funds from other accounts (e.g., Economic Support Fund (ESF), Freedom Support Act (FSA), Assistance for Eastern Europe and the Baltics (AEEB), and Andean Counterdrug Initiative (ACI)) are used by USAID for health activities, then such use of those funds should also comply with this guidance.

Managers and technical and financial officers must do careful planning, monitoring, and reporting (see Automated Directives System (ADS) Series 200 for detailed guidance), follow parameters set forth by the Office of the Director of U.S. Foreign Assistance (F) and (for HIV/AIDS assistance) the Office of the U.S. Global AIDS Coordinator (S/GAC), and adhere to Congressional earmarks and, as appropriate, directives and other Agency guidelines.

To ensure that legislative and policy guidelines are followed, the Director of Foreign Assistance (F) is responsible for the appropriate allocation and tracking of GH/CS Account funds. The Bureau for Global Health, in collaboration with regional bureaus, the Office of the General Counsel, the Bureau for Legislative and Public Affairs, and F, takes the lead in: (1) communicating issues on the GH/CS Account to the appropriate parties; and (2) responding to external inquiries from Congress and others on the planning, implementing, and monitoring of the GH/CS Account funds assigned to USAID.

Scope, Definitions, Authorities, and Prohibitions

Funds must be used within the parameters set by Congress, the Department of State and Agency for International Development (USAID, or the Agency) Strategic Plan for Fiscal Years 2007 to 2012, S/GAC (for HIV/AIDS assistance), and this Guidance, and then applied to global, regional, and country needs. The Agency places considerable emphasis on local ownership and participation in planning and implementing programs, because these are important to

effectiveness and achieving lasting results. While USAID’s management structure allows the flexibility to build strong local ownership and allows front-line managers to respond to local opportunities and circumstances, these responses must remain within the bounds of the GH/CS budget categories and sub-categories.

Operating units should explicitly communicate this Guidance to partners implementing activities with GH/CS Account funds, particularly as this Guidance affects their planning, implementation, monitoring and evaluation. Contractors, recipients, and grantees should be given documentation requirements (i.e., workplan requirements, program reports) in the scope of work and program description for acquisition and assistance instruments. Operating units should ensure that scopes of work and program descriptions for new awards reflect this Guidance on the definitions and appropriate use of funds for activities covered by GH/CS Account funds.

Operating units are required to implement activities that comply with the guidance for their discrete funding allocations and to report accordingly. Managers as well as technical and financial officers must ensure that GH/CS funds are used for the purpose for which they are appropriated by following the parameters set forth by F, and adhering to this Guidance for Congressional earmarks and directives and corresponding budget categories.

B. Modifications to the 2004 Guidance and Highlights of the Guidance

- This Guidance expands and clarifies previous guidance. This Guidance supersedes the July 22, 2004 Guidance on the Definition and Use of the Child Survival and Health Programs Fund and the Global HIV/AIDS Initiative Account (“2004 Guidance”).
- The text incorporates the changes made to the GH/CS Account (formerly the CSH Programs Fund and the GHAI Account) in the FY 2005 Foreign Operations, Export Financing and Related Programs Appropriations Act (“FY 2005 Appropriations Act”), the FY 2006 Foreign Operations, Export Financing and Related Programs Appropriations Act (“FY 2006 Appropriations Act”), the FY 2007 Continuing Appropriations Resolution, and the FY 2008 Department of State, Foreign Operations, and Related Programs Appropriations Act (“FY 2008 Appropriations Act”).
- The text is primarily organized by program elements under the Foreign Assistance Standardized Program Structure and Definitions (SPS) rather than Congressional budget category.
- Within each element, there is a distinction between “legal requirements and Congressional directives” and “USAID guidance.”
- In Chapter I.A (Purpose of the Guidance) and III.1.B (Allowable Uses of Funds for Agency Programming Purposes: General: USAID Guidance), there is clarification of what accounts are covered by the Guidance.
- The 2004 Guidance Chapter II (Preserving the Integrity of the Child Survival and Health Programs Fund and the Global HIV/AIDS Initiative Account) has been eliminated.

- Chapter I.A (Summary: Purpose of the Guidance) clarifies the purpose of the Guidance and the responsibilities of the Office of the Director of U.S. Foreign Assistance. References to the Bureau for Policy Planning and Coordination (PPC) in the 2004 Guidance have been deleted.
- Chapter II (Element Relationship to Budget Categories) was added to detail the relationship between the health elements and the Congressional budget categories, replacing the 2004 Guidance Chapter III (Relationship of the Budget Categories to the State/USAID Strategic Plan). References to goals and objectives from the SPS have been included.
- In Chapter III.1.B (Uses of Funds for Agency Programming Purposes: General: USAID Guidance), there is updated language on the two key justifications for using GH/CS funds: “direct impact” and “optimal use of funds.”
- In Chapter III.2.A (Allowable Uses of Funds for Agency Programming Purposes: HIV/AIDS: Legal Requirements and Congressional Directives) there is:
 - information on the “Prostitution and Sex Trafficking” requirement to reflect language regarding the application of provisions in Acquisition and Assistance Policy Directive (AAPD) 05-04 to U.S. organizations; and
 - guidance on the circumstances under which HIV/AIDS assistance can be provided to the military, police, prisons or other law agencies, and the procedures for relying on notwithstanding authority.
- In Chapter III.2.B (Allowable Uses of Funds for Agency Programming Purposes: HIV/AIDS: USAID Guidance) there is:
 - guidance regarding USAID support for Abstinence, Be faithful, correct and consistent Condom use (“ABC”) programs, including a new Appendix: “*Guidance for USG In-Country Staff and Implementing Partners Applying the ABC Approach to Prevention of Sexually Transmitted HIV Infections Within the President’s Emergency Plan for HIV/AIDS Relief*”;
 - guidance on “HIV/AIDS Prevention Programs for Injecting Drug Users (IDU),” including updated examples of permissible activities targeting IDU and HIV/AIDS prevention, and a new Appendix: “The U.S. President’s Emergency Plan for AIDS Relief HIV Prevention among Drug Users Guidance #1: Injection Heroin Use (March 2006);”
 - guidance on the provision of palliative care for people living with HIV/AIDS and their families, including the addition of a new Appendix: “*HIV/AIDS Palliative Care Guidance #1 For the United States Government in-Country Staff And Implementing Partners*”;
 - a section on the use of GH/CS funds for Human Capacity Development;
 - guidance on Prevention of Mother-to-Child HIV Transmission (PMTCT);
 - guidance on orphans and vulnerable children affected by HIV/AIDS, and updates relating to the legislative provision requiring that 10 percent of GH/CS funds appropriated to the Department of State for HIV/AIDS be spent on assistance for orphans and vulnerable children affected by HIV/AIDS;

- guidance on procedures related to the use of the Commodity Fund, including the availability of female condoms;
 - a section on the use of GH/CS funds for Supply Chain Management;
 - a section on the use of GH/CS funds for the HIV/AIDS Working Capital Fund;
 - guidance on TB/HIV co-infection, outlining the uses of HIV/AIDS funds for TB/HIV activities;
 - guidance on the provision of antiretroviral treatment, including essential elements for pediatric treatment;
 - guidance on injection safety, including a list of sample activities to reduce the spread of HIV in health care settings by making medical injections safe;
 - guidance on the use of HIV/AIDS funds to support specific health system strengthening interventions, including the major components of health systems and sample interventions;
 - guidance on the role of gender in HIV prevention, care, and treatment; and
 - language on providing support to the Global Fund to Fight AIDS, Tuberculosis and Malaria.
- In Chapter III.3.A (Allowable Uses of Funds for Agency Programming Purposes: Tuberculosis: USAID Guidance), there is a new background section and guidance on allowable uses of funds for TB programs.
 - In Chapter III.4.A (Allowable Uses of Funds for Agency Programming Purposes: Malaria: USAID Guidance), there is:
 - updated guidance on the allowable uses of GH/CS funds appropriated to USAID for malaria, both for programs that are directly part of the President’s Malaria Initiative (PMI) and malaria programs outside of the PMI, including a new appendix: the December 23, 2005 Executive Message on the President’s Malaria Initiative.
 - In Chapter III.5.A (Allowable Uses of Funds for Agency Programming Purposes: Avian Influenza: USAID Guidance), there is:
 - guidance on the allowable uses of GH/CS funds appropriated to USAID for avian influenza, including two appendices: the September 26, 2005 Executive Message “USAID’s Response to Avian Influenza” and the November 3, 2005 Executive Message “Providing Interim Budgetary Guidance for Reprogramming of Funds for Urgent Avian Influenza Related Activities.”
 - **In Chapter III.6** (Allowable Uses of Funds for Agency Programming Purposes: Other Public Health Threats), there is
 - information on the Congressional earmark for neglected diseases; and
 - updates to allowable uses of GH/CS funds under the Other Public Health Threats element, including neglected tropical diseases, antimicrobial resistance containment, and surveillance.

- In Chapter III.7.B (Allowable Uses of Funds for Agency Programming Purposes: Maternal and Child Health: USAID Guidance), there is guidance on allowable uses of funds for maternal health and allowable uses of funds for child health.
- In Chapter III.7.B.a (Allowable Uses of Funds for Agency Programming Purposes: Maternal and Child Health: USAID Guidance: Allowable Uses of Funds for Maternal Health) and Chapter III.8.B.c (Allowable Uses of Funds for Agency Programming Purposes: Family Planning and Reproductive Health: USAID Guidance: Allowable Uses of Family Planning/Reproductive Health Funds for Integrated Family Planning Activities), there is language on integrating gender, including gender-based violence and male involvement, into maternal health and FP/RH programs.
- In Chapter III.7.B.i (Allowable Uses of Funds for Agency Programming Purposes: Maternal and Child Health: USAID Guidance: Allowable Uses of Funds for Maternal Health) and Chapter III.8.B.c (Allowable Uses of Funds for Agency Programming Purposes: Family Planning and Reproductive Health: USAID Guidance: Allowable Uses of Family Planning/Reproductive Health Funds for Integrated Family Planning Activities), there is language on prevention and repair of fistula.
- Chapter III.8 (Allowable Uses of Funds for Agency Programming Purposes: Family Planning and Reproductive Health) now contains a reorganized/merged version of Chapter IV.E (Family Planning/Reproductive Health) and Appendix IV (Guidance on the Definition and Use of Family Planning and Reproductive Health (FP/RH) Funds) of the 2004 Guidance, eliminating redundancies.
- In Chapter III.8.A (Allowable Uses of Funds for Agency Programming Purposes: Family Planning and Reproductive Health: Legal Requirements, Policy Requirements, and Congressional Directives), there is guidance providing a complete listing of legislative and policy requirements, including a new appendix: USAID Family Planning Requirements—Statutory and Policy.
- In Chapter III.8.A (Allowable Uses of Funds for Agency Programming Purposes: Family Planning and Reproductive Health: Legal Requirements, Policy Requirements, and Congressional Directives), there is language on the application of legislative and policy requirements to integrated programs which include both family planning and HIV/AIDS activities.
- In Chapter III.9 (Allowable Uses of Funds for Agency Programming Purposes: Water Supply, Sanitation, and Hygiene), there is guidance on the use of GH/CS funds appropriated to USAID in water programs.
- Language in Chapter III.10 (Allowable Uses of Funds for Agency Programming Purposes: Vulnerable Children) has been reduced and simplified. It also contains information on the “Assistance for Orphans and Other Vulnerable Children in Developing Countries Act.”

- In Chapter III.11.A.a (Allowable Uses of Funds for Agency Programming Purposes: Other: Construction), there is new guidance on when GH/CS funds can be used for construction, including a threshold amount as well as a clarification on the distinction between construction and improvements (additions/renovations).
- There is a section on the use of GH/CS funds appropriated to USAID in Rebuilding Countries. See chapter III.12 (Allowable Uses of Funds for Agency Programming Purposes: Rebuilding Countries).
- In Chapter III.14 (Allowable Uses of Funds for Agency Programming Purposes: Co-Programming), language was added to clarify that operating units should consult with health staff and/or core team leaders when GH/CS funds are used for integrated activities or programmed with funds from other sectors.
- In Chapter IV (Additional Guidance: Procedures for Deviations from the Guidance), the procedures for deviating from the guidance contained within this document have been modified to include a two-phase approach. The first phase involves a technical consultation; the second phase involves approval from the Administrator of USAID and is only required if consensus is not reached during the first phase. A sample template for documenting technical consultations has been added as an appendix.
- APPENDIX III of the 2004 Guidance (Operational Guidelines on the Use of CSH Programs Funds in the Context of Multi-sectoral Programs for HIV/AIDS Activities (includes Annex I, II, and III)) has been removed.
- Emphasis area coding information previously included in Acronyms, Chapter IV.G, and Appendix V in the 2004 Guidance has been removed.

C. Structure of the Guidance

This document consists of four chapters and ten appendices.

- Chapter I defines the purpose and structure of the Guidance and indicates the most significant modifications to the 2004 Guidance.
- Chapter II describes how the budget categories of the GH/CS Account relate to the health elements under the Foreign Assistance Standardized Program Structure, and how the health elements contribute to the goals of the Foreign Assistance Framework.
- Chapter III discusses allowable uses of GH/CS funds within each of the health elements, distinguishing between legal requirements/Congressional directives and USAID guidance. This chapter also addresses areas of special concern, including health systems, health programming in rebuilding countries, administrative/management costs, and co-programming for health activities funded by other non- GH/CS accounts.
- Chapter IV outlines procedures for operating units who wish to deviate from the Guidance.

D. Points of Contact

Direct general questions concerning the overall guidance to the Director of the Bureau for Global Health's (GH's) Strategic Planning, Budgeting, and Operations Office.

II. RELATIONSHIP BETWEEN PROGRAM ELEMENTS AND BUDGET CATEGORIES

A. Appropriate Elements under the Foreign Assistance Framework

The Health Program Area goal: “to contribute to improvements in the health of people, especially women, children, and other vulnerable populations in countries of the developing world, through expansion of basic health services, including family planning; strengthening national health systems, and addressing global issues and special concerns such as HIV/AIDS and other infectious diseases” is primarily supported by activities funded with GH/CS Account funds. Operating Units develop Operational Plans specific to local conditions. Such Operational Plans include activities which are grouped into program elements used for summarizing and reporting on programs. The program elements specific to the health program area are:

- 3.1.1 HIV/AIDS
- 3.1.2 Tuberculosis
- 3.1.3 Malaria
- 3.1.4 Avian Influenza
- 3.1.5 Other Public Health Threats
- 3.1.6 Maternal and Child Health
- 3.1.7 Family Planning and Reproductive Health
- 3.1.8 Water Supply and Sanitation

The GH/CS account also includes funding for vulnerable children, which may be programmed in the following elements of the Social Services and Protection for Especially Vulnerable Populations program area:

- 3.2.1 Vulnerable Children
- 3.2.5 Host Country Strategic Information Capacity
- 3.2.6 Program Design and Learning
- 3.2.7 Administration and Oversight

Program elements are subject to adjustment annually, and are included in the Foreign Assistance Standardized Program Structure and Definitions, available at <http://www.state.gov/documents/organization/93447.pdf>. The SPS can also be found at: http://inside.usaid.gov/A/F/docs/plan/guidance/s_FAStandardizedProgramStructureandDefinitions-UpdatedforFY2008.pdf.

B. Budget Categories

The FY 2002 House Appropriations Committee Report clearly defined a set of five budget categories within the CSH Programs Fund (now the GH/CS Account) and specifically outlined how CSH funds were to be allocated. The GH/CS Account structure reflects certain directives and expectations of funding levels for specific parts of USAID’s health programs. This category structure has been retained annually in Appropriations Acts, including that for 2008. As a matter of policy, the Agency utilizes these categories for all health programs regardless of funding

source. The relationship, or crosswalk, among the elements in the Foreign Assistance Framework and the five budget categories set forth in the FY 2008 Appropriations Act is as follows:

Budget Categories:

- ***Child Survival and Maternal Health***, which includes the following activities identified by Congress: Primary Causes of Mortality and Morbidity, Polio, Micronutrients, and the Vaccine Fund (associated with GAVI).

Associated Program Element:

- **3.1.6 Maternal and Child Health**

- ***Vulnerable Children***, which includes the following line items: Displaced Children and Orphans Fund (DCOF), Blind Children, and Other Vulnerable Children. Funds are used to support a set of programs designed to address critical needs of children at risk and needs of children in crisis, including orphans, though orphans affected by HIV/AIDS are part of the HIV/AIDS budget category.

Associated Program Element:

- **3.3.2 Social Services**

Associated Program Sub-Elements:

- **3.3.2.1 Vulnerable Children**
- **3.3.2.5 Host Country Strategic Information Capacity**
- **3.3.2.6 Program Design and Learning**
- **3.3.2.7 Administration and Oversight**

- ***HIV/AIDS***. The Agency may be required to meet directives for microbicides and the International AIDS Vaccine Initiative (IAVI). The 2006 Conference Report explained that the funds in the Global HIV/AIDS Initiative Account would be used for programs in the 15 AIDS Initiative “focus” countries, and that the funds in the CSH Programs Fund were not appropriated for HIV/AIDS country programs in the focus countries. Rather, the CSH Programs Fund would be used for HIV/AIDS programs in other bilateral countries, regional programs, and central programs.¹ The Conference Report also strongly encouraged the Office of the Global AIDS Coordinator (S/GAC) to “continue its policy of providing additional funding to ‘non-focus’ countries.”

Associated Program Element:

- **3.1.1 HIV/AIDS**

- ***Infectious Diseases***, which includes the following activities identified by Congress: tuberculosis, malaria, other infectious diseases, including neglected diseases (e.g., intestinal parasites, schistosomiasis, lymphatic filariasis, onchocerciasis, trachoma, and leprosy), avian influenza, and anti-microbial resistance and surveillance.

¹The FY 2008 Conference Report reiterates that: “The Appropriations Committees intend this [GH/CS] account to clarify overall United States Federal government spending on global health programs, and in no way is the consolidated health account intended to change the authorities or implementation of global health programs.”

Associated Program Elements:

- **3.1.2 Tuberculosis**
- **3.1.3 Malaria**
- **3.1.4 Avian Influenza**
- **3.1.5 Other Public Health Threats**

- ***Family Planning/Reproductive Health.*** There are no specific activities identified by Congress within this budget category. The Agency is encouraged to undertake and implement reproductive health and family planning programs, including in areas where population growth threatens biodiversity and endangered species. Family planning represents the core reproductive health intervention of USAID's FP/RH program and the primary use of FP/RH funds. The Agency is reminded that all USAID-supported family planning programs must be free from coercion of any kind and should offer assistance appropriate to low resource settings to help people in these countries attain their desired family size.

Associated Program Element:

- **3.1.7 Family Planning and Reproductive Health**

III. ALLOWABLE USES OF FUNDS FOR AGENCY PROGRAMMING PURPOSES

This chapter describes both legal requirements and Congressional directives, as well as USAID requirements.

All legal requirements are mandatory. Congressional directives in the health sector are also treated as mandatory.

USAID guidance is issued to ensure effective, evidence-based programming, and to increase consistency and predictability of operations. This guidance has been determined based on decades of experience in health programming and represents the best understanding of leading technical experts. Although Operating Units (OUs) should generally follow these practices, there are situations where an OU may wish to deviate from them or adapt them to particular situations, especially when such deviations correspond to the guiding principles of direct impact and optimal use. Please see Chapter IV on the procedures for deviating from USAID requirements.

1. General

A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES

a. Statutory Authorities

Statutory authorities for use of the GH/CS Account are as follows:

- **Authorization Authority:** The GH/CS Account (formerly the CSH Programs Fund and the GHAI Account) is authorized by the Foreign Assistance Act of 1961, as amended, the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (the “PEPFAR Authorization”) and the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008 (the “PEPFAR Reauthorization”), including amendments made in the 2000 Global AIDS and Tuberculosis Relief Act and the PEPFAR Authorization. Relevant excerpts are included in Appendix I.

Appropriation Authority: Funds from the GH/CS Account are appropriated in the annual Appropriations Act for the Department of State, Foreign Operations, and Related Programs. In terms of the scope of the legislation, the FY 2006 Appropriations Act authorized CSH activities by providing “for necessary expenses...for child survival, health, and family planning/reproductive health activities....” The FY 2006 Appropriations Act appropriated the CSH Programs Fund to remain available for obligation until September 30, 2007. Pursuant to Section 511 of the FY 2006 Appropriation Act, Child Survival and Health Programs Funds that were obligated during the initial period of availability may

be de-obligated and re-obligated, without USAID losing the funds, until September 2011.

The 2006 Appropriations Act funded Global HIV/AIDS Initiative activities by providing “for necessary expenses to carry out the provisions of the Foreign Assistance Act of 1961 for the prevention, treatment, and control of, and research on, HIV/AIDS.” The FY 2006 Appropriations Act appropriated Global HIV/AIDS Initiative funds to remain available until expended and consequently can be deobligated and reobligated.

In 2007, a Continuing Appropriations Resolution extended full-year continuing appropriations under the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 2006, which made appropriations available through September 30, 2008 under the terms and conditions of the FY 2006 Appropriations Act.

The FY 2008 Appropriations Act created a new account, the Global Health and Child Survival Account, which combines the CSH Programs Fund and the GHAI Account. The FY 2008 Appropriations Act authorizes funding by providing “for necessary expenses...for global health activities....” The Conference Report states that “in no way is the consolidated health account intended to change the authorities or implementation of global health programs.” These appropriations are available for obligation through September 30, 2009. The same deobligation/reobligation authority that existed in the FY 2006 Appropriations Act is contained in sec. 611 of the FY 2008 Act.

See Appendix I for excerpts from the FY 2006 Appropriations Act, the FY 2007 Continuing Resolution, the FY 2008 Appropriations Act, the PEPFAR Authorization, the PEPFAR Reauthorization, and relevant Report language for definitions and further elaboration. To ensure compliance, USAID staff should consult the applicable authorization and appropriation legislation each fiscal year as changes may occur.

- **Notwithstanding Authority:** The “notwithstanding” authority in Section 622 of the 2008 Appropriations Act allows USAID to use funds for “child survival activities or disease programs including activities relating to research on, and the prevention, treatment, and control of HIV/AIDS...*notwithstanding any other provisions of law except for the provisions under the heading ‘Global Health and Child Survival’ and the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003*” as amended. In other words, when required for program efficiency, USAID may carry out activities regardless of country prohibitions or certain procurement regulations, personnel regulations, competitive process standards, or other restrictions that would otherwise prohibit or restrict programming. Please note that utilizing the notwithstanding authority to provide GH/CS Account assistance applies specifically to provisions of law or regulation relevant to that program. The notwithstanding authority, however,

does *not* extend to FP/RH activities. If operating units have questions about certain provisions of law related to activities funded under the GH/CS, they must consult with the regional legal advisor or the Office of the General Counsel (GC) before providing such assistance.

A decision to rely on notwithstanding authority provides USAID legal flexibility, but must be carefully coordinated with appropriate offices in accordance with Agency policy and PEPFAR policy. Operating units must request approval from their relevant Regional Bureau Assistant Administrator, and obtain clearances from the Assistant Administrator of the Bureau for Global Health, the Assistant General Counsel for their Regional Bureau, the F IIP lead, and S/GAC (for HIV/AIDS activities only). F is responsible for tracking operating units that make use of the “notwithstanding” authority

b. Nonproject Assistance

The FY 2008 Appropriations Act directs that “...none of the [GH/CS] funds appropriated under this paragraph [which includes USAID Child Survival and Maternal Health, USAID Vulnerable Children, USAID Infectious Diseases, USAID Family Planning/Reproductive Health and USAID HIV/AIDS] may be made available for nonproject assistance, except that funds may be made available for such assistance for ongoing health activities.” One example of such prohibited non-project assistance would be monetary payments to host country governments as part of sector reform efforts without reference to specific activities or results.

B. USAID GUIDANCE

GH/CS funds shall be used only where their direct impact on health objectives and their optimal use provide adequate justification.

- **“Direct impact”** means that the results (outcome/impact) of an activity can be linked and measured (using health elements and health indicators) against the purposes for which the funds supporting the activity were appropriated, as defined in the FY 2008 Appropriations Act and the relevant House, Senate, and Conference Reports and under the health element goal: “To contribute to improvements in the health of people, especially women, children, and other vulnerable populations in countries of the developing world, through expansion of basic health services, including family planning; strengthening national health systems, and addressing global issues and special concerns such as HIV/AIDS and other infectious diseases.” Thus, the goal of the activity must include a specific and measurable health impact.

In addition, the justification for use of GH/CS funds rests solely on the expected health impact of the activity. The impact of an activity on other goals, even those as valuable to development as poverty reduction, economic growth or education, is not relevant in justifying the use of GH/CS funds. While activities in other

sectors are likely to have positive impact on health, the selection of GH/CS-funded activities cannot take into account any impact outside of health.

- **“Optimal use of funds”** refers to the prioritization of the funding of an activity in terms of its effectiveness and efficiency. Activities that produce the greatest impact on the objective should be funded with the GH/CS Account over those that will show a lesser impact. This requires comparing the expected result of a planned activity with the best alternative and should be accompanied by monitoring and reporting on the achievement of those results. Effectiveness implies that there has been some analysis to determine that the proposed use of funds will likely achieve the greatest possible impact with the funding made available. Indicators and measurements exist for the different child survival and health interventions that have been legitimized by the peer reviewed literature, including The Lancet. Efficiency implies that the proposed activity can be implemented in a way that maximizes results relative to inputs. Country factors such as the severity and magnitude of the problem, overall developmental needs, program stage or maturity, relative cost- and program-efficiency of the intervention, and host country and other donor resources help determine optimal use.

The types of activities which are generally funded under the GH/CS Account include, but are not limited to:

- *Direct service delivery*
- *System strengthening in both public and private sectors*
- *Community participation and mobilization*
- *Development of management capacity*
- *Policy analysis and dialogue*
- *Training, quality assurance, and supervision*
- *Information, education, and communication (IEC) activities*
- *Data collection and analysis*
- *Pilot projects and applied research including the development, testing and introduction of new or improved interventions and delivery approaches*
- *Efforts to secure a stable and diversified resource base*
- *Rational management and use of essential drugs/commodities and commodity procurement*
- *Strong, ongoing monitoring and evaluation mechanisms to encourage continuous improvement of the management and quality of programs and systems*

The following sections further define allowable uses of funds in each specific category. If an operating unit needs clarification or has a question about whether an activity falls within these parameters, it may contact the Office Director of GH/SPBO, its Regional Bureau technical officer for health, S/GAC, GC’s Regional Legal Advisor, or the IIP lead in F, as appropriate. See Chapter IV for further details and procedures for deviations from the USAID requirements.

2. HIV/AIDS

This budget category corresponds to the element 3.1.1 HIV/AIDS.

Background:

During his 2003 State of the Union Address, President Bush announced the creation of the President's Emergency Plan for AIDS Relief (PEPFAR), a five-year, \$15-billion initiative to combat the global HIV/AIDS pandemic. In May 2003, President Bush signed into law the "United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003" (P.L. 108-25, the "PEPFAR Authorization") which authorizes the activities of the Emergency Plan, including efforts in prevention, treatment, and care (including care for orphans and vulnerable children). Under the PEPFAR Authorization and PEPFAR Reauthorization, the U.S. Global AIDS Coordinator has authority to provide "oversight and coordination of all resources and international activities of the United States Government to combat the HIV/AIDS pandemic." During its first five years, the Emergency Plan set goals to support antiretroviral treatment (ART) for two million HIV-infected individuals, prevention of seven million HIV infections, and care for 10 million people infected or affected by HIV/AIDS, including orphans and vulnerable children.

The law was reauthorized by 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, the "PEPFAR Reauthorization.") President Bush has announced new goals to support ART for at least 3 million people, prevent 12 million HIV infections, and care for 12 million people infected or affected by HIV/AIDS, including 5 million orphans and vulnerable children.

S/GAC provides guidance for HIV/AIDS activities worldwide through guidance documents, including the annual Country Operational Plan (COP) and Mini-COP Guidance, which inform planning by interagency teams at the country level. Key policy documents are available in the appendices to this Guidance. For other questions, please contact the Office Director of GH/OHA.

Allowable activities for HIV/AIDS are those that contribute directly to prevention, care (including care for infected individuals and affected orphans and vulnerable children), and treatment of HIV/AIDS. These goals require a comprehensive, locally tailored approach that engages sufficient community, government, NGO, and donor resources in a consistent and complementary manner. The strategies should reflect the stage of the epidemic and focus efforts on "those most likely to contract or transmit" HIV.

The following guidance is directed to all programs providing HIV/AIDS assistance worldwide.

A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES

a. Prostitution and Sex Trafficking

Section 301 of the PEPFAR Authorization entitled “Assistance to Combat HIV/AIDS” includes certain restrictions on the use of HIV/AIDS funds relating to prostitution and sex trafficking.² This provision was left unchanged in the PEPFAR Reauthorization. Specifically, Section 301 (e) prohibits the use of U.S. Government funds for HIV/AIDS activities to promote or advocate the legalization or practice of prostitution or sex trafficking. Section 301 (f) requires non-governmental organizations and certain Public International Organizations³ receiving U.S. Government funds for HIV/AIDS activities to have a policy explicitly opposing prostitution and sex trafficking.⁴ USAID’s Acquisition and Assistance Policy Directive (AAPD) 05-04 implements these provisions. Prime recipients of assistance agreements (grants and cooperative agreements) for HIV/AIDS activities must provide a certification before receiving funds that they are in compliance with the applicable standard provisions included in AAPD 05-04. See AAPD 05-04: http://www.usaid.gov/business/business_opportunities/cib/pdf/aapd05_04.pdf. USAID is currently enjoined from enforcing this requirement against certain organizations. You must check with the Office of the General Counsel or the Regional Legal Advisor to obtain current guidance on this policy requirement. AAPDs are revised from time to time. Please make sure that the correct AAPD that implements the provision is being followed, and that the proper clauses are included in all relevant awards for HIV/AIDS activities.

USAID and its implementing partners may work with high-risk groups, such as people engaged in prostitution, as long as PEPFAR funds are not used to "promote or advocate the legalization or practice of prostitution and sex trafficking." The following HIV/AIDS prevention, care, and treatment activities are specifically permitted by the PEPFAR

² Section 301 includes the following provisions:

(e) LIMITATION. – 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. Nothing in the preceding sentence shall 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.

(f) LIMITATION. – No funds made available to carry out this Act, or any amendment made by this Act, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.

³ The FY 04 Appropriations Act amends Section 301(f) of the AIDS Authorization by exempting the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative and any “United Nations agency” from that section. The Statement of Managers states that the conferees “intend that for purposes of this provision, the World Health Organization includes its six regional offices: The Americas (PAHO); South-East Asia (SEARO); Africa (AFRO); Eastern Mediterranean (EMRO); Europe (EURO); and Western Pacific (WPRO).”

⁴ This requirement is the subject of ongoing litigation. USAID is enjoined from enforcing this requirement against certain organizations. Please contact your cognizant RLA or GC/EGAT&GH if you have any questions regarding application of this requirement.

Authorization: "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." The Agency also supports the provision of other HIV/AIDS prevention activities, such as behavior change communication, to people engaged in prostitution.

b. Condoms

Within the GH/CS Account, HIV/AIDS funds may be used appropriately for purchasing condoms for HIV/AIDS prevention (see Commodity Fund, Chapter III.2.B.j).

The FY 2008 Appropriations Act provides that "information provided about the use of condoms as part of projects or activities that are funded from amounts appropriated by this Act shall be medically accurate and shall include the public health benefits and failure rates of such use." Such information should be consistent with USAID's fact sheet entitled, "USAID: HIV/STI Prevention and Condoms," available at: http://www.usaid.gov/our_work/global_health/aids/TechAreas/prevention/condomfactsheet.html.

c. Conscience Clause

The PEPFAR Authorization permits recipients of HIV/AIDS funds not to endorse, utilize or participate in a prevention method or treatment program to which the organization has a religious or moral objection.

Under section 301(h) of the PEPFAR Reauthorization, "an organization, including a faith-based organization, that is otherwise eligible to receive assistance shall not be required, as a condition of receiving such assistance to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements... for refusing to meet any [such] requirement."

Clauses implementing these provisions must be included in HIV/AIDS assistance awards and contracts. See Acquisition and Assistance Policy Directive (AAPD) 05-

04: http://www.usaid.gov/business/business_opportunities/cib/pdf/aapd05_04.pdf

d. Military, Police, Prisons or other Law Enforcement Agencies

In many HIV high-prevalence countries, military and police populations are known to be high-risk groups that have a direct influence on the HIV transmission dynamics in the general civilian population. With HIV prevalence in some militaries estimated at 40-60 percent, their potential to infect others is enormous. In other countries where that prevalence is not yet high, it is essential to head off such an extreme situation before it occurs. In both cases, failure to include such groups in HIV/AIDS activities will pose a severe threat to the health of the public at large and diminish the likelihood that any HIV/AIDS prevention and mitigation program could succeed. Funds from the GH/CS Account may be used to address HIV/AIDS in military, police, prisons or other law

enforcement agencies, subject to the following guidance. Where possible, U.S. Department of Defense (DoD) HIV/AIDS experts should be consulted and engaged in programs addressing these groups.

1. Assistance to foreign military or to police, prison or other law enforcement personnel that is part of a larger public health initiative. Section 531(e) of the Foreign Assistance Act of 1961, as amended (FAA), and general principles of appropriation law prohibit the use of economic assistance funds for military purposes. In addition, Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that these prohibitions will not apply to assistance used only for the prevention, treatment, care and control of, and research on HIV/AIDS in the military or police, prison or other law enforcement personnel, if the following conditions are met:

- a) The programs or activities in which the military or police, prison or other law enforcement personnel would participate are part of a larger public health initiative to combat HIV/AIDS, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the military or police, prison or other law enforcement personnel must be similar to that received by other population groups similarly situated, in terms of HIV/AIDS transmission risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program, can be readily adaptable for military or police, prison or other law enforcement personnel purposes.

GC has emphasized that the requirement for similar programs (b above) means similar in subject content, e.g., how HIV/AIDS is acquired, how it is transmitted, and how transmission can be avoided. As long as the training and materials are designed to deal with such acceptable subjects, they meet the test. It is not required that there be one uniform set of training materials appropriate for use by military and also by the other groups in society, such as younger school children. Clearly the language, content, and method of delivery could and should vary depending on the audience.

The Office of the General Counsel has also advised that it would be appropriate to have particular activities that are directed only toward the military or police, prison or other law enforcement personnel as long as they are designed only to support HIV prevention and combat its transmission. A conference or design workshop attended only by military personnel may be funded for the frank discussion of HIV/AIDS among the military and how to combat it (e.g., an officer's responsibility to see that his subordinates are fully informed and are discouraged from engaging in high-risk behavior or from frequenting known high-risk establishments). Under the same HIV/AIDS country or regional program, a conference for village health workers on avoiding mother-to-child transmission may well exclude military personnel as not being relevant to them. Both, however, are in pursuit of the broader goal and thus appropriate for USAID funding.

Therefore, it is appropriate and legally permissible to include the military, police, prison or other law enforcement personnel in comprehensive HIV/AIDS programs in conformance with the three legal criteria outlined above. Indeed, including those groups may well be critically important to the success of the programs. In the design and implementation of HIV/AIDS programs, it is also appropriate to have training sessions or materials focused specifically on individual groups as long as the activities are in pursuit of the overall program goal. Where possible, DoD HIV/AIDS experts should be consulted and engaged in programs addressing these groups, and in certain contexts with foreign militaries, it may be appropriate for DoD to implement these activities.

2. Notwithstanding authority for assistance to police, prison, or other law enforcement personnel. For HIV/AIDS programs, Section 622 of the FY 2008 Appropriations Act also provides USAID, when required for program efficiency, with “notwithstanding” authority to overcome the prohibition found in Section 660 of the FAA.

In relying on “notwithstanding” authority for this purpose, operating units need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of HIV/AIDS activities permitted by this guidance. In addition, for programs with foreign militaries, consideration should be given to the possibility of implementation by DoD. If an operating unit decides to rely on “notwithstanding” authority, the clearance procedures described below must be followed.

Moreover, operating units should be aware that certain activities involving prisoners, as opposed to prison personnel, may not fall within the prohibition of Section 660 at all, and therefore would not require the reliance on “notwithstanding” authority to fund. If in doubt about the applicability of Section 660, contact your Regional Legal Advisor or GC for assistance.

3. Clearances. From a legal standpoint, use of GH/CS Account funds to provide HIV/AIDS assistance that is part of a larger public health initiative to the military or to police, prison or other law enforcement personnel does not require a specific, written request or formal approval if this guidance is followed. However, operating units should be aware that as a policy matter, the approval of Bureaus or Offices in USAID/W might be required before such HIV/AIDS assistance is provided to the military or police, prison or other law enforcement personnel; therefore, Missions are asked to confirm procedures with their Bureaus. Regardless of whether or not formal Bureau or Office clearance is required, operating units must document the decision to include military, police, prison or other law enforcement personnel in HIV/AIDS activities that are part of a larger public health initiative; such documentation should show how the legal criteria discussed above have been applied and how any bureau approval procedures have been followed. If it is a close question, or if there is confusion about applying the three criteria above to determine whether inclusion of the military or police, prison or other law enforcement personnel as part of a larger overall HIV/AIDS program is appropriate or authorized, please contact your regional legal advisor or GC advisors.

Because relying on “notwithstanding” authority to provide assistance to prisons, police, or other law enforcement personnel may raise sensitive policy issues, operating units must request approval from their relevant Regional Bureau Assistant Administrator, and obtain clearances from the Assistant Administrator of the Bureau for Global Health, the Assistant General Counsel for their Regional Bureau and the F IIP lead. F is responsible for tracking operating units that make use of the “notwithstanding” authority.

e. Earmarks and Directives

The FY 2008 Appropriations Act requires that \$550 million in GH/CS Account funds appropriated to the Department of State be used for the Global Fund to Fight AIDS, Tuberculosis and Malaria. There are also Congressional directives in the FY 2008 Appropriations Act and the accompanying Conference Report for microbicides.

Under the PEPFAR Reauthorization, of the amounts appropriated for HIV/AIDS assistance, for fiscal years 2009 through 2013, for each fiscal year:

- More than half shall be expended 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; and
- Not less than 10 percent shall be expended for assistance for orphans and other children affected by, or vulnerable to, HIV/AIDS, of which such amount at least 50 percent shall be provided through non-profit, nongovernmental organizations, including faith-based organizations, that implement programs on the community level.

The law requires the Coordinator to “provide balanced funding for sexual transmission prevention activities for sexual transmission of HIV/AIDS,” and to “ensure that activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction are implemented and funded in a meaningful and equitable way in the strategy for each host country based on objective epidemiological evidence as to the source of infections and in consultation with the government of each host country involved in HIV/AIDS prevention activities.”

The Coordinator is to establish a sexual transmission prevention strategy in each country with a generalized epidemic. If the strategy provides less than 50 percent of funds for “activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction,” the Coordinator is required, not later than 30 days after the issuance of this strategy, to report to Congress on the justification for this decision.

Programs or activities that implement or purchase new prevention technologies or modalities, such as medical male circumcision, blood safety, promoting universal precautions, investigating suspected nosocomial infections, pre-exposure pharmaceutical prophylaxis to prevent transmission of HIV, or microbicides and programs and activities

that provide counseling and testing or PMTCT interventions, shall not be included in determining compliance with this requirement.

For further guidance on how countries should expend resources for treatment, care (including orphans and vulnerable children programs), and prevention, see Chapter III.2.B.

B. USAID GUIDANCE

a. Prevention of Sexual Transmission

PEPFAR has adopted interagency guidance on implementation of programs to prevent sexual transmission through the ABC⁵ approach in the policy document, “Guidance for USG In-Country Staff and Implementing Partners Applying the ABC Approach to Prevention of Sexually Transmitted HIV Infections Within the President’s Emergency Plan for HIV/AIDS Relief,” available at: <http://www.state.gov/documents/organization/57241.pdf> and attached as Appendix II. Like all PEPFAR guidance, the guidance applies to all funding used for HIV activities, including GH/CS (formerly CSH and GHAI), ESF, FSA, AEEB, ACI, or Title II funding.

Sexual Prevention activities supported by PEPFAR include promotion of abstinence, including delay of sexual activity or secondary abstinence, fidelity (including partner reduction, and related social and community norms), the purchase and promotion of condoms, STI management (outside of palliative care settings/context), and messages/programs to reduce risks of persons engaged in high-risk behaviors.

Section 403 of the PEPFAR Reauthorization requires the Coordinator to “provide balanced funding for sexual transmission prevention activities for sexual transmission of HIV/AIDS,” and to “ensure that activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction are implemented and funded in a meaningful and equitable way in the strategy for each host country based on objective epidemiological evidence as to the source of infections and in consultation with the government of each host country involved in HIV/AIDS prevention activities.”

The Coordinator is to establish a sexual transmission prevention strategy in each country with a generalized epidemic. If the strategy provides less than 50 percent of funds for “activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction,” the Coordinator is required, not later than 30 days after the issuance of this strategy, to report to Congress on the justification for this decision.

⁵ The ABC Approach encompasses a range of risk-reduction behaviors, focusing on:
-- Abstinence until marriage, including delay of sexual debut among youth, and “secondary abstinence;”
-- Being faithful within marriage relationships and partner reduction outside of marriage; and
-- Condom use, correct and consistent use for at-risk/non-regular partners and sexually active sero-discordant couples.

For more information, please see the current COP or Mini-COP Guidance.

b. **Biomedical Prevention**

Biomedical prevention includes activities for blood safety, safe injection, injecting and non-injecting drug users and male circumcision. Programs or activities that implement or purchase new prevention technologies or modalities, such as medical male circumcision, blood safety, promoting universal precautions, investigating suspected nosocomial infections, pre-exposure pharmaceutical prophylaxis to prevent transmission of HIV, or microbicides and programs and activities that provide counseling and testing or PMTCT interventions, shall not be included in determining compliance with the 50% requirement for generalized epidemics cited above.

For more information, please see the current COP or Mini-COP Guidance.

Injecting Drug Users (IDUs)

USAID is committed to supporting effective strategies to prevent the spread of the HIV/AIDS pandemic among IDUs. Consistent with U.S. Government policy, Emergency Plan funding (funds for HIV/AIDS activities, including GH/CS (formerly CSH and GHAI), ESF, FSA, AEEB, and ACI) may not be used to support needle or syringe exchange programs.

Funds for HIV/AIDS activities may support the following:

- Policy activities that encourage countries to remove barriers to medication-assisted treatment for heroin users as an important component of their national HIV/AIDS treatment and prevention plans;
- Formative research and assessments of the contribution of substance use to the HIV epidemic globally;
- Confidential, routine HIV counseling and testing in substance abuse programs;
- Community-based outreach for drug users that addresses HIV prevention, risk reduction, and substance use with links to appropriate care services;
- Prevention education on the risks of injecting drugs and sharing syringes, and education and counseling on how to reduce or stop injecting drugs;
- Programs for prevention of sexual transmission of HIV among IDUs;
- Education of health professionals and policymakers regarding best practices for HIV prevention strategies for substance users;

- HIV treatment or referral to treatment for the HIV-infected IDU in the context of a comprehensive prevention program; and
- Substance abuse treatment programs for HIV-infected individuals, including medication-assisted treatment with methadone, buprenorphine and naltrexone. For those who are HIV-negative, the Emergency Plan can only support these programs on a pilot basis. All medication-assisted substance abuse therapy programs will require prior S/GAC approval.

For further guidance, please see Appendix III: The U.S. President's Emergency Plan for AIDS Relief HIV Prevention among Drug Users Guidance #1: Injection Heroin Use (March 2006). For help with questions, please contact GH/OHA.

Male Circumcision

According to the FY 09 COP and Mini-COP guidance:

PEPFAR guidance is consistent with the March 2007 WHO/UNAIDS recommendations on male circumcision for HIV prevention. Under the leadership of host country governments, and consistent with local policies and norms, HIV/AIDS funds can now be utilized to support the implementation of safe male circumcision services. In FY 2009, there is no funding limit per country for safe male circumcision services or other safe male circumcision activities. It is critical to ensure appropriate follow-up and treatment of any complications of male circumcision procedures, while continuing to emphasize the importance of comprehensive prevention messages focusing on an ABC approach. Recognizing that male circumcision is not 100 percent protective, it is essential for countries that are incorporating male circumcision service delivery to place it within a comprehensive HIV prevention package. The Male Circumcision task force is available to provide additional support and information as you consider the introduction of this important but challenging prevention intervention.

Male circumcision (MC) activities include: feasibility studies and needs assessment activities; communication, training, service delivery and monitoring and evaluation. MC services must be delivered within a comprehensive package of prevention services focusing on an ABC approach, which include provider-initiated and -delivered HIV counseling and testing; active exclusion of symptomatic STIs and syndromic treatment where required; provisional promotion of correct and consistent use of condoms; and counseling on behavior change, including a gender component that addresses male norms and behaviors and sexual violence. Currently MC is NOT recommended for men who are HIV-positive. All male circumcision service delivery sites must include HIV counseling and testing for all patients (the USG follows the WHO MC for HIV prevention recommendations and therefore strongly encourages but does not mandate HIV testing). All MC sites should include links or referrals to HIV care and treatment for HIV-positive men. For countries that are planning MC service

delivery, S/GAC requires a letter from the Minister of Health requesting USG assistance for such work.

For more information, please see the current COP or Mini-COP Guidance.

c. Prevention of Mother-to-Child HIV Transmission (PMTCT)

The 2008 PEPFAR Reauthorization sets a goal of providing access to prevention of mother-to-child transmission interventions to 80 percent of pregnant women in heavily affected countries. In the PEPFAR Reauthorization, Congress has not specified a target amount of funding for PMTCT. Nevertheless, in areas where prevalence is high (exceeding five percent in pregnant women), PMTCT programs are an important gateway to HIV/AIDS and other maternal/child health services. Missions are strongly encouraged to develop PMTCT activities. In order to use GH/CS funds to improve services for pregnant and postpartum women, Missions should be able to demonstrate a direct contribution to increased access to PMTCT services.

PMTCT funds should be used to increase focus on providing access to PMTCT interventions, supporting ART provision for treatment-eligible HIV-positive pregnant women, and collecting and reporting data on the numbers of HIV-positive pregnant women initiating ART while pregnant, which is a required PEPFAR indicator. Ensuring this sub-group of HIV-infected women are appropriately screened and treated will dramatically reduce the risk of HIV transmission to their infants and improve overall maternal health and child survival.

For more information, please see the current COP, Mini-COP, and Technical Consideration Guidance.

d. Orphans and Vulnerable Children Affected by HIV/AIDS

Caring for orphans and vulnerable children is a critical part of PEPFAR's efforts to mitigate the impact of AIDS. In FY 2007, PEPFAR supported over 2.7 million children directly or indirectly, the majority through USAID programs. While this is a substantial number, it still represents just a small portion of the millions more in need. To underline the importance of expanding coverage, the PEPFAR Authorization for FY 06-FY08 (as well as the PEPFAR Reauthorization), stipulate that at least 10% of funds authorized to be appropriated be programmed for OVC. All countries/regions preparing a COP or Mini-COP are required to meet this earmark.

USAID programs with GH/CS funding for OVCs affected by HIV/AIDS may be directed to: (1) community-based efforts that impact on the protection and well-being of orphans and other children and adolescents affected by HIV/AIDS; (2) increasing capacity and systems at local and national levels for program design, implementation, monitoring and evaluation, and for sustaining effective efforts; (3) operations research to identify program models that are effective, efficient and sustainable; and (4) sharing lessons learned with local, national, and global partners.

Pediatric care and treatment are also priorities and should have their own dedicated funds. Funding for pediatric care and pediatric treatment will not be counted towards meeting the OVC budgetary requirement. Programs that have depended on pediatric HIV care activities to help fulfill the 10% OVC earmark in the past will need to plan for a reasonable transition in budgeting to ensure care for HIV infected children is not disrupted. In such cases a budget justification should be submitted (a justification template is available on PEPFAR.net). Other justifications, where they make sense, for example where extensive national coverage of OVC services with other donor or host country resources already exist, may also be acceptable. For more information on programming for OVC, please refer to the current COP or Mini-COP guidance, as well as the “Orphans and Other Vulnerable Children Programming Guidance,” available at <http://www.pepfar.gov/pepfar/guidance/78161.htm>.

e. HIV/TB

Tuberculosis (TB) is the leading cause of death among people living with HIV/AIDS. In some countries, up to 80 percent of people living with HIV/AIDS (PLWHA) are co-infected with the organism that causes TB, *Mycobacterium tuberculosis*, and up to 60 percent of people infected with HIV living in sub-Saharan Africa will develop active TB disease. HIV/AIDS is the strongest risk factor for developing active TB, as an HIV-infected individual has a 10 percent chance of developing active TB each year (compared to a 10 percent lifetime risk of developing TB in a non-HIV-infected individual). Diagnosis and treatment of active TB disease and latent TB infection using proven, effective strategies dramatically reduces the morbidity and mortality associated with TB/HIV and are among the most important medical interventions that can be offered to HIV-infected individuals living in high TB-prevalence areas. Individuals co-infected with HIV and TB fall under the Emergency Plan goals to provide care and support for people living with HIV/AIDS.

In countries or areas with a high burden of HIV/AIDS, the prevalence of HIV infection among patients in TB clinical settings is high, and thus patients in TB clinical settings are “high yield” for identification and referral for HIV prevention, care and treatment. TB increases mortality in PLWHA and complicates management of treatment for HIV. With the additional specter of extensively-drug resistant TB emerging among PLWHA both in communities and care settings, TB/HIV activities must be urgently scaled up.

Since TB is the leading infectious killer in people with AIDS, and TB, with proper therapy, is both preventable and curable for most individuals regardless of HIV status, addressing TB among HIV-infected persons is a high priority for HIV/AIDS care programs and may be supported using HIV/AIDS funds. Activities that may be supported include (but are not limited to):

- Screening of HIV-infected individuals (including individuals in PMTCT programs) for symptoms of active TB;
- Support for developing and refining referral systems for HIV-infected individuals to ensure that TB suspects have access to both diagnosis and treatment facilities and that they continue to access HIV care;

- Provision of HIV counseling and testing of all those with active or suspected TB -- either within TB clinics or through referral mechanisms;
- Implementation of the “Three I’s” at HIV entry points as priority activities in TB/HIV (isoniazid preventive therapy, intensified TB case-finding, and TB infection control);
- Development of systems to manage HIV/TB co-infected individuals in either integrated treatment and care programs or across multiple health care programs, including reporting systems to monitor the provision of TB/HIV services, TB-program effectiveness and multi-drug resistant TB in HIV-infected individuals;
- Coordinated planning, training and monitoring and evaluation of TB/HIV collaborative activities; and
- Surveillance to measure the rate of TB and HIV co-infection.

TB/HIV collaborative activities are an important component of national level plans for both TB and for HIV/AIDS. Assistance can be provided to help develop these plans and PEPFAR resources for TB/HIV should also support the priorities outlined in these plans.

To maximize the impact USG investments and to avoid duplication, resources and support for TB/HIV activities should be coordinated with programs and funding from other sources including GH/CS funds appropriated to USAID and grants from the Global Fund to Fight AIDS, TB and Malaria. The formation of interagency technical working groups and joint monitoring and technical assistance visits can help to facilitate this coordination.

For further information or guidance, please contact GH/OHA or see the current COP or Mini-COP guidance for PEPFAR.

f. Counseling and Testing

HIV testing is a critical intervention that serves as a linchpin connecting prevention to treatment and care. Knowledge of HIV status is a vital tool for helping individuals learn to avoid behaviors that place them at risk of HIV infection, leading people to protect themselves and others from HIV infection. An emerging priority is the scale up of counseling and testing services that are strategically located to maintain a strong focus on prevention, while also identifying and reaching those individuals most likely to be in need of care and treatment services. In particular, the USG and its partners are supporting the provision of routinely-offered, provider-initiated counseling and testing in clinical and other settings such as STI and TB treatment programs; increasing access to confidential testing and counseling by expanding the range of settings in which services are offered; and encouraging the adoption of policies that prevent stigma, utilize appropriate HIV testing technology, and support the uptake and availability of counseling and testing services. Programs that support HIV testing and counseling should simultaneously consider strategies for the care, support, and treatment of HIV-positive persons identified through these testing activities, by establishing functional referral systems, and the prevention needs of HIV-negative persons so identified.

According to the FY 09 COP and Mini-COP guidance, “Counseling and 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) or provider initiated counseling and testing.” For more information, please see the current COP or Mini-COP Guidance.

g. Human Resources for Health

Human resources for health (HRH) are critical for a functioning health system. Effective health systems depend on a trained and motivated health workforce that can carry out the tasks and build the systems needed to achieve PEPFAR goals. These tasks include: HRH strategy development and workforce planning; human resource information systems; pre-service and in-service training and training for task-shifting; performance assessments; retention strategies; twinning and volunteers; management and leadership development; and support for salaries.

Questions often arise regarding support for long-term training and the use of USG funds to pay salaries of staff in government facilities, or to pay salary supplements. The following guidance is pursuant to S/GAC’s “Support for Host Government Staffing: PEPFAR Guidance (8/16/06)” and the FY 2009 Country Operational Plan Guidance.

Long-term training

PEPFAR funds may be used to support long-term training of health professionals such as medical doctors, nurses, pharmacists, medical social workers; auxiliary workers or “associate professionals” such as clinical officers, assistant or general nurses, and laboratory and pharmacy technicians; advanced degrees in disciplines such as public health, public administration, epidemiology, and pharmacology.

Long-term training may be supported within certain parameters:

- For each PEPFAR country operational plan, other bilateral program, or operating unit, no more than 3.0 percent of annual HIV/AIDS budget levels or \$6,000,000 per year (whichever is less) may be used to support long-term training;
- The types of personnel eligible for long-term training are only those who are directly involved in HIV/AIDS service delivery or program management support;
- All personnel should have a requirement to serve in areas of need and to deliver HIV/AIDS services upon completion of their program; and
- A strong monitoring and evaluation component should be included in order demonstrate the linkage to improved access to quality HIV/AIDS services.

Countries are encouraged to look at innovative approaches that leverage other resources from different donors, e.g., support the proportion of training that is HIV/AIDS-specific and ask other donors to support the remainder.

Salaries

USAID *shall not* pay for salaries of permanent civil service employees on public health institution payrolls. However, HIV/AIDS funds may be used by USG program contractors or grantees to pay for time-limited contractors to carry out activities essential to HIV/AIDS program goals. In addition, NGOs may hire personnel to be placed in the Ministry or other government health facilities or in their own organizations. USAID, through its contractors, already pays for staff seconded to the Ministry of Health (MOH). USG teams and their implementing partners are urged to be cautious about paying salaries or other benefits that attract staff away from their current positions in local public and private agencies. In all cases, countries should develop a transition plan to ensure that contract staff can eventually be absorbed through sustainable long-term approaches using non-USG resources.

Payment of salary supplements, or “top-ups”, to host government employees is not permitted. However, it is permissible to pay bonuses or incentives to personnel (public or private sector) that meet performance-based criteria that are directly linked to achieving HIV/AIDS goals, e.g., working overtime to increase patient access or achieving quality performance targets above and beyond routine job requirements. Any performance-based financing scheme should first be implemented on a pilot basis and include monitoring and evaluation and reporting of results achieved as well as any broader impacts on service delivery. Successful models of performance-based health programs that can be applied to HIV/AIDS service delivery already exist in a number of countries.

In addition, there are a number of ways to motivate health care providers to stay on their jobs that do not involve financial-incentive schemes. HIV/AIDS funds may be used to support a number of these including:

- ART for health care providers and their families;
- housing support in rural areas;
- Providing basic infection-prevention supplies to reduce fear of HIV infection;
- Improving morale and empowerment through continuing education courses, supportive supervision, and in-house support groups;
- Placing a human resource professional at service facilities to plan for ART scale-up, ensure a workplace prevention program, develop a training plan, and rework job descriptions to reflect current responsibilities for HIV/AIDS service providers; and
- Establishing better linkages with community groups that provide care for HIV/AIDS patients at home.

For further information or guidance, please contact GH/OHA or see the current COP or Mini-COP guidance for PEPFAR.

h. Microbicide Research and Development for HIV/AIDS Prevention
In the Conference Report accompanying the FY 2008 Appropriations Act, Congress directed that \$45 million in GH/CS funds appropriated to USAID shall be used for

microbicides. USAID/W anticipates funding microbicide efforts through central agreements. Examples of activities include the following:

- Supporting the discovery, development, and preclinical evaluation of topical microbicides (alone and/or in combination with each other or with condoms);
- Developing and assessing acceptable formulations and modes of delivery for microbicides; bridging knowledge and applications from the chemical, pharmaceutical, physical, bioengineering, and social sciences;
- Conducting clinical studies of candidate microbicides to assess safety, effectiveness, and acceptability in reducing sexual transmission of HIV and/or other STIs in diverse populations in international and domestic settings;
- Conducting basic and applied behavioral and social science research to enhance microbicide development, testing, acceptability, and use domestically and internationally; and
- Establishing and maintaining the appropriate infrastructure (including training) needed to conduct microbicide research domestically and internationally.

Missions may be asked for advice by USAID/W on local policies (such as HIV-testing policies) and assistance in coordinating HIV/AIDS prevention, care, and treatment program activities with clinical trial activities.

i. Vaccine Research for HIV/AIDS

USAID/W funds vaccine research efforts through IAVI. USAID/W will fund research and development, including clinical trials, through central agreements. Examples of activities include: vaccine research and development including clinical trials; training of personnel in good clinical practices; preparing communities for vaccine trials; training for developing country journalists; policy efforts to encourage national governments to establish practical and effective public policies for accelerating HIV/AIDS vaccine development and testing; and policy efforts to ensure that once a vaccine is developed it is widely accessible in as short a time as possible.

Missions may be asked for advice by USAID/W on local policies and assistance in coordinating HIV/AIDS program activities with clinical trial activities.

j. Commodity Fund (CF)

Condom availability and use in most countries is inadequate, especially for those most at risk. The Commodity Fund (CF) helps fill this important gap. The fund will centrally fund condoms for HIV prevention and ensure their expedited delivery to countries. The fund is intended to increase condom availability and use by making condoms for HIV prevention free of charge to other bilateral programs, subject to resource availability and program need, as elaborated below. It is expected that these condoms will be additive to country programs in an effort to expand HIV/AIDS activities and that Missions will not swap condom provision responsibilities with other donors such that availability and use remain unchanged.

Missions in other bilateral programs can request male and female condoms for free from the CF.

Focus countries will need to budget and pay for the male and female condoms they need and will not be eligible to obtain them free of charge from the CF. Countries that submit COPs or mini-COPs are required to include male and female condoms as an activity/budget line item in their COPs. Focus countries are expected to use USAID's centralized procurement mechanism (Central Contraceptive Procurement Project, 936-3057) for all condom procurement.

If a Mission has an insufficient CF level or funding constraints and limited options for obtaining needed condoms, please consult GH/PRH/CSL. There may be some flexibility on a country-by-country basis to assist in a limited way, on an emergency basis. For focus countries, these expenses must be reimbursed to USAID/GH with GH/CS funds appropriated to the State Department.⁶ Missions should not reduce orders based on funding constraints without first corresponding GH/PRH/CSL about program needs and possible assistance.

Both focus countries and missions in other bilateral programs should follow the same ordering procedures as in prior years. Detailed ordering guidance has been sent separately to Missions.

For clarification on condoms, the HIV/AIDS budget category shall not be used for the purchase of contraceptives *for family planning only* nor used to make up for shortfalls in the FP/RH category activities or in any other program. However, within the GH/CS Account, HIV/AIDS budget category funds may be appropriately used for purchasing condoms *for HIV/AIDS prevention*.

k. Commodities

HIV/AIDS commodities (condoms, HIV test kits, and drugs) are critical for prevention, diagnosis, and treatment of opportunistic and sexually transmitted infections, including HIV/AIDS. The GH/CS Account may be used for commodity procurement for HIV/AIDS. Operating units are encouraged, if possible, to use GH/CS funds and other USAID resources to *leverage and mobilize* other donor/local resources in order to help meet the enormous needs worldwide.

⁶ This is based on language from the FY 2006 Conference Report, which specifies that, “[a]gain this year, no funding for HIV/AIDS programs in the 15 Emergency Plan for AIDS Relief ‘focus’ countries is appropriated in [this CSH] account. Funding for the ‘focus’ countries is appropriated under the heading ‘Global HIV/AIDS Initiative,’” as well as language in the FY 2008 Conference Report which reiterates that: “The Appropriations Committees intend this [GH/CS] account to clarify overall United States Federal government spending on global health programs, and in no way is the consolidated health account intended to change the authorities or implementation of global health programs.”

Please consult the most recent annual Country Operational Plan Guidance issued by S/GAC for information about the use of HIV/AIDS funds for family planning commodities.

l. Partnership for Supply Chain Management System (SCMS)

Funded by the PEPFAR, SCMS brings together 16 private sector, nongovernmental, and faith-based organizations under one contract to procure essential medicines and supplies at affordable prices; help strengthen and build reliable, secure and sustainable supply chain systems; and foster coordination of key stakeholders. The contract with the Partnership for Supply Chain Management (PSCMS) is unique, because PSCMS services and expertise are available to USG agencies, foreign governments, USG-financed contractors, grantees, and other organizations doing HIV/AIDS work. Country teams are encouraged to use PSCMS because of the efficiency of centralized procurement and its expertise in supply chain management.

PSCMS purchases antiretroviral drugs (ARVs), other essential drugs, laboratory supplies and equipment (including rapid test kits), other medical supplies, vehicles, and other equipment (e.g., audio-visual). Use of the PSCMS contract increases efficiency and reduces costs by volume purchasing and being a single point of contact for manufacturers and consumers. By leveraging the economies of scale created by USG-pooled procurement, PSCMS is currently at or below the lowest reported price for all ARVs, generic or innovator. All USG agencies should consider using the procurement services of PSCMS and phasing out other agreements for ARVs, other essential drugs, test kits and other laboratory supplies and equipment, and other commodities that lend themselves to centralized purchasing.

PSCMS provides a full range of supply chain management services, including drug forecasting, quantification, overall management, warehouse and inventory control, procurement, freight and freight forwarding, quality assurance, information systems management, and in-country technical assistance and support. Technical assistance is available regardless of who is purchasing the commodities. Other donors, such as the Global Fund, also use PSCMS.

If you have questions, please contact the USAID Supply Chain Management team, More information about PSCMS is available at <http://scms.pfscm.org/scms>. Please also see the current COP or Mini-COP guidance for PEPFAR.

m. Working Capital Fund

The HIV/AIDS Working Capital Fund (WCF) is a Congressionally-authorized account that facilitates the procurement of HIV/AIDS commodities. Funds deposited into the WCF become no-year funds and are co-mingled with other funds. This gives the agency the flexibility to shift funds within the WCF to respond to changes in country needs to ensure protection against stock-outs and to meet a other program needs.

GH/OHA/SCMS manages the WCF and it is primarily used to fund the Supply Chain Management System project and its principal contractor, the Partnership for Supply Chain Management. While the WCF is principally funded through the COP process,

field support and MARRD funds can also be deposited into the WCF. The WCF can also accept funds from other agencies and other public and private entities.

n. Adult and Pediatric Care and Treatment

According to the FY09 COP and Mini-COP Guidance:

Adult Care and Treatment comprises all facility-based and home/community-based activities for HIV-infected adults and their families (HIV-affected individuals) aimed at extending and optimizing quality of life for HIV-infected individuals from the time of diagnosis throughout the continuum of illness, through provision of clinical, psychological, social, spiritual, and prevention services. Clinical services should include antiretroviral therapy, prevention and treatment of opportunistic infections (OIs) (excluding TB), a preventative care package 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. 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. Adult Care and Treatment also includes the purchase, distribution, and management of OI drugs, excluding TB drugs.

The Office of the Global AIDS Coordinator has issued guidance on palliative care called, "HIV/AIDS Palliative Care Guidance #1 for the United States Government in Country Staff and Implementing Partners," attached as Appendix IV.

Pediatric care and treatment programs should address linkages with PMTCT, efforts to rapidly scale up early infant diagnosis through dry-blood spot/DNA PCR laboratory networks, training of healthcare workers in the provision of pediatric care and treatment, and other key aspects of pediatric care and treatment. Pediatric care and treatment programs comprise all health facility-based activities for HIV exposed and HIV-infected children (<2 years and 2-14 years) and their families (HIV-affected individuals) aimed at extending and optimizing quality of life for HIV-infected children from the time of diagnosis throughout the continuum of illness, through provision of clinical, psychological, social, spiritual and prevention services. Clinical services should include early infant diagnosis, appropriate counseling and testing for at-risk children and adolescents, antiretroviral therapy, 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. A key component of clinical services is provision of the Preventive Care Package for children. Other services – psychological, social, spiritual and prevention services – should be provided as appropriate. These services are provided within programs for orphans and vulnerable children (OVC) and clinic based partners should make linkages to OVC services and service providers to ensure the continuum of care for

these children. Pediatric Care and Treatment also includes the purchase, distribution, and management of OI drugs, excluding TB drugs. Readers are referred to Appendix IV, HIV/AIDS Preventive Care Guidance, which includes two sections, one regarding programming for adults, and the other regarding programming for children ages 0-14.

For more information, please also see the current COP or Mini-COP Guidance.

o. Injection Safety

HIV transmission in the health care setting can occur through unsafe injection practices that put both patients and providers at risk. Congress has strongly recommended that HIV/AIDS funds be used to support initiatives in the focus countries to reduce the spread of HIV in health care settings by making medical injections safe. S/GAC assigned this activity to be implemented by both the Centers for Disease Control and Prevention (CDC) and USAID. Beginning in FY 2004, through HIV/AIDS funds approved by S/GAC, USAID/W has provided central funding for medical injection safety activities. Activities include rapid assessments of current injection practices; training programs and systems to improve provider skills; improved commodity security; procurement and management of safe-injection supplies and equipment; better treatment guidelines that emphasize oral medications where appropriate; strengthened health care waste management systems, especially for sharps; improved knowledge about injection safety and advocacy to reduce inappropriate demand for injections; and the development and implementation of national injection-safety plans and policies. Where needed, Missions should consider safe-injection program elements along these lines.

p. Health Systems Strengthening

Health systems strengthening is an important foundation for ensuring sustainability of service provision and other HIV/AIDS services and interventions. HIV/AIDS programs need to be supported by systems that develop and implement sound policies, provide pharmaceuticals and laboratory services, finance health services, assure quality and efficiency of care, manage the health workforce, and provide the required information to operate effectively.

- To address weaknesses in host-country leadership and management that make HIV/AIDS services less effective and waste resources, funds may be used for broad policy reform and system wide approaches and for making management processes more transparent and accountable. Examples include improving donor coordination and strengthening local partner organizations, particularly in financial and program management, policy development and leadership.
- Where financial systems are not adequate to reveal funding deficiencies for HIV/AIDS programs, funds may be used to improve planning-unit approaches to the allocation of resources. Examples include conducting focused expenditure reviews for HIV/AIDS in order to provide policymakers with a clearer understanding of the current strengths and weaknesses of financial arrangements for priority areas.

- Where weaknesses in pharmaceutical management limit access to treatment, funds may be used to support strengthening the capacity of host government institutions to develop policies and plan, manage and implement HIV programs, including national procurement, logistics, and pharmacovigilance systems to ensure the quality, safety and rational use of medicines such that desired therapeutic outcomes are achieved.
- Where weaknesses in information limit the availability and use of reliable and timely information for evidence-based HIV/AIDS policy making and program management, funds may be used to support the collection, analysis, dissemination, and use of reliable and timely information. Examples include support to the development and use of harmonized core indicators for program planning, monitoring and evaluation; strengthening the quality of data sources, such as service records; addressing constraints to the use of information for program management; and implementing evaluations to assess the impact of program interventions.
- Where there is an inadequate number of HIV/AIDS human resources, funds may be used to support innovative recruitment and retention schemes. Examples include assessing health worker productivity and motivation.

Interventions in the following areas may also be supported with health systems strengthening funds:

- Strengthening leadership and the policy environment to reduce stigma and discrimination including addressing key gender issues;
- Support for construction and renovation, subject to the guidance contained in Chapter III.11 on Health Systems and Capacity Strengthening.
- Strengthening leadership and policy environment to expand access to HIV care and treatment services for children and documenting any positive outcomes from previous years' investments in this area (e.g., new policy or guidelines, new legislation, etc.);
- Strengthening the GFATM management structure.

For more information, please refer to the most current COP or Mini-COP guidance. Please also see Chapter III.11 on Health Systems and Capacity Strengthening.

q. Gender

PEPFAR recognizes that gender norms and inequalities help fuel the epidemic and its impact, and need to be considered in a successful response. The issues around gender and HIV/AIDS are complex, and can vary from one country to another; however, addressing these challenges successfully is critical to the achievement of PEPFAR's prevention, treatment, and care goals.

PEPFAR employs a two-pronged approach: 1) gender mainstreaming into all prevention, care, and treatment programs, and 2) programming to address five cross-cutting gender

strategic areas: Increasing gender equity in HIV/AIDS activities and services; Reducing violence and coercion; Addressing male norms and behaviors; Increasing women's legal protection; and Increasing women's access to income and productive resources.

Illustrative activities include (but are not limited to) interventions to:

- work with communities, men and women to transform traditional gender norms that perpetuate gender-based violence, sanction cross-generational and transactional sex, and promote multiple sex partners;
- address barriers to women's and men's access to quality PMTCT, counseling and testing, and care and treatment services, including adherence to treatment;
- increase couple communication and men's constructive involvement as supportive partners;
- provide counseling that considers fear of negative outcomes, such as violence, on disclosure of HIV status, and as a deterrent to testing and to accessing services;
- support family-centered care where appropriate;
- promote non-stigmatizing support networks for women infected and affected by HIV/AIDS;
- address the unequal burden of care on mothers/wives and other female household members; and
- ensure inheritance and property rights for women and access to productive resources, e.g., linking income-generation and microfinance as "wraparound" interventions with care and support activities.

Activities should include collection of sex-disaggregated data and/or build the capacity of data systems to enable collection of sex-disaggregated data. For additional guidance on activities per program area and five gender strategic areas, please see the most current COP and Mini-COP guidance. Please contact PEPFAR gender technical working group members in OHA for further information and assistance.

r. Support to the Global Fund to Fight AIDS, Tuberculosis and Malaria
The FY 2008 Appropriations Act requires that \$545.545 million in GH/CS Account funds appropriated to the Department of State be used for the Global Fund to Fight AIDS, Tuberculosis and Malaria. The U.S. Government is the largest bilateral donor to the Global Fund with more than \$3.3 billion in contributions to date. Over seven grant rounds, the Global Fund Board has approved \$10.8 billion for more than 550 grants in 136 countries. In order to ensure the most successful implementation of these grants, Mission staff should participate in Country Coordinating Mechanisms (CCMs) and work closely with Global Fund Principal Recipients (PRs) and sub-recipients (SRs) where possible. In August 2007, GH/OHA awarded a Global Fund technical assistance contract – later named Grant Management Solutions (GMS) – to Management Sciences for Health (MSH) and partners. Global Fund PRs and CCMs in almost all countries are eligible to apply for technical assistance in organizational development, program and financial management, procurement and supply management, and monitoring and evaluation. Missions also are encouraged to use their GH/CS funds to support technical assistance to Global Fund grants where appropriate. The USAID Global Fund Liaison and S/GAC's Multilateral Diplomacy staff can answer questions about Global Fund policies and

procedures as well as USAID and U.S. Government policies and procedures regarding the Global Fund.

s. Integrated Family Planning and HIV/AIDS Activities

S/GAC has issued guidance on the use of HIV/AIDS funds in integrated family planning and HIV/AIDS activities. Please consult the most recent annual Country Operational Plan Guidance issued by S/GAC for information about this subject.

3. Tuberculosis

This budget category corresponds to the element 3.1.2 Tuberculosis.

Background:

Globally, TB is one of the leading causes of death due to infectious diseases, and kills about 1.6 million people each year, primarily in the developing world. TB is a major cause of morbidity, is economically devastating to families and communities worldwide, and remains the leading cause of death among people living with HIV/AIDS in sub-Saharan Africa. USAID plays an essential global leadership role in international TB control. USAID's programs support implementation of the STOP TB strategy, building on directly observed therapy, short-course (DOTS) as the key set of interventions to reduce transmission of TB and slow the emergence of drug resistant TB.

USAID's goal is to detect at least 70 percent of estimated TB cases and to successfully treat at least 85 percent of those detected cases in USAID focus countries by 2011. By 2015, USAID's goal is to reduce by 50 percent the number of deaths due to TB in USAID focus countries. These goals are fully consistent with the STOP TB Partnership's Global Plan to STOP TB 2006 – 2015.

Allowable activities are those that contribute directly to improving the rates of case detection and treatment success. These include DOTS expansion and enhancement; engagement of all public and private providers in DOTS; improvement in the management of TB/HIV co-infection; diagnosis and treatment of multi-drug resistant (MDR) TB and extensively drug resistant (XDR) TB; care and support for people with TB (such as community participation in TB care and engagement of persons affected by TB); development of new tools; operations research to improve program performance and assess impact; monitoring and evaluation; health systems components; support for GFATM grants addressing TB; human resource development; drug and laboratory commodity management strengthening; advocacy, communication and social mobilization; and engagement of civil society in TB activities.

A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES

a. TB in Prisons

1. Assistance that is part of a larger public health initiative.

Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that these prohibitions will not apply to assistance used only for DOTS anti-tuberculosis programs in prisons for law enforcement forces, if the following conditions are met:

- a) The programs or activities in which the law enforcement personnel would participate are part of a larger public health initiative to combat tuberculosis, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the law enforcement personnel must be similar to that received by other population groups similarly situated, in terms of tuberculosis transmission risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program, can be readily adaptable for law enforcement personnel purposes.

GC has emphasized that the requirement for similar programs (b above) means similar in subject content, e.g., how tuberculosis is acquired, how it is transmitted, and how transmission can be avoided. As long as the training and materials are designed to deal with such acceptable subjects, they meet the test. It is not required that there be one uniform set of training materials appropriate for use by law enforcement personnel and also by the other groups in society, such as younger school children. Clearly the language, content, and method of delivery could and should vary depending on the audience.

The Office of the General Counsel has also advised that it would be appropriate to have particular activities that are directed only toward the law enforcement personnel as long as they are designed only to support TB prevention and combat its transmission. A conference or design workshop attended only by law enforcement personnel may be funded for the frank discussion of TB among the law enforcement personnel and how to combat it (e.g., an officer's responsibility to see that his subordinates are fully informed). Under the same anti-tuberculosis country or regional program, a conference for village health workers may well exclude law enforcement personnel as not being relevant to them. Both, however, are in pursuit of the broader goal and thus appropriate for USAID funding.

Therefore, it is appropriate and legally permissible to include law enforcement personnel in comprehensive DOTS anti-tuberculosis programs in conformance with the three legal criteria outlined above. Indeed, including those groups may well be critically important to the success of the programs. In the design and implementation of DOTS anti-

tuberculosis programs, it is also appropriate to have training sessions or materials focused specifically on individual groups as long as the activities are in pursuit of the overall program goal.

2. Notwithstanding authority.

Section 622 of the FY 2008 Appropriations Act provides USAID, when required for program efficiency, with “notwithstanding” authority for disease programs to overcome the prohibition on providing training or advice or financial support for police, prisons, or other foreign law enforcement forces found in Section 660 of the Foreign Assistance Act of 1961, as amended (FAA).

In relying on “notwithstanding” authority for DOTS anti-tuberculosis programs in prisons for law enforcement forces, operating units need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of TB activities permitted by this guidance. If an operating unit decides to rely on “notwithstanding” authority, the clearance procedures described below must be followed.

3. Clearances.

From a legal standpoint, use of GH/CS Account funds to fund DOTS anti-tuberculosis programs in prisons for law enforcement forces that is part of a larger public health initiative does not require a specific, written request or formal approval if this guidance is followed. However, operating units should be aware that as a policy matter, the approval of Bureaus or Offices in USAID/W might be required before such TB assistance is provided to the law enforcement personnel; therefore, Missions are asked to confirm procedures with their Bureaus. Regardless of whether or not formal Bureau or Office clearance is required, operating units must document the decision to include law enforcement personnel in TB activities that are part of a larger public health initiative; such documentation should show how the legal criteria discussed above have been applied and how any bureau approval procedures have been followed. If it is a close question, please contact your regional legal advisor or GC advisors.

Because relying on “notwithstanding” authority to provide assistance for a DOTS program in prisons for law enforcement forces may raise sensitive policy or legal issues, operating units must request approval from their relevant Regional Bureau Assistant Administrator, and obtain clearances from the Assistant Administrator of the Bureau for Global Health, the Assistant General Counsel for their Regional Bureau and the F IIP lead. F is responsible for tracking operating units that make use of the “notwithstanding” authority.

B. USAID GUIDANCE

Missions may use funding in the TB element to support activities in any or all of the areas described below. Missions may also support activities that strengthen TB and DOTS implementation within overall health system strengthening. USAID’s strategy

also emphasizes expanding the involvement of private providers and PVOs/NGOs in DOTS implementation.

Link to five-year plans of National TB Programs (NTPs) – NTP five-year plans that are consistent with the STOP TB Partnership Global Plan to STOP TB 2006 – 2015 and with the STOP TB Strategy should serve as the basis for planning for USAID assistance. USAID can help to develop these plans, and USAID assistance should support the priorities outlined in these plans. In implementing TB programs, it is critically important that Missions coordinate with the National TB Program in-country to identify the most important role for USAID.

Technical interventions of the STOP TB strategy – USAID programs support implementation of the STOP TB Strategy. The six key elements of the STOP TB Strategy are summarized below and are also available at the following web site:

http://www.stoptb.org/resource_center/assets/documents/The_Stop_TB_Strategy_Final.pdf

- 1) Pursue high-quality DOTS expansion and enhancement:
 - i) Political commitment with increased and sustained financing: linked to long-term strategic plans prepared by NTPs which include technical and financial requirements, promote accountability, and where appropriate, are backed up by national legislation.
 - ii) Case detection through quality-assured bacteriology:
 - (1) expansion of sputum smear microscopy;
 - (2) expansion of capacity for culture and drug susceptibility testing;
 - (3) internal and external quality assurance for laboratories;
 - (4) strengthening the performance of the laboratory network through regular training, supervision, monitoring and evaluation;
 - (5) national laboratory guidelines and standard operating procedures aligned with international guidelines, including biosafety measures;
 - (6) decentralization of diagnostic services;
 - (7) organization and management of the laboratory network, including laboratory commodities.
 - iii) Standardized treatment, with supervision and patient support:
 - (1) for all adult and pediatric TB cases (including sputum smear positive, negative, and extra-pulmonary cases);
 - (2) treatment support may be based in health facility, workplace, community, or at home;
 - (3) measures to identify and address barriers to accessing TB treatment services, such as expanded treatment outlets in poor rural and poor urban settings, addressing of gender issues, and improvement of staff attitudes;
 - (4) adherence counseling and use of enablers to promote patient adherence.
 - iv) Effective drug supply and management system:
 - (1) drug selection, product quality assurance, procurement, and distribution;
 - (2) use of fixed dose combinations, and packaging, such as patient kits to improve logistics, drug administration, and adherence.
 - v) Monitoring and evaluation systems, and impact measurement:
 - (1) standardized recording of patient data;

- (2) training staff in the analysis and interpretation of data, as well as the use of electronic recording systems, to improve data quality and data sharing between peripheral and central TB levels.
- 2) Address TB/HIV, MDR-TB, XDR-TB, and other challenges:
- i) Implement collaborative TB/HIV activities, such as:
 - (1) creation of national joint TB/HIV coordinating body
 - (2) development and implementation of a joint national plan, policies and guidelines
 - (3) HIV testing of TB patients
 - (4) HIV surveillance among TB patients
 - (5) monitoring and evaluation of TB/HIV activities
 - (6) referral system between HIV and TB services
 - (7) infection control measures in health care and congregate settings
 - (8) provision of co-trimoxazole preventive therapy to TB patients with HIV infection
 - ii) Prevent and control multi-drug resistant TB (MDR) and extensively resistant (XDR) TB:
 - (1) needs assessment to determine capacity of TB program to manage drug-resistant TB
 - (2) assurance of quality-assured first- and/or second-line anti-TB drugs
 - (3) measures to promote adherence to treatment by patients and to its proper provision by health care providers
 - (4) infection control measures in health care and congregate settings
 - (5) expanded culture and drug sensitivity testing
 - (6) drug resistance surveys
 - (7) development and implementation of MDR and XDR guidelines, treatment regimens, and policies
 - iii) Address prisoners, refugees, and other high-risk groups and special situations, including:
 - (1) Identifying risk groups, such as displaced people, orphaned and homeless, ethnic minorities, marginalized groups, substance abuse victims, victims of unexpected population movements due to political unrest, war, natural disasters
 - (2) Assessing problems faced and defining strategies to ensure access to high-quality TB services
- 3) Contribute to health system strengthening
- i) efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems
 - ii) human resource development for TB control – pre-service and in-service training; curriculum development and training materials; and human resource information to track deployment, rotation, and trained staff; and institutional capacity building to strengthen national or sub-regional training institutions
 - iii) application of innovations that strengthen TB control, including the Practical Approach to Lung Health
 - iv) adaptation of innovations from other fields (e.g., primary care outreach in MCH programs, social mobilization, use of regulatory actions, financing initiatives to reach the poorest, cooperation with broader information platforms and surveys)

- 4) Engage all care providers (including informal and formal providers, including public sector health providers outside of the MOH, nongovernmental and private providers such as village doctors, drug sellers, private medical providers, health insurance organizations, general and private hospitals):
 - i) piloting and scaling up approaches based on public-public and public-private mix (PPM)
 - ii) support for implementation of the International Standards of TB Care to enhance support for TB control efforts, including among professional medical and nursing organizations and academic institutions

- 5) Empower people with TB and affected communities:
 - i) advocacy, communication and social mobilization to increase support and demand for TB services
 - ii) community participation in TB care
 - iii) patient's charter for TB care

- 6) Enable and promote research:
 - i) operational research to assess and/or improve program performance and delivery of TB services
 - ii) development and dissemination of tools (such as improved laboratory techniques or improved treatment regimens)
 - iii) development of new drugs, diagnostics, and vaccines

In addition to supporting implementation of the STOP TB Strategy described above, funding in the TB element may be used to provide technical assistance to ensure the success of Global Fund to Fight AIDS, TB and Malaria (GFATM) TB grants, including:

- development of quality proposals to the GFATM;
- building technical, administrative and organizational capacity of Country Coordinating Mechanisms and Principal Recipients; and
- development of implementation, procurement, supply management, and monitoring and evaluation plans for GFATM grants.

4. Malaria

This budget category corresponds to the element 3.1.3 Malaria.

A. USAID GUIDANCE

USAID's malaria prevention program is designed to improve malaria prevention, control, and treatment.

The December 23, 2005 executive message from the Administrator on the President's Malaria Initiative defined the rules and requirements for all allocations and for the use of all USAID malaria funding – for programs that are directly part of the President's Malaria Initiative (PMI) as well as those outside of the PMI. These rules and requirements are significantly different from those in the past. This notice in its entirety

is included in Appendix VI. The notice has been incorporated into the ADS and the provisions continue to apply to FY 2008 funds for malaria. The following summarizes the elements in the notice related to budgeting and funding:

1. The Agency's Malaria Coordinator will:
 - Approve all malaria allocations and malaria staffing
 - Approve all malaria-related acquisition and assistance plans
2. In FY 2006, 40 percent of USAID's non-directed malaria funding was designated for commodities, and 25 percent was designated for indoor residual spraying (IRS). The FY 2006 allocations for malaria for each Mission and operating unit included directives for commodities and IRS. Missions and other operating units are required to meet these marks.
3. Budgets were set centrally by F following recommendations of the Malaria Coordinator. Approval from the Malaria Coordinator is required for any change in budgets or to shift funding between sub-elements.
4. No country malaria program or regionally-managed country program will be funded at less than \$1.5 million annually. This has been addressed in the FY 2006 country and regional program allocation.
5. All operating units are required to submit reports as requested to the new malaria data management system. To meet Congressional reporting requirements for FY 2006, Missions will also be required to respond to queries every 90 days on allocations of FY 2006 malaria funding.
6. For PMI countries, the PMI website, www.fightingmalaria.gov, will include all procurement documents funded under the PMI. GH is responsible for managing this process, but PMI countries are required to submit all procurement documents (after redaction by the contractor/grantee).
7. No Agency malaria funds are allowed to fund non-malaria activities, including cross-cutting programs or initiatives, "taxes" to cover non-malaria costs or common costs, or any other mechanism, regardless of past practice, without the express consent of the Malaria Coordinator.⁷
8. In substance, interventions that malaria funds may be used for include:
 - Prevention of malaria including increased access to and use of insecticide-treated bednets and indoor residual spraying;

⁷ This would not preclude the use of malaria funds for common costs or cross-cutting programs allowable under Objective 6 (See Section III. 13).

- Improved use of effective drugs for treatment of malaria, reduction of the emergence and spread of drug resistant strains, and improved recognition, diagnosis and treatment of malaria;
- Improved prevention and management of malaria in pregnancy through the scale-up of intermittent preventive treatment; and
- Some limited research and development of new approaches/technologies for preventing, diagnosing and treating malaria.

5. Avian Influenza

This budget category corresponds to the element 3.1.4 Avian Influenza.

A. USAID GUIDANCE

In an Executive Message dated September 26, 2005, attached as Appendix VII, the USAID Administrator announced that crafting an effective response to avian influenza (AI) was a priority for all Missions and posts worldwide, given the health and development ramifications of H5N1 AI outbreaks and its potential to spark a human influenza pandemic. USAID is an essential partner in a cross-USG effort to combat AI. A multi-sector AI Unit, housed in GH, coordinates all USAID AI planning, budgeting, and programming. The AI Unit serves as USAID's central coordinating body for all USAID supported activities and as the primary management unit coordinating all operational field activities with those of other USG departments and agencies as outlined in the U.S. *National Strategy for Pandemic Influenza: Implementation Plan*. In addressing AI, USAID operating units are asked to be flexible and prepared to respond to sudden priority shifts within countries if/when outbreaks occur in either animal or human populations. Operating units are also asked to work within existing central mechanisms to respond to dynamic and highly fluid circumstances that surround the spread of AI as much as possible. USAID's primary programmatic focus for AI is to limit the potential for the emergence of a human influenza pandemic by containing the virus in animals, limiting human exposure to infected animals, minimizing the number of human AI cases, and ensuring adequate and appropriate response to a pandemic should it occur. To accomplish these objectives USAID's AI activities focus on five key areas: planning and preparedness, animal and human surveillance, animal and human response, behavior change communication and messaging for increased public awareness, and stockpiling of essential commodities.

The following summarizes the elements in the Agency notice dated November 3, 2005, attached as Appendix VIII, related to budgeting and funding. This notice has been incorporated into the ADS and applies to FY 2008 funding as well:

1. All AI allocations and all AI-related implementation plans must be reviewed and approved by the Deputy Director of the AI Unit.
2. In the FY 2006 Supplemental Appropriations Act, \$161 million was appropriated for AI: \$75.3 million of CSH funds for programmatic activities, and \$56 million of

international disaster and famine assistance (IDFA) funds designated for international and regional stockpiling of essential commodities (personal protective equipment, disinfectant, sprayers, etc). The FY 2007 Supplemental Appropriations Act included \$161 million in CSH funds for AI. The FY 2008 Appropriation included \$115 million for AI. All funding is notified by GH/HIDN-AI.

3. The use of Agency funds to purchase antivirals or human influenza vaccines (including Tamiflu, the brand name, FDA-approved antiviral medication produced by Roche) is prohibited, pursuant to the General Notice issued by the Administrator, "Interim Budgetary Guidance for Reprogramming of Funds for Urgent Avian Influenza Related Activities," dated November 3, 2005, and attached as Appendix VIII.
4. Missions are allowed and encouraged to be creative and to consider existing platforms, including central mechanisms as much as possible, for AI efforts. Missions are allowed to reprogram funds for AI related activities, but this should only be done after careful discussions with the Regional Bureau and the AI Unit⁸. Reprogramming efforts (the funding of AI activities with non-CD/AI funds) must first be approved by the AI Unit for technical merit as well as budgetary compliance. Missions should submit requests to the AI Unit through regional bureau AI points of contact. The AI Unit will consider the request and make a determination based on the technical merit of the activity, availability of funds within existing statutes and earmarks, and the activity's appropriateness given the level of threat in the country. Final approval for reprogramming rests with the Director of Foreign Assistance, within the approved reprogramming guidelines. Missions and regions will not be reimbursed for reprogrammed funds.
5. All operating units are required to submit reports on the status of AI activities to meet Congressional reporting requirements. Per AI Unit guidance, Missions will also be required to respond to queries on obligations and expenditures of AI funds. The data collection will be conducted through the Avian Influenza Monitoring and Evaluation and Budget Analysis (AIMEBA) database. All operating units are also required to provide activity tracking codes for all approved activities. These codes are available in AIMEBA.
6. No Agency AI funds are allowed to fund non-AI activities, including cross-cutting programs or initiatives, "taxes" to cover non-AI costs or common costs, or any other mechanism, regardless of past practice, without consent of the AI Unit.⁹
7. In substance, AI interventions include:
 - Planning and Preparedness, including establishing and strengthening in-country working groups, and designing/updating and testing national multi-sector AI and pandemic plans;
 - Animal and Human Surveillance, including enhancing in-country laboratory capacity, linking animal and human surveillance activities, strengthening regular

⁸ For FY 07 and FY 08, F clearance is required to move funds into or out of any health or education element.

⁹ This would not preclude the use of AI funds for common costs or cross-cutting programs allowable under Objective 6 (See Section III. 13).

monitoring for AI and reporting of suspected outbreaks/cases, strengthening information channels and reporting pathways, supporting early-warning networks, tracking the movement of AI in birds, and identifying key risk factors for disease transmission;

- Animal and Human Response, including establishing, training and supporting rapid response teams for animal and human outbreaks; providing support for collection and transport of samples to laboratories; increasing access to appropriate diagnostic capacity; assisting with implementation of appropriate containment measures during outbreaks; promoting safe culling and disposal procedures and improved bio-security practices in outbreak settings; and deploying and distributing essential commodities;
- Communications and messaging, including mobilizing communication networks, designing AI-specific communication strategies, conducting research on key populations and practices for improved and targeted outreach, broadcasting AI awareness and behavior change messages, and ensuring quality and coordinated messages are being released; and
- Stockpiling of essential commodities, including determining and procuring essential commodities, deployment strategies, establishing release triggers for mobilizing deployment of stockpiled commodities, and stockpile replenishment.

On May 3, 2006, the Administrator approved an Action Memorandum entitled "Expedited Acquisition and Assistance Procedures for Activities and Programs Related to USAID's Avian Influenza Pandemic Emergency Preparedness and Response Efforts," dated April 27, 2006. The Action Memorandum was extended for 12 months until May 3, 2008. M/OAA has promulgated AAPD 06-06 to disseminate and implement the Action Memorandum.

The original approved recommendations and associated determinations and findings related to this AAPD provided for:

- 1) One-year Authorization to Initiate Activities prior to Completion and Approval of a Strategic Plan. The waiver of the (ADS 201.3.4.5) requirement that obligations always be covered by an existing approved strategic objective is no longer required because all of AI's strategic objectives are already in place under the Foreign Assistance Strategic Framework.
- 2) Grants and Cooperative Agreements—Authorization for Other than Fully Competitive Procedures. This was included in the extension.
- 3) Procurement of Goods and Services—Authorization for Other Than Full and Open Competition. This was included in the extension.
- 4) Source, Origin, and Nationality Blanket Waiver for Goods and Services, including Vehicles and Pharmaceuticals. This was included in the extension.

6. Other Public Health Threats

This budget category corresponds to the element 3.1.5 Other Public Health Threats (OPHT).

A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES

Earmarks and Directives: The FY 2008 Appropriations Act contains a \$15-million earmark for neglected tropical diseases (NTDs). This funding has been centrally allocated within the Global Health Bureau budget. The earmark for NTDs mandates an integrated approach to the management of NTDs that can be controlled through mass drug administration. Missions with overlapping NTD disease burdens (i.e., at least 3 diseases) that want to support the integration of mass drug administration may buy into the NTD control project managed by Research Triangle Institute. Otherwise, funds to support the control of any NTDs are appropriately planned under this element but will not count toward the congressional earmark.

B. USAID GUIDANCE

The Other Public Health Threats (OPHT) element provides an umbrella for activities targeting several key areas in the prevention and management of infectious diseases. Specifically, this element supports activities that address neglected tropical diseases (NTDs) and other infectious diseases that are not captured elsewhere in the framework (e.g., dengue, cholera, Japanese encephalitis, leprosy). This element also supports critical cross-cutting work related to the containment of anti-microbial resistance (AMR), surveillance, and epidemiology. This element is not designed to absorb entire budgets for health systems strengthening activities. Funding for health systems strengthening activities should be attributed across the elements, including but not exclusively OPHT.

Other Public Health Threats funding may be used to support the following areas of work:

- a. Neglected tropical diseases and other infectious diseases of major public health importance

Missions may use OPHT funds to address other infectious disease issues, provided they are of significant public health importance for the country, and there is a clear role for USAID. This includes activities that control and reduce the burden of neglected tropical diseases (e.g., onchocerciasis, schistosomiasis, soil-transmitted helminthes, lymphatic filariasis, trachoma, etc.) and other infectious diseases of public health importance (e.g., Japanese encephalitis, dengue hemorrhagic fever, etc.), including effective and wide-scale drug treatment and other proven interventions. On February 20, 2008, President Bush announced a five-year, \$350 million initiative to provide integrated treatment to control and eliminate the burden of neglected tropical diseases in Africa, Asia, and Latin America. The Presidential Initiative will target the following seven neglected tropical diseases through mass drug administration: lymphatic filariasis (elephantiasis); schistosomiasis (snail fever); trachoma (eye infection); onchocerciasis (river blindness); and three soil-transmitted helminthes (hookworm, roundworm, and whipworm).

- b. Antimicrobial Resistance (AMR) Containment

Activities funded under the directive for reducing antimicrobial resistance, may include (but are not limited to):

- interventions designed to “preserve the effectiveness of currently available antimicrobials,” including educational activities such as formal and continuing

education (pre- and in-service training, seminars and workshops for health professionals);

- curricular development involving concepts of AMR and rational use of antimicrobials;
- development of printed and other media-based materials (clinical literature, newsletters, radio and TV spots, flyers, videos) and face-to-face approaches for practitioner and public awareness on appropriate treatment-seeking behavior, self-medication and adherence to recommended therapy;
- other behavior change and communication strategies;
- establishment of drug information centers to provide accurate, up-to-date and unbiased drug information/materials;
- support for global and regional AMR advocacy and containment networks and country-level approaches;
- managerial activities involving the design and implementation of standard tools to promote rational medicine selection, procurement and use such as formularies, pharmacoconomics, limited procurement lists, standard diagnostic and treatment guidelines, and drug utilization reviews;
- promotion of proven approaches to facilitate effective uptake of new treatment technologies and practices;
- Drugs and Therapeutics Committees;
- infection control programs;
- efforts to develop pharmaceutical management capacity and appropriate financing and incentive schemes for improved access to and use of medicines; and
- regulatory activities such as strengthening regulatory authority capacity, quality control laboratories and quality assurance mechanisms such as drug registration and surveillance systems to detect counterfeit and substandard medicines.

AMR containment activities specific to disease control areas highlighted elsewhere in the framework (e.g., TB, malaria, avian influenza, HIV/AIDS) should be included in their respective elements, not within the OPHT element.

c. Surveillance

Surveillance and Collection and use of health information to respond to endemic and epidemic infectious diseases:

Activities funding under the directive for surveillance and response may include (but are not limited to):

- Strengthening epidemiological surveillance and response capacity by improving collaborating partnerships;
- Improve the use of surveillance and health data to respond to disease threats and improve programs;
- Expanding capacity building including training and improved laboratory capacity, including performance in diagnostic techniques for new and re-emerging pathogens; and

- Development and use of improved tools, including rapid diagnostics, policy tools, data gathering tools, and strengthened field epidemiology capacity and the understanding of disease patterns and trends.

Surveillance activities need not be limited to antimicrobial resistance, tuberculosis, or malaria, and are encouraged to cover a wider range of infectious disease or public health surveillance issues. However, surveillance activities specific to disease control areas highlighted elsewhere in the framework (e.g., TB, malaria, avian influenza, HIV/AIDS) should be included in their respective elements, not within the OPHT element.

- d. Non-communicable public health threats
GH/CS funds may not be used for non-communicable public health threats.

7. Maternal and Child Health

This budget category corresponds to the element 3.1.6 Maternal and Child Health.

A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES

Earmarks and Directives: In the FY 2008 Appropriations Act and the accompanying Conference, House, and Senate Reports, Congress has established specific funding levels for the GAVI Fund, polio, micronutrients, and iodine deficiency disorder. For further guidance on recommended uses of the funds within each of these directives, please see Chapter III.7.B immediately below.

B. USAID GUIDANCE

- a. Allowable Uses of Funds for Maternal Health

Allowable activities using funds for maternal health include those that contribute directly to the element 3.1.6 Maternal and Child Health. Specifically, maternal health and survival activities are primarily directed to adolescent girls and women of reproductive age and are centered on eight related areas:

- *Increasing access to and use of quality maternal and reproductive health interventions at community, family, and individual levels*, through educational preparation for childbearing; encouraging healthy behaviors and access to related health services; and modification of services to become more available, culturally appropriate, and effective.
- *Improving maternal nutritional status throughout the reproductive life-cycle* through nutrition education and appropriate micronutrient interventions, including iron folate and vitamin A supplementation, and other communications interventions to improve variety and amount of food consumption.
- *Strengthening preparation for birth*, including antenatal care; planning for a clean and safe delivery attended by a skilled, professional attendant; preventing, detecting, and treating infections including tetanus, intestinal parasites, syphilis, malaria,

HIV/sexually transmitted infections (STIs), and others; recognition and treatment of complications; and planning for transport.

- *Promoting safe delivery and postpartum care*, including use of the partogram, clean delivery, active management of the third stage of labor, and elimination of harmful practices; recognition, referral, and treatment of maternal and newborn complications; postpartum and neonatal care that includes identification and treatment of complications; and postpartum and neonatal preventive care, including counseling on proper rest, nutrition, breastfeeding, hygiene, and child spacing. (Child spacing is limited, as in the past, to those activities in which child spacing efforts are conducted as a part of a larger maternal health and child survival effort with the objective of improving maternal health and reducing infant and child mortality; no contraceptives may be purchased with MCH funds—see below).
- *Improving management and treatment of life-threatening obstetrical complications* including providing information to family and community members on complications of pregnancy and provision of obstetric first aid; communication and emergency transport; and timely, high quality care for obstetric and newborn complications by skilled, professional providers.
- *Providing care for women who suffer from long term disability as a result of pregnancy and birth*, including repair and rehabilitation of obstetric fistula and treatment of anemia. Activities for preventing and repairing fistula may include: 1) repair, 2) prevention, 3) reintegration, and 4) monitoring and evaluation and research. The fistula program should be funded with a combination of funds from both the MCH and FP elements. A typical distribution of funds within a comprehensive fistula program would include 70 percent of funding from the 3.1.6 Maternal and Child Health element and 30 percent of funding from the 3.1.7 Family Planning and Reproductive Health element. FP funds should be focused on community-based prevention and post-repair counseling, while MCH funds should focus on obstetric prevention and repairs. Activities to prevent the occurrence of fistula may include supporting family planning to prevent unintended pregnancies, delaying marriage and first birth, and increasing community awareness of danger signs in pregnancy and delivery.
- *Improving long-term capacity and systems of local institutions to provide quality maternal health care*, including diagnostic assessments; improved health policies; standard treatment guidelines; use of data for decision-making processes; quantification, costing, and rational management of commodities and services; sustainable maternal health financing arrangements such as prepayment schemes, franchising, insurance and targeted subsidies; improved capacity and use of health sector personnel and financial resources; and enhanced monitoring, evaluation, and quality improvement systems.
- *Improving Gender Relationships*: Interventions to transform traditional gender norms that limit women and men’s access to maternal health information and services,

including community mobilization and behavior-change interventions seeking to improve couple communication and increase constructive male involvement in maternal health counseling and decision-making, and to prevent or mitigate gender-based violence as related to maternal health and to give women a greater role in care and care-seeking for themselves and their newborns.

b. Allowable Uses of Funds for Child Survival

Allowable activities for this category are those that make a direct impact on improving infant/child health and nutrition and reducing infant/child mortality. Specific interventions include the following:

Expanding access to and use of key child health interventions that primarily focus on the prevention, treatment, and control of primary childhood diseases, such as diarrhea, acute respiratory disease, malnutrition, malaria (in general, malaria-related activities are supported with malaria funding), vaccine-preventable diseases, and diseases and conditions affecting the newborn. Interventions directed toward these areas are the core of USAID's child survival program.

Enhancing the quality, availability, and sustainability of key child health interventions through activities that improve planning, organization, and management of health systems and services; increase promotion and delivery of key interventions by communities; build in-country capacity; promote private sector service delivery; improve the use of health sector financial resources; enhance the availability and appropriate use of health commodities; and promote positive health policies.

Addressing child malnutrition and improving nutritional status through promotion of general child nutrition via nutrition policy improvement; support and promotion of breastfeeding; growth monitoring and promotion; young child nutrition; community therapeutic care; and prevention of nutritional deficiencies in children, especially through delivery of micronutrients.

Developing, testing, and replicating priority environmental health interventions to prevent the spread of childhood disease due to environmental factors, such as improving household-level water supply and sanitation, promoting good hygiene behavior, and controlling vector-borne diseases that represent important threats to children's survival, health, or nutrition.

c. Special Considerations for Maternal and Child Health: Other Funding Considerations

i. Polio Eradication Activities

In the Conference Report accompanying the FY 2008 Appropriations Act, Congress recommended that \$32 million in USAID Child Survival and Maternal Health funds be used for polio; the 653(a) agreement reflects this recommendation. USAID has joined

forces with other international, bilateral, and national efforts to eradicate polio. Intensive efforts are underway to interrupt virus transmission in endemic countries, maintain immunity in polio-free areas, and establish or maintain certification-standard surveillance in all countries. Polio directive funds must be used to directly support polio eradication activities, the primary purpose of the funding. In addition, a governing principle of USAID's polio strategy is to contribute to the eradication of polio in a way that strengthens health systems, particularly for the delivery of polio vaccines. Accordingly, polio directive funds may be used to support the following polio eradication interventions:

- Developing effective partnerships to support polio eradication and vaccination (e.g., interagency coordinating committees; nongovernmental organization (NGO) participation);
- Strengthening immunization delivery systems as a secondary impact of investments in polio eradication (e.g., cold chain, communications, supervision);
- Improving timely planning, implementation and monitoring of supplemental polio immunizations (e.g. micro-planning, training, independent monitors);
- Improving acute flaccid paralysis surveillance and response (e.g., facility and community-based surveillance and laboratory diagnosis, Expert Review Committees);
- Supporting certification, containment, and post-certification policy development; and
- Improving timely dissemination and use of information to continuously improve the quality of polio eradication activities.

Missions should contact the USAID Polio Eradication Coordinator to jointly determine how best to program polio funds to assure specific activities are allowable under the directive and to maximize the impact of these funds towards achieving the polio eradication goals.

ii. Micronutrient Activities

In the House and Senate Reports accompanying the FY 2008 Appropriations Act, Congress recommends that \$30 million in USAID Child Survival and Maternal Health funds be used for micronutrients. The Conference Report provides \$20 million for vitamin A deficiency. Reducing child and maternal morbidity and mortality can be achieved through improved micronutrient status. Interventions that may be funded with the micronutrient directive funds include food supplementation, fortification, and dietary improvement. Expanded delivery of vitamin A is central to USAID's micronutrient strategy because of its demonstrated cost effectiveness, relative to other proven child survival interventions, to reduce illness and deaths due to measles, diarrhea, and other common childhood infections. In countries or regional areas where vitamin A deficiency is prevalent, operating units are strongly encouraged to incorporate vitamin A capsule delivery as a key element of their child survival programs. Other important micronutrient interventions are those that address iron, zinc, and iodine deficiencies. Micronutrient activities may be linked to and integrated within other nutrition, health, and agricultural activities, but the focus should be on *direct measurable (and reportable) impact* on specific micronutrient deficiencies. Micronutrient funds may be used for breastfeeding and similar child nutrition activities to the extent that the impact of these activities on

reducing micronutrient deficiencies is clear. Generally, no more than 20 percent of these integrated programs should be supported from micronutrient funds.

iii. GAVI

In the FY 2008 Appropriations Act, Congress directed that \$72.5 million in USAID Child Survival and Maternal Health funds should be used for the GAVI Fund. Funds for GAVI are managed by the Bureau of Global Health through a pooled funding mechanism which purchases vaccines and provides funding to countries to support immunization and health system strengthening.

iv. Prohibition on Purchase of Contraceptives

USAID Child Survival and Maternal Health funds should not be used for the purchase of contraceptives, including condoms, nor used to make up for shortfalls in FP/RH funding or in any other program. Child spacing activities are limited to those education and service activities in which child spacing efforts are conducted as part of a larger maternal health and child survival effort with the objective of improving maternal health and reducing infant and child mortality. Programs designed to provide contraceptives for integrated Child Survival / Family Planning / Reproductive Health programs should use FP/RH funds for those appropriate portions of their programs. Language from the FY 2002 House Report clearly defines the parameters of use for CS/MH funds and FP/RH funds (see Appendix I).

v. Child Survival Grant Program

Allowable uses of Child Survival/Maternal Health directive funds include the Child Survival Grants Program, which is intended to enhance the participation of private voluntary organizations (PVOs) in implementing programs related to all of the health-related elements and to strengthen their organizational, managerial, and technical competencies in these areas. Though centrally administered, Missions have the opportunity for input during the review of all U.S. PVO applications submitted to GH for funding. GH is responsible for programming and reporting these activities.

8. Family Planning and Reproductive Health (FP/RH)

This budget category corresponds to the element 3.1.7 Family Planning and Reproductive Health.

Background

USAID is a leader among international donors in creating and sustaining the conditions necessary for individuals to access safe, voluntary, and high quality family planning information and services. Consensus-based agreements negotiated at international conferences have highlighted the strong linkages among women's position in society, small family size, and women and children's health and well-being. As these agreements reaffirmed, family planning is a key component of reproductive health care.

Family planning represents the core of USAID's FP/RH program and the primary use of FP/RH funds. A family planning program should serve the objective of creating the necessary conditions for women and men to have the number and spacing of children that they desire. Such a program must be free of coercion of any kind and should offer assistance appropriate to low resource settings to help individuals and couples attain their ideal family size.

Key family planning and reproductive health outcomes for FP/RH funds include, but are not limited to: correct, voluntary use of contraceptive methods; healthy spacing of births; reduction of unmet need and total fertility rate; increased age at sexual debut and age at birth of first child; and prevention of abortion as a method of fertility regulation.

Allowable activities for this category are those that make a direct measurable impact in the reduction of unintended pregnancies and contribute to the optimal use of funds. Direct impact means the activity directly reduces unplanned pregnancies and other risks to reproductive health, while maintaining family planning as the core focus. Optimal use of funds means the activity is the most effective, cost- and program-efficient way to reach significant, critical populations with FP/RH information and services and reflects USAID's comparative advantages within the local context. Programs in family planning and reproductive health will: expand access to high-quality, voluntary, family planning services and information; expand access to reproductive health care to reduce unintended pregnancy; promote healthy reproductive behaviors of men and women; reduce abortion; and reduce maternal and child mortality and morbidity, as noted in the Joint State/USAID Strategic Plan. Operating units are strongly encouraged to review applicable legislation and Agency guidelines before programming this program element.

Innovations to promote family planning information and services as part of a broader package of reproductive health care are crucial to fulfilling USAID's continuing commitment to reproductive health, and are encouraged. However, due to the integrated nature of some FP/RH programs, questions often arise about the requirements of joint funding from other program elements within the health program area or from other program areas or accounts. Please see Chapter III.14 on Co-Programming.

A. LEGAL REQUIREMENTS, POLICY REQUIREMENTS, AND CONGRESSIONAL DIRECTIVES

a. Authority

USAID's FP/RH Program is authorized by the Foreign Assistance Act (FAA) of 1961, as amended.¹⁰ Restrictions on the use of FP/RH funds for FP/RH-related activities are clearly outlined in current legislation and policy, and continue to govern programming within the family planning/reproductive health element.

b. Legislative Requirements on the Use of FP/RH Funds

USAID supports the freedom of individuals to choose voluntarily the number and spacing of their children through family planning. Since its inception, USAID's FP/RH program has helped effect the conditions that make it possible for individuals to exercise this fundamental freedom. USAID places highest priority on ensuring that its FP/RH activities adhere to the principles of free choice in deciding whether and how to practice family planning ("*voluntarism*") and *informed choice*. The Agency considers an individual's decision to use a specific method of family planning or to use any method of family planning as being *voluntary* if it is based upon the exercise of free choice and is not obtained by any special inducements or any element of force, fraud, deceit, duress or other forms of coercion or misrepresentation. USAID defines *informed choice* to include effective access to information on family planning choices and to the counseling, services, and supplies needed to help individuals choose to obtain or decline services, to seek, obtain, and follow up on a referral, or simply to consider the matter further.

Through legislated requirements, presidential policy, and its own policies and practices, USAID has taken special measures to protect individuals against potential abuses and coercion in family planning programs. References to each of these legislative and policy requirements are included in a chart entitled: "USAID Family Planning Requirements," attached as Appendix IX. The following legislative and policy requirements are also generally reflected in the standard provisions of USAID awards for family planning. See ADS 303 for the latest provisions for assistance awards and CIB 99-06 for the latest provisions for contracts.

- *Tiahrt*: The principles of voluntarism and informed choice are codified in the Tiahrt Amendment, which requires that USAID-assisted family planning projects meet certain standards of voluntarism. The Tiahrt Amendment was first included in the FY 1999 Appropriations Act, and has been included each year thereafter. Under the Tiahrt Amendment, voluntary family planning projects receiving

¹⁰ Section 104 (b) of the FAA of 1961, as amended, states that "In order to increase the opportunities and motivation for family planning and to reduce the rate of population growth, the President is authorized to furnish assistance, on such terms and conditions as he may determine, for voluntary population planning. In addition to the provision of family planning information and services, including also information and services which relate to and support natural family planning methods, and the conduct of directly relevant demographic research, population planning programs shall emphasize motivation for small families."

family planning assistance from USAID (including in the form of funds, commodities, technical assistance, or training) must meet five requirements:

- Service providers or referral agents in the project must not implement or be subject to targets or quotas of number of births, number family planning “acceptors,” or “acceptors” of specific family planning methods.
 - The project must not pay incentives, bribes, gratuities, or financial rewards to (1) individuals in exchange for becoming a family planning “acceptor,” or (2) program personnel for achieving family planning targets.
 - The project must not deny any right or benefit, including the right of access to participate in any program of general welfare or the right of access to health care, because an individual decides not to accept family planning services.
 - Projects must provide comprehensible information to “acceptors” about the health benefits and risks, inadvisabilities, and adverse side effects of the family planning method chosen.
 - Experimental contraceptives can only be provided in the context of a scientific study in which participants are advised of potential risks and benefits.
- *DeConcini Amendment:* Family planning funds may only be available to voluntary family planning projects which offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services.
 - *Livingston-Obey Amendment:* In awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant’s religious or conscientious commitment to offer only natural family planning, and all applicants must comply with the aforementioned DeConcini Amendment and Tiahrt Amendment.
 - *Helms Amendment:* USAID funds may not be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. Under the Leahy Amendment, the term “motivate,” as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
 - *Biden Amendment:* USAID funds may not be used to pay for any biomedical research that relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. Epidemiological or descriptive research to assess the incidence, extent or consequences of abortions is not covered by the amendment and is therefore permitted.

- *Kemp-Kasten Amendment*: USAID funds may not be made available to any organization or program that, as determined by the President of the United States,¹¹ supports or participates in the management of a program of coercive abortion or involuntary sterilization. The FY 2008 Appropriations Act provides that a determination made under the Kemp-Kasten Amendment must be made no later than six months after the date of enactment of the Appropriations Act, and must be accompanied by a comprehensive analysis as well as the complete evidence and criteria utilized to make the determination.
- *Siljander Amendment*: USAID funds may not be used to lobby for or against abortion.
- *Additional provision relating to voluntary sterilization*: USAID funds may not be used to pay for the performance of involuntary sterilizations as a method of family planning, or to coerce or provide any financial incentive to any person to undergo sterilization.

c. Policy Requirements on the Use of FP/RH Funds

- *Mexico City Policy*: On January 22, 2001, President Bush restored the Mexico City Policy that had been in place from 1985-1993. The Mexico City Policy requires foreign non-governmental organizations (FNGOs) to certify that they will not perform or actively promote abortion as a method of family planning as a condition for receiving USAID assistance for family planning. The Mexico City Policy applies to FNGO's funds from all sources (See CIB 01-08 (R), Restoration of the Mexico City Policy, White House Memorandum for the Acting Administrator of the U.S. Agency For International Development, 03/28/01, (REVISED 03/29/01), http://www.usaid.gov/business/business_opportunities/cib/pdf/cib0108r.pdf)

In August of 2003, the President extended this policy to “voluntary population planning” assistance provided by the Department of State. The President’s memorandum excludes from the Mexico City Policy “foreign assistance furnished pursuant to the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003.” The President’s memorandum may be viewed at: <http://www.whitehouse.gov/news/releases/2003/08/print/20030829-3.html>. Therefore, assistance only for HIV/AIDS activities is not subject to the Mexico City Policy.

In an integrated program that includes both HIV/AIDS activities and voluntary family planning activities, any partner that receives U.S. Government funding for both purposes must comply with the respective requirements applicable to each activity; this may include, in the case of a foreign non-governmental organization,

¹¹ This authority has been delegated to the Secretary of State and the USAID Administrator.

the Mexico City Policy. However, in an integrated program, different organizations may be responsible for different types of activities, as not all organizations will necessarily do both voluntary family planning and HIV/AIDS activities. Any partner that does not receive funds for family planning activities is thus not subject to the Mexico City Policy.

- *Post-abortion Care*: USAID FP/RH funds may be used to support post-abortion care activities, regardless of whether the abortion was legally or illegally obtained. The press release accompanying President Bush's Memorandum of January 22, 2001 restoring the Mexico City Policy stated that "[t]he President's clear intention is that any restrictions do not limit organizations from treating injuries or illnesses caused by legal or illegal abortions, for example, post-abortion care" (available at <http://www.whitehouse.gov/news/releases/20010123.html>). However, no USAID funds may be used to purchase or distribute manual vacuum aspiration (MVA) kits for any purpose. Foreign NGOs may also perform and promote post-abortion care without affecting their eligibility to receive USAID assistance for family planning/reproductive health.
- *Policy Determination-3 (PD-3)*: In 1982, USAID issued a policy paper on population assistance, which clearly states its commitment to voluntarism in the provision of family planning services. The Population Policy of 1982, in Annex PD-3, includes specific requirements for USAID-supported programs that include voluntary sterilization. These requirements cover informed consent, ready access to other methods, and guidelines on incentive payments, which affect payments to acceptors, providers, or referral agents. The requirements of PD-3 are implemented in conjunction with the Tiahrt requirements. Further requirements that apply to voluntary sterilization include documentation of informed consent.

B. USAID GUIDANCE

Allowable Uses of Funds for Family Planning/Reproductive Health

a. Allowable Uses of FP/RH Funds for Family Planning Activities

The vast majority of FP/RH-designated funds should be used to support family planning activities, primarily through family planning information and services, including integration into other reproductive health or general health activities. USAID's approach to family planning includes the following allowable activities:

- *Expanding access to and use of family planning information and services*, including partnerships with the commercial sector (taking care to avoid the appearance of USG favoring one recipient over another) and faith- and community-based organizations; policy development to encourage a favorable environment for providing family planning information and services; support for mass media and other kinds of public information initiatives; and initiatives

focused on underserved populations and in areas where population growth threatens biodiversity or endangered species.

- *Supporting the purchase and supply of contraceptives and related materials*, including the purchase of contraceptive commodities and related equipment, and commodity and logistics support. In the case of condom procurement, one must consider the purpose for which the condoms are to be used (HIV/AIDS or STI prevention versus pregnancy prevention) in determining the proper source of funds for their purchase (HIV/AIDS and/or FP/RH funds).
- *Enhancing quality of family planning information and services*, including interpersonal communications: training and human resource management; quality assurance; incorporation of a gender approach into family planning programs, for example, by training providers to identify signs of gender-based violence that should be addressed as part of family planning counseling; record-keeping; and monitoring and evaluation.
- *Increasing awareness of family planning information and services*, including behavior change communications, encompassing interpersonal communications, mass media, and promotion of community involvement with special attention to raising awareness about family planning information and services and social marketing of contraceptive products.
- *Expanding options for fertility regulation and the organization of family planning information and services*, including research to develop and introduce new options for expanding contraceptive choice; and social science research to improve the organization and quality of family planning information and services. Note that FP/RH funds may be used to pay for operations research activities that include broader health or non-health components or linkages provided that the objective of the study is to improve family planning and related reproductive health activities.
- *Integrating family planning information and services into other health activities*, including communications, awareness-raising, and training activities that weave family planning messages into related themes, such as responsible behavior, limiting sexual partners, abstinence, delay of marriage, child spacing, well-baby care, parenting skills, and breastfeeding. Integrated activities can produce economies of scale and synergistic benefits for both activities. The costs of adding family planning to another health program may be paid for with FP/RH-designated funds alone.
- *Assisting individuals and couples who are having difficulty conceiving children* by providing information and services appropriate for low resource settings. Appropriate activities for low resource settings include those aimed at increasing awareness and knowledge of the fertile period.

b. Allowable Uses of FP/RH Funds for FP/RH System Strengthening Activities

FP/RH system strengthening activities include the following:

- *Fostering the conditions necessary to expand and institutionalize family planning information and services*, including building national and local level support for family planning; strengthening of management systems, including information systems, human resources, supervision, training, and financial systems; and leadership training and development.
- *Contributing to the sustainability of family planning information and services*, including initiatives with the commercial sector and health and social insurance programs to leverage private resources for family planning; mobilization of public sector resources to finance family planning information and services; measures to ensure reliable supplies of contraceptives; and policy and program actions to maximize the positive effects of health reform on family planning services.

c. Allowable Uses of FP/RH Funds for Integrated Family Planning Activities

There are two categories of integrated family planning activities included in this guidance: i. Intra-sectoral Family Planning/Reproductive Health Activities, and ii. Multi-Sectoral Family Planning/Reproductive Health Activities. Intra-sectoral activities are integrated across various elements within the health program area. Multi-sectoral activities are integrated with funds from other accounts and/or program areas. Examples of each are included below. Integrated family planning activities support USAID family planning objectives, but are not considered stand alone family planning activities. Integrated family planning activities often strengthen or complement a family planning program, facilitate the achievement of family planning program objectives, or contribute to the results of a family planning activity. Integrated activities often have similar key audiences as family planning activities, are co-located, or require the skills of a single health services provider.

To help decide whether a non-family planning activity represents an appropriate use of FP/RH funds, the activity should satisfactorily address the criteria of:

- direct measurable impact in the reduction of unintended pregnancies and optimally used funds as described in the introduction to Chapter III.8 Family Planning/Reproductive Health, and
- programmatic linkage to existing family planning activities.

In the case of both intra-sectoral and multi-sectoral family planning/reproductive health activities, an integrated family planning activity funded by USAID requires joint funding of FP/RH-designated funds and non-FP/RH-designated funds. For example, the use of non-FP/RH-designated funds is required to help support integrated FP/HIV activities that also receive FP/RH-designated funds. Likewise, USAID funding for mentoring activities that are intended to keep girls in school by building their self-esteem while also modeling

positive reproductive health behaviors requires joint funding from FP/RH-designated and non-FP/RH-designated accounts.

i. Intra-sectoral Family Planning/Reproductive Health Activities

Reproductive health needs vary over the course of an individual's life. Therefore, FP/RH funds should be used to help countries provide women and men with the convenience of co-located or linked health services that respond to a broad set of reproductive health needs.

Research suggests that linking family planning with STI, including HIV, prevention efforts or perinatal services or broader youth development efforts is associated with improved client satisfaction, higher utilization rates and sustained and satisfied use of family planning and related health or other services. Further, support for strengthened linkages between family planning and other reproductive health areas is consistent with the objectives of the Programme of Action adopted by the USG at the 1994 International Conference on Population and Development, which called for, *inter alia*, universal access to a full range of safe and reliable family planning methods and related reproductive health care.

(See <http://www.un.org/popin/icpd/conference/offeng/poa.html>).

Illustrative examples of the allowable intra-sectoral family planning/reproductive health activities that may be supported with FP/RH-designated funds include, but are not limited to, the following:

- *Integrating family planning and antenatal, neonatal, and postpartum care.* Activities may include safe motherhood initiatives such as community education and awareness raising about delivery complications and increasing access to emergency obstetrical care.
- *Providing post-abortion care*, including emergency treatment for complications of induced or spontaneous abortion; post-abortion family planning counseling and services; linking women to family planning and other reproductive health care; and community awareness and support to help women get emergency treatment, recover and prevent future unplanned pregnancy. However, no USAID funds may be used to purchase manual vacuum aspiration (MVA) kits.
- *Integrating and coordinating family planning and HIV/AIDS and STI prevention programs* as well as, in some special instances, treatment programs. Illustrative activities include promotion of dual protection, encompassing condom promotion and other behavioral change efforts to reduce pregnancy and STI/HIV risk; development and introduction of microbicides; and integration of family planning counseling and services (or referral for services) into voluntary counseling and testing centers for women and men who wish to avoid future childbearing and into programs focused on preventing mother-to-child-transmission of HIV/AIDS. (See Family Planning/HIV Integration: Technical Guidance for USAID-

Supported Field Programs, September, 2003:

http://www.usaid.gov/our_work/global_health/pop/publications/docs/fphiv.pdf).

S/GAC has issued guidance on the use of HIV/AIDS funds in integrated family planning and HIV/AIDS activities. Please consult the most recent annual Country Operational Plan Guidance issued by S/GAC for information about this subject.

- *Linking contraceptive information and services to broad-based youth development activities* that promote self-efficacy and responsibility by strengthening life-skills (e.g., programs such as *Better Life Options* and *It's Your Life*).
- *Preventing and repairing fistula*. Activities may include: 1) repair, 2) prevention, 3) reintegration, and 4) monitoring and evaluation and research. The fistula program should be funded with a combination of funds from both the MCH and FP elements. A typical distribution of funds within a comprehensive fistula program would include 70 percent of funding from the 3.1.6 Maternal and Child Health element and 30 percent of funding from the 3.1.7 Family Planning and Reproductive Health element. FP funds should be focused on community-based prevention and post-repair counseling, while MCH funds should focus on obstetric prevention and repairs. Activities to prevent the occurrence of fistula may include supporting family planning to prevent unintended pregnancies, delaying marriage and first birth, and increasing community awareness of danger signs in pregnancy and delivery.
- *Integrating gender into family planning programs*: Illustrative activities include interventions to transform traditional gender norms that perpetuate gender-based violence and limit women and men's access to FP/RH information and services. Community mobilization and behavior-change interventions seek to improve couple communication and increase constructive male involvement in FP/RH counseling and decision-making, and to prevent or mitigate gender-based violence as related to FP/RH.

ii. Multi-sectoral Family Planning/Reproductive Health Activities

Officers are encouraged to seek opportunities to develop mutually productive linkages with other health activities and development sectors such as education, democracy and governance, environment, micro-enterprise and income generation programs, and to those with specific gender objectives. Such linkages can serve multiple purposes. Often, they expand the entry points for introducing family planning information and services, particularly when coupled with HIV and child survival and maternal health (CS/MH) services.

While FP/RH-designated funds can be used to support the FP/RH components of multi-sectoral activities, funds from non-FP/RH sources must be used to support activities that do not directly affect FP/RH outcomes.

Within an integrated family planning activity, non-family planning/reproductive health and non-health activities must be supported with non-FP/RH funds in combination with FP/RH-designated funds. Illustrative examples include, but are not limited to, the following:

- *Non-Family Planning/Reproductive Health.* Addition of non-family planning products and promotion to a family planning social marketing campaign, for example, addition of oral rehydration salts (ORS) or impregnated bed nets can enhance a social marketing system that delivers and promotes family planning products. *Note:* FP/RH funds must not be used to pay for non-FP/RH products and their promotion. In this case, non-FP/RH-designated funds would pay for the non family planning products and their promotion.
- *Education.* Pregnancy and dropout among schoolgirls are sometimes precipitated by poor school performance. Mentoring programs that help adolescent girls succeed in school while also providing them with reproductive health information and counseling combine the two forces that are needed to reduce dropout due to pregnancy. *Note:* Basic education activities must be paid for with funds that are designated for that purpose. FP/RH funds may not be used to support basic education activities.
- *Democracy and Governance.* Education and awareness-raising about reproductive issues, such as voluntarism in family planning programs, can be supported as a component of broader awareness-raising and education about women's rights.
- *Environment.* Awareness-raising activities for environmental issues that look at a wide range of policy responses, including ones related to FP/RH. Also appropriate are national environmental planning activities that include consideration of demographic factors.
- *Microenterprise and Income Generation.* Linking family planning volunteers, including peer educators, to microenterprise and income generation activities. For example, FP/RH-designated funds may be used along with non-FP/RH designated funds to subsidize small loans, training or skills development activities that are directed to family planning volunteers, or peer educators as rewards for length or quality of service. Also, income-generating activities may help to generate resources for FP/RH activities, for example, microfinance activities to assist women to sell family planning and related health products.
- *Gender.* Linking family planning clients to sources of legal counsel about gender based violence, property, custody, and other rights of women. Additional best practice examples for integrating gender-based violence initiatives into health programs are included in the document, *Addressing Gender-based Violence Through USAID's Health Programs: A Guide for Health Sector Program*

Officers. The document is available at http://pdf.usaid.gov/pdf_docs/PNADH194.pdf.

9. Water Supply, Sanitation, and Hygiene

A. USAID GUIDANCE

This guidance applies to the use of GH/CS funds appropriated to USAID and included under Element 3.1.8, Water Supply and Sanitation, or under sub-Element 3.1.6.7, Household Level Water, Sanitation, Hygiene and Environment of Element 3.1.6 Maternal and Child Health. Operating units considering use of GH/CS funds to support water supply, sanitation, and hygiene activities as part of other Program Elements, including but not limited to those addressing environmental protection, democracy and governance, and humanitarian relief, should consult with USAID/W as described in Chapter IV, to help ensure that such programs maximize health impact and are consistent with any other programmatic guidance. Additional specific guidance on the use of HIV/AIDS funds for water, sanitation, and hygiene activities is found in Appendix IV, HIV/AIDS Preventive Care Guidance and should also be consulted.

Diarrheal diseases and related malnutrition account for virtually all of the deaths and nearly 90% of the overall disease burden associated with unsafe water supply, sanitation, and hygiene (WSH). For this reason, GH/CS funds shall be used for WSH components that have a primary goal of reducing the prevalence of diarrheal diseases in groups for which mortality from diarrhea is a significant public health concern, primarily children under five and people living with HIV/AIDS.

From the diarrheal disease prevention perspective, a comprehensive WSH program includes interventions in hardware (e.g., water supply through public utility, community, or household wells/taps; rainwater harvesting/water storage capacity; latrines and handwashing facilities; or household-level technologies and products); complementary hygiene promotion and behavior change activities (e.g., community mobilization for sustained management and repair of hardware; social marketing of products and behaviors; or schools and clinic programs in the public and private sector); and interventions to support an enabling environment (political leadership/sector reform; supportive national and state policies; community organizations; institutional capacity strengthening; and financing). Typically, GH/CS funds would be used to fund components of an operating unit's overall WSH activity in combination with DA or other funds, exploiting the comparative advantage of health activities as appropriate. For example, promotion of safe drinking water treatment and storage, effective sanitation, and hygiene improvement at the household level through community-based health workers can serve to build demand for and help sustain infrastructure investments.

Key health-focused WSH interventions are those that increase access to and effective use of improved drinking water supply and sanitation; increase water quantity per capita used for drinking and hygiene improvement; ensure microbiologically safe drinking water quality, measured at the household level; improve handwashing practices; or result in the

effective use of a sanitary means of excreta disposal. Each of these interventions has been shown to reduce diarrhea prevalence approximately 30-50%.

GH/CS funds should be used for WSH activities that are consistent with the “optimal use of funds” guidance of Chapter III.1.B. This includes efficiency not only amongst the various eligible WSH activities, but also in considering efficiency of WSH interventions with respect to other approaches to achieve an identified health objective, such as the reduction of child mortality.

WSH activities eligible for GH/CS funding include:

- **Increasing access to improved drinking water supply as defined by the Millennium Development Goals**, i.e., the availability of at least 20 liters per person per day from an "improved" source within one kilometer of the user's dwelling. An improved source is one that is likely to provide safe water, including household connections to a water supply distribution network, public standpipes (connected to networked systems, or from a community well or surface water source), boreholes, protected dug wells, protected springs, and rainwater collection. Access to improved sources can be rural or urban, and may be provided through utilities, community-based systems, self supply, and/or other long-term and permanent systems. Unprotected wells, unprotected springs, rivers or ponds, vendor-provided water, bottled water, and tanker truck water are not considered improved.
- **Increasing access to improved sanitation at the household level as defined by the Millennium Development Goals**. Sanitation facilities are considered improved if they are private and if they separate human excreta from human contact, including connection to a public sewer, connection to a septic system, pour-flush latrines, simple covered pit latrines, and ventilated improved pit latrines. Access provided can be rural or urban, and may be provided through community managed simplified systems, utility-managed central network systems, or self-supply.
- **Increasing access to public or shared improved sanitation facilities in communal or institutional settings** (e.g., health clinics, schools, public markets, etc.) if they adequately separate human excreta from human contact and have a sustainable management and maintenance system in place, as well as sufficient hygiene facilities.
- **Supporting availability of, access to, and use of products to treat and properly store drinking water at the household level or other point of use (POU), in order to ensure the safe microbiological quality of drinking water; facilitate effective handwashing; or ensure safe excreta management practices.**
- **Supporting behavior change through hygiene promotion, including household drinking water management, handwashing, and feces management (e.g. sanitation promotion and marketing).**

There are also other WSH-related activities that are eligible for partial GH/CS funding, consistent with the guidance provided on Co-Programming in Chapter III.14 of this document. The appropriate fraction of GH/CS funding will be determined by the extent

to which the activity contributes to the health-focused WSH interventions described above. Operating units are encouraged to consult with USAID/W, as described in Chapter IV, to help determine the appropriate fraction of GH/CS funding. These include:

- **Improving the quality of existing drinking water supply or sanitation services**, including increasing the number of hours of water access per day or quantity of water available, improving the quality of water delivered, improving the maintenance of systems and reducing the number of days out of service, or increasing the number of household connections for people who already have access to a communal improved source.
- **Provision of multiple-use water services** that include both domestic drinking water supply and water supply for productive use needs of the community (e.g., small-scale agriculture/gardening/animal husbandry).
- **Protection of surface water and groundwater quality** of potable water supply system from direct contamination prior to distribution to users, including installation of barriers to prevent access to the water point by animals, people, or other contamination sources, or water quality protection activities where there is a credible, direct, and specific cause-effect linkage between the contaminating activity and the degradation of an otherwise high-quality drinking water source.
- **Institutional strengthening and reform** related to drinking water supply, sanitation and hygiene, including capacity building of government and other key actors and organizational development, water supply and wastewater utility governance/corporatization and utility reform.
- **Water and sanitation infrastructure financing**, including increased access to credit, strengthening of domestic private capital markets, and facilitating support from domestic financial institutions.
- **Small-scale community-managed wastewater collection and/or treatment infrastructure.**

The following categories of water-related activities are not eligible for GH/CS funding, because they are not directly associated with health-focused WSH outcomes described earlier in this section:

- **Water resources management**, including management of water and associated natural resources, analysis of hydrologic resources and ecosystems, developing allocation strategies among multiple competing human demands for water resources, and water resources management governance structures.
- **Water productivity**, including economic or productive uses of water in agriculture, industry, commerce, services, or energy resources.
- **Water security**, including the management of transboundary or shared water resources.

10. Vulnerable Children

A. LEGAL REQUIREMENTS AND CONGRESSIONAL DIRECTIVES

Earmarks and Directives: The FY 2008 Appropriations Act and Conference Report contain a directive for vulnerable children (\$15 million), which includes \$1.85 million for blind children. For further guidance on recommended uses of the funds within each of these directives, please see Chapter III.10.B.

Orphans and Vulnerable Children Act: In November, 2005 the “Assistance for Orphans and Other Vulnerable Children in Developing Countries Act” was signed into law (the “OVC Act”). This was authorizing legislation and no funds have been appropriated for this Act; thus, there are no specific requirements for how GH/CS funds may be used for OVC activities. However, the OVC Act calls for a comprehensive U.S. government-wide strategy for OVC programs and annual reporting on the status of USG-funded OVC programs. For more information, please contact the USAID OVC Special Advisor in GH.

B. USAID GUIDANCE

a. Vulnerable Children

The Vulnerable Children budget category includes the following line items: Displaced Children and Orphans Fund (DCOF), Blind Children, and Other Vulnerable Children. This budget category corresponds to the sub-element 3.3.2.1 Vulnerable Children.

The FY 2008 Appropriations Act includes \$15 million for children displaced or orphaned by causes other than HIV/AIDS, and is programmed centrally in Washington.

Based on experience gained over the past 15 years, the Agency is pursuing a strategy whereby allowable uses for funds reserved for “vulnerable children” support a set of programs designed to address the critical *needs of children most at risk* as well as to *address disabilities, family separation*, and other problems that can put children at risk. Family reunification is a primary objective for children outside of family care. At the center of this strategy are programs that strengthen the capacity of families and communities to address the physical, social, educational, and emotional needs of children in crises. Children that have been identified as requiring special attention include: (1) children displaced, orphaned or otherwise severely affected by the consequences of complex emergencies, armed conflict (including child soldiers), and natural disasters; (2) separated children who are outside the care of their parents or normal guardians; and (3) children with disabilities. For more information on children affected by HIV/AIDS, please see Chapter III.2.B.g.

b. Displaced Children and Orphans

The Displaced Children and Orphans Fund (DCOF) directive within the Vulnerable Children budget category provides financial and technical assistance for the care and protection of orphans and other vulnerable children who are displaced or separated from their families, are at risk of losing family care and protection, or are faced with other sources of extreme duress.

The DCOF focuses primarily on children affected by war (including child soldiers), children with disabilities, and other disenfranchised or unaccompanied children, such as street children.

DCOF places strong emphasis on strengthening family and community capacity for identifying and responding to the special physical, social, educational, and emotional needs of these children. The definition of children includes adolescents.

Allowable activities include the following:

- *Documenting, tracing, and reuniting children* (including child soldiers) separated from their families and supporting their community reintegration;
- *Addressing psychological and emotional issues of children* affected by conflict or other emergencies;
- *Mobilizing communities and strengthening families to care for and protect their most vulnerable children*;
- *Working with host country governments* and others to develop and execute policy and programmatic reform regarding vulnerable children; and
- *Enhancing economic opportunities* for vulnerable children and their families.

c. Other Vulnerable Children Activities

In addition to the types of activities described above, operating units may use “Other Vulnerable Children” funds to: (a) finance a variety of activities in countries of “special need” where there are an unusually large number of, or especially disadvantaged, vulnerable children for whom increased accessibility to mainstream health services and/or other psychological or social services are critically needed; or (b) finance special opportunities which fall outside of mainstream USAID strategies, but which because of special circumstances or opportunity, are deemed to be of critical importance to at-risk children.

For more detailed guidance on the above activities, please contact the Displaced Children and Orphans Fund manager.

NOTE: Activities specifically targeting Children Affected by HIV/AIDS are *not* appropriate uses of Vulnerable Children funds. All activities specifically addressing Children Affected by HIV/AIDS must be funded by HIV/AIDS funds.

11. Other: Health Systems and Capacity Strengthening

A. USAID GUIDANCE

a. Construction

Construction of Facilities: USAID has legal authority to perform construction and renovation overseas, which, like the Department of State, is based on authorities under the Foreign Assistance Act. Construction refers specifically to new construction, as distinguished from improvements (renovation/alteration). New construction is defined as: “the erection of a building, structure or facility; including the installation of equipment, site preparation, landscaping, and associated roads, parking, environmental mitigation, and utilities, which provides area or cubage not heretofore available. It includes...additional wings or floors...and any other means to provide usable program space that did not previously exist.¹²” Improvement (renovation/alteration) is defined as “any betterment or change to an existing property to allow its continued or more efficient use within its designed purpose (renovation), or for the use of a different purpose or function (alteration). Improvements do not include the addition of wings, floors, or other increases to usable program area cubage; such projects constitute new construction. The only added areas or cubage which may be construed as a building improvement rather than new construction involves stairwells, elevator towers, pipe chases, etc., not providing useable program space....Such renovation activities cannot add to the size of the facility.¹³”

Although USAID has legal authority to perform both construction and improvements, USAID usually prefers to avoid using health funding for construction. This is based on the view that the construction of facilities is resource-intensive and does not ordinarily result in *optimal use* of GH/CS funds. Optimal use is defined throughout this guidance as those activities that are most effective and efficient in reaching significant, critical populations and/or providing *sustainable* community-based services. This requires balancing the use of funds for construction against other factors, such as the severity and magnitude of the problem, overall developmental needs, program stage or maturity, relative cost- and program-efficiency of the intervention, and host country and other donor resources.

To assist with this determination, USAID/Washington review is required when GH/CS funds exceeding \$100,000 of an OU’s portfolio (per year) are used for new construction. The following procedures should be followed:

- a) If a construction project is funded exclusively with GH/CS funds appropriated to the Department of State, as in a PEPFAR focus country, the review can be incorporated into the County Operational Plan (COP) review process, and approval of the COP would equate with approval to construct with no further waivers required.

¹² Definition from the Health and Human Services (HHS) Facilities Program Manual (Volume I).

¹³ HHS Guidance.

- b) If a construction project is funded exclusively with GH/CS funds appropriated to USAID, in any element, the Mission must follow the guidance for deviations from the guidance, as outlined in Chapter IV.
- c) If a construction project is funded with both GH/CS funds appropriated to the Department of State and GH/CS funds appropriated to USAID, and the country is submitting a COP or mini-COP to S/GAC, then the review can be incorporated into the COP review process. In addition to approval of the COP, Missions must submit a copy of the documentation approving the funding (including the request, the rationale, and the response from S/GAC) to GH/SPBO, and GH/SPBO will share the documentation with the IIP lead in F and the appropriate Regional Bureau health team.
- d) If a construction project is funded with both GH/CS funds appropriated to the Department of State and GH/CS funds appropriated to USAID, and the country is *not* submitting a COP or mini-COP to S/GAC, then the procedure set forth in paragraph b above should be followed for the GH/CS funds appropriated to USAID. For the GH/CS funds appropriated to the Department of State, prior approval must also be granted from S/GAC.

If GH/CS funds appropriated to USAID are used for improvements (renovation/alteration), USAID/W review is not required. If GH/CS funds appropriated to the Department of State are used for improvements (renovation/alteration), these activities should be included in the COP and the review can be incorporated into the County Operational Plan (COP) review process. Approval of the COP would equate with approval to renovate with no further waivers required.

All awards involving construction or renovation of structures, facilities, or buildings are required to comply with USAID’s AAPD 05-07: “Supporting USAID’s Standards for Accessibility for the Disabled in Contracts, Grants, and Cooperative Agreements.”

b. Health Systems/Systems Strengthening

At this time, health systems activities may be allocated to any health program element. The rules for program elements may be updated annually in the Operational Plan Guidance; please be sure to follow current guidance. Please use the health sub-elements for systems work corresponding to the health elements such work supports. Results achieved should benefit programs in proportion to the funding category (family planning, maternal and child health, etc.) used. For sustainable progress toward achieving Agency goals, operating units must seek to foster an institutional environment that is favorable to development, working closely with partner and customer organizations. In the course of planning, implementing, and appraising programs, USAID managers often find that achievement of results is constrained by either an inappropriate institutional framework or a partner organization’s lack of capacity. Increasing the capacity for institutional and organizational effectiveness promotes sustainability in all of the goal areas.

- *Support for the development of institutions* focuses on three areas: (1) formulation and coordination of policy (i.e., rules and norms in the policy making process); (2) rules and norms shaping efficient and effective delivery systems for

goods and services; and (3) development of motivated and effective staff for rulemaking and enforcement. These are largely, though not exclusively, public sector functions. They are frequently the focus of USAID's policy reform efforts. Assistance is also provided to ensure the sustainability of a policy-making process, as well as of incentive and sanction mechanisms (e.g., public budgeting and expenditure functions, transparency and accountability measures, adjudication systems, etc.).

- *Support to strengthen an organization's ability to provide quality and effective goods and services, while being viable as an organization.* This means supporting an organization to be: (1) programmatically sustainable (providing needed and effective information and services); (2) organizationally sustainable (with strong leadership and having necessary systems and procedures to manage by); and (3) assured that it has sufficient resources (human, financial, and material) that are utilized well.

Allowable Uses of Funds for Systems Strengthening

- **Funding Considerations:** At this point, there is no directive or special budget category for health systems development or capacity strengthening. Therefore, to the extent that the activity is part of any health program for the purpose of that program, it should be funded with monies from the FP/RH, Child and Maternal Health, Vulnerable Children, HIV/AIDS, and Infectious Diseases budget categories, using any of the eight health elements or the Social Services element.

Within each of the categories above, allowable activities for uses of GH/CS funds relate to the Agency's sustainability objective of assuring the long-term accessibility, efficiency, effectiveness, quality, equity, and sustainability of child health/survival, maternal health/survival, family planning/reproductive health, other infectious diseases, HIV/AIDS, water and sanitation, other public health threats, and vulnerable children's programs. Specifically, recommended activities geared towards building self-reliance include the following:

- *Improving appropriate health sector reforms* that support and protect policies related to health programs;
- *Assuring quality, effectiveness, and financial sustainability* of health programs in the context of decentralization and health sector reform, including reducing corruption;
- *Establishing fair, efficient, and equitable financing* to protect access by the poor to health programs by improving cost controls and rationalizing application of user fees, privatization, and health insurance programs;

- *Reorganizing health sectors*, including realignment of roles within the health sector, such as redefining which institutions deliver services, make policies, and set standards on financing services and supplies;
- *Strengthening health information systems and resources* to inform the making of better health policy, management decision-making, and monitoring and analysis of program activities;
- *Improving the quality of and capacity* to deliver health care services that are responsive to patient and community needs;
- *Strengthening human resources and management*, often with progressive decentralization and work at the community level;
- *Involving the private sector, including faith- and community-based organizations*, actively in the provision of health care;
- *Improving commodity management systems* for pharmaceuticals and improving drug quality, supplies, equipment, and facilities, to include use of the commercial sector more extensively for distribution of commodities; and
- *Developing new and improved technologies and approaches* to effectively plan and deliver quality child survival and health services.

12. Rebuilding Countries

A. USAID GUIDANCE

The goal of USAID’s Fragile States Strategy is "to guide USAID's efforts in reversing decline in fragile states and advancing their recovery to a stage where transformational development progress is possible" (available at: http://inside.usaid.gov/DCHA/CMM/documents/USAID_FragileStatesStrategy.pdf). To support this goal, USAID staff will need to explore how health development assistance can address key risk factors associated with state fragility and determine how health programs can be implemented to make the greatest possible contribution to a country’s stability, resilience, and recovery and at the same time achieve the purposes for which the funds were appropriated.

The guiding principles of using GH/CS funds to achieve “direct impact,” and the Agency’s responsibility to assure “optimal use” of GH/CS funds, still apply in fragile state environments (see below). Mission staff will therefore need to develop program approaches that deliver situation-appropriate health programs in ways that also contribute to reconstruction and stability objectives, while respecting existing earmarks and directives.

a. Allowable Uses of Funds for Fragile States

The guidance in this chapter on rebuilding countries applies to the use of GH/CS funds appropriated to USAID. In order to use GH/CS funding for these activities, the activities should meet two established criteria: “direct impact” and “optimal use of funds.” “Direct impact” means that the results of the activity can be linked and measured directly (using the health elements and standard indicators) against the purposes for which they were appropriated, as defined in the FY 2008 Appropriations Act and the relevant House, Senate, and Conference Reports and under the health element goal: “To contribute to improvements in the health of people, especially women, children, and other vulnerable populations in countries of the developing world, through expansion of basic health services, including family planning; strengthening national health systems, and addressing global issues and special concerns such as HIV/AIDS and other infectious diseases.” “Optimal use of funds” means ensuring that those activities that are most effective and efficient in reaching significant, critical populations and/or providing sustainable community-based services receive priority for funding. Under the direct impact and optimal use of funds criteria, activities undertaken with GH/CS funds in fragile environments and during stabilization and reconstruction actions should contribute to the effective use and delivery of the interventions for which those funds were appropriated, as referenced in Chapter III of this Guidance. Such activities should be linked to health outcomes as well as stabilization and reconstruction objectives.

In addition to what is outlined in Chapter III of this guidance on the recommended uses of GH/CS funds, the following areas have been identified as needing additional guidance.

Health sector governance activities

Rebuilding countries are characterized by weak governance and lack of capacity and/or willingness on the part of the government to work together with public and private providers and the community to deliver services. Strengthening the ability of national, local, and community institutions to manage a country's resources and affairs in a manner that is open, transparent, accountable, equitable, and responsive to the needs of the people is an important goal of programming in fragile environments.

The following activities may be funded when they directly impact the delivery and use of services for the directive and sub-directive areas for which the funds used were appropriated:

- Expanding and institutionalizing health services, including but not limited to:
 - Establishing or strengthening the delivery of services and the procurement of pharmaceuticals and medical supplies, including supply chain management;
 - Drafting national health policy and promoting legislation and regulation¹⁴;
 - Improving infrastructure and institutional capacity to deliver services and manage health programs;
 - Strengthening corruption prevention;
 - Training, quality assurance and human resource development;

¹⁴ The Siljander Amendment prohibits USAID funds being used to lobby for or against abortion.

- Establishing fair, efficient, and equitable health sector financing; and
- Strengthening national and local level management, information, financial systems, and leadership training/development.
- Reestablishing or strengthening basic health services with particular attention to previously underserved, socially marginalized, and vulnerable populations in ways that promote longer-term re-engagement with national governments and building capacities of national governments to use health resources effectively.
- Building the capacity of public sector institutions and strengthening the relationship between government institutions and non-government providers at all levels in the health sector by:
 - Assuring that non-government organizations in the health sector are aligned with the national government and contribute to building state capacity;
 - Strengthening the capacity of local NGOs to engage with and be accountable to government (where feasible) and to implement and report on health programs.
- Increasing the participation of civil society, local government, and community institutions in health activities by:
 - Increasing the role of communities in planning, decision-making, and resource management for health activities;
 - Strengthening organization and capacities of communities and local government;
 - Supporting the provision of health empowering information to families and communities;
 - Supporting the development of local mechanisms to monitor health status and plan effective responses; and
 - Increasing accountability and responsiveness of local health authorities.

Multi-sectoral programming

Many of the factors that drive state fragility are rooted in the political, security, economic, or social sectors. Development efforts to address grievances in these factors in rebuilding countries that have limited absorptive capacity presents a major challenge--particularly in post-conflict situations. USAID health officers are encouraged to seek opportunities to develop mutually productive linkages with other sectors such as education, democracy and governance, and economic development. For example, in a post-conflict situation both the agriculture and education sectors may be investing in strengthening district governments to provide services to vulnerable populations; GH/CS funds could be used to develop a consistent approach to strengthening health sector governance at the district level. Use of a common governance model would decrease duplication of effort among the sectors and contribute to aid efficiency and effectiveness.

While GH/CS funds should be used to support the GH/CS components of multi-sectoral activities, funds from non- GH/CS sources must be used to support activities that do not directly affect GH/CS outcomes. Examples of multi-sectoral activities that can be funded with GH/CS funds include the following:

- Support for the health component of a larger government-wide decentralization, corruption-prevention or management strengthening activity;

- Addition of child survival, maternal health, or family planning education component to employment, income generation, or agricultural programs;
- Support for food aid programs that increase the nutritional status of households; and
- Provision of field guidance and training in high impact child survival interventions in complex emergencies.

The relationship of health to stability

There is not extensive data on the degree to which health sector activities contribute to stabilization and reconstruction objectives, however improved governance, enhanced government effectiveness and credibility, and improved health service delivery are seen as a catalyst for broader transformations in national development. There is evidence that public security plays an important role in health outcomes. A nationwide study in the Democratic Republic of Congo showed that, even though violence was not a significant proximate cause of death, overall mortality rates and child mortality rates were significantly elevated in health zones where incidents of armed conflict were reported, compared to those in which peace reigned.

- GH/CS funds may be used to establish the evidence base for the impact of health sector activities on the fragile state objectives.

13. Administrative/Management Costs

A. USAID GUIDANCE

Agency regulations on the appropriate use of operating expense and program funds for administrative and management positions are found in ADS 601. ADS 601 is applicable to the use of GH/CS Account funds, and Missions must carefully review costs where there may be doubt about the proper source of funding. Regarding funding sources, E601.5.7 states:

“In most instances the appropriate funding source will be clear, particularly viewed in conjunction with the examples provided in the Mandatory References to this policy. In cases where it is not clear which funding source is to be used, the cognizant technical office or other requesting office, after consultation with the cognizant GC or M/B, as appropriate, must document the funding source decision. Such documentation will be in the form of a statement that the requestor has reviewed the scope of work and determined that the appropriate source of funding is (identify funding source).”

Operating units should consult health officers, either in Missions or in USAID/Washington, when GH/CS funds are used for administrative and/or management costs. If any doubt remains as to whether a position should be funded by Operating Expenses (OE) or GH/CS Account funds, operating units are urged to err on the side of caution and to use OE funds for the position.

Use of Objective 6:

It is important for operating units to ensure that overhead costs allocated to specific positions (for example, office leases and utilities, building maintenance, warehouse costs,

etc.) are properly funded and that the GH/CS Account bears its fair share of these costs (see [E601.5.8b](#)). As with every Program Element, Operating Units must ensure that those costs that are considered cross-cutting truly do fall within this category and that all Program Elements within the portfolio are proportionately supporting the costs. Operating Units should clearly document the justified funding amounts. For additional guidance on the use of program funds for cross-cutting program support expenses, please see the Operational Plan Guidance and associated Annex, “Operating Unit Management Costs and Program Support,” including any subsequent changes to the Foreign Assistance Standard Program Structure and Definitions.

For complete policy guidance on determining appropriate funding sources, see the following documents:

ADS 601: Funding Source Policy

<http://www.usaid.gov/policy/ads/600/601.pdf>

Mandatory Reference: Office of Federal Procurement Policy (OFPP) Policy Letter 92-1, Inherently Governmental Functions

<http://www.arnet.gov/Library/OFPP/PolicyLetters/Letters/PL92-1.html>

Mandatory Reference: Cost of Doing Business

<http://www.usaid.gov/policy/ads/600/601.pdf>

- **Program Funded Technical Expertise:** Under the Agency’s allowable activities, operating units can use the GH/CS funds appropriated to USAID to obtain technical expertise through a variety of mechanisms such as Personal Services Contracts (PSCs), Intergovernmental Personnel Act Assignments (IPAs), Participant Agency Service Agreements (PASAs), Participating Agency Program Agreements (PAPAs), the Technical Advisors in AIDS and Child Survival Program (TAACS)¹⁵, Cooperative Assistance Support Units (CASUs), and the Fellows Programs for the design, implementation, and evaluation of health programs. For additional information on the CASU or Fellows Programs, contact the appropriate Cognizant Technical Officer in the GH Bureau. Note that the FY 2008 Appropriations Act limits to 25 the number of PSCs that can be employed in USAID/W under this authority; no more than 10 can be assigned to any bureau or office. Allocations are made by the agency’s human resources office (M/HR) and the Chief of Staff in USAID/W. Missions still have full PSC authority, which is not affected by this language. PSCs can also be hired with GH/CS funds under the “notwithstanding” authority in Section 622 of the FY 2008 Appropriations Act. See Appendix I, excerpt 2, Section 622.

Program to Operating Expenses: Under the 2008 Appropriation Act, up to \$6,000,000 may be transferred to and merged with funds appropriated by the Appropriation Act under the heading “Operating Expenses of the United States Agency for International Development” for costs directly related to global health.

¹⁵ Current Agency policy is not to hire additional TAACSs.

Foreign Service Limited (FSL): The FY 2008 Appropriations Act includes a provision that funds may be made available to “hire and employ individuals in the United States and overseas on a limited appointment basis pursuant to the authority of sections 308 and 309 of the Foreign Service Act of 1980.”

This provision requires that the number of limited Foreign Service hires shall not exceed 175 in any fiscal year. The authority to hire individuals expires on September 30, 2009, and may only be used to the extent that an equivalent number of positions that are filled by personal services contractors or other non-direct hire employees of USAID, who are compensated with funds appropriated to carry out part I of the Foreign Assistance Act of 1961, are eliminated.

14. Co-Programming

A. USAID GUIDANCE

Co-Programming

Intra-sectoral and multi-sectoral integrated activities are an increasing component of Agency sector portfolios. Intra-sector activities are co-programmed across various elements within the health program area. Multi-sectoral activities are co-programmed with GH/CS funds and with funds from other accounts and/or program areas. While such integrated activities are encouraged, careful attention must be given to ensure that GH/CS funds are used for their intended purposes. To this end, operating units must ensure that funding levels from the respective elements and/or other accounts are *proportionate* to the percentage breakdown of relevant activities within the larger project. Operating units must also clearly document how the percentage breakdown among the various types of funds was determined and how specific funds are being used. Operating units should consult health officers, either in Missions or in USAID/Washington, when GH/CS funds are used for integrated activities. Missions are encouraged to contact USAID/W for assistance where such a breakdown might be difficult to determine.

a. Intra-sectoral Programming: Co-Programming Across Various Elements Within the Health Program Area. Co-programming for a single intra-sectoral health program requires joint funding from the relevant elements across the health program area, funded by the GH/CS Account. For example, an antenatal clinic that also provides voluntary counseling and testing for HIV/AIDS must be proportionately funded through the maternal and child health element and the HIV/AIDS element. Roughly, if the clinic devotes approximately 75 percent of its resources to providing maternal and antenatal care and approximately 25 percent to voluntary counseling and testing (VCT), the amount of MCH and HIV/AIDS funds must be proportionate to their respective balance of activities in the clinic.

In an integrated program that includes both HIV/AIDS activities and voluntary family planning activities, any partner that receives U.S. Government funding for both purposes must comply with the respective requirements applicable to each activity; this may include, in the case of a foreign non-governmental organization, the Mexico City Policy.

However, in an integrated program, different organizations may be responsible for different types of activities, as not all organizations will necessarily do both voluntary family-planning and HIV/AIDS activities. Any partner that receives funds solely for HIV/AIDS activities is thus not subject to the requirements applicable to family planning activities, including the Mexico City Policy.

b. Multi-sectoral Programming: Co-Programming of GH/CS Funds with Other Program Areas and/or Accounts. Under certain restrictions, GH/CS funds may be used with other account funds in a single integrated program. However, GH/CS funds must be used for the purposes intended by Congress as detailed in this guidance, and must be accounted for and reported separately. The above proportionality rule applies to multi-sectoral programming and operating units must clearly document how the percentage breakdown among the various types of funds was determined and how GH/CS funds are being used. Again, where such a breakdown might be difficult to determine, Missions are encouraged to contact USAID/W for assistance. Operating units will also be required to disaggregate GH/CS-funded and other activities in Congressional notifications and in annual reporting.

c. Co-Programming Using Food for Peace (FFP) -- P.L. 480 Title II: GH/CS funds may be used in conjunction with P.L. 480 Title II food security resources to provide a more complete maternal/child health, nutrition, or HIV/AIDS activity. Operating units are encouraged to work with Agency partners to strategically program activities funded by GH/CS funds with those supported by Title II resources. In that effort, operating units are reminded that while the activity areas may overlap, each resource must be used within its specified activity area (either GH/CS or Title II). Title II resources are provided to cover the cost of commodity procurement, ocean transportation and, where applicable, inland transportation for all Title II activities. For emergency activities, Title II resources may be provided to cover costs associated with internal transport, storage, and handling costs. For Title II non-emergency (development) activities, operating units with FFP and GH/CS activities are encouraged to consider the integration of GH/CS activities with those from Title II where they would be mutually supportive. Where activities are integrated, the Title II component may also receive direct Title II support with either Section 202(e) or monetization resources when they are available. Both programs must be reported separately.

IV. PROCEDURES FOR DEVIATIONS FROM THE GUIDANCE

This document describes both legal requirements and Congressional directives, as well as USAID guidance.

All legal requirements are mandatory.

USAID guidance is issued to ensure effective, evidence-based programming, and to increase consistency and predictability of operations. This guidance is determined based on decades of experience in health programming and represents the best understanding of leading technical experts. If an Operating Unit seeks clarification or has a question about whether an activity falls within the parameters of the requirements, the OU should seek additional guidance by contacting the IIP lead in F or GH/SPBO, and GH/SPBO will coordinate a review and response with the Regional Bureau technical officer, GC/Washington, or the GC's Regional Legal Advisor, as appropriate.

Although Operating Units should generally follow these practices, there are situations where an OU may wish to deviate from them or adapt them to particular situations, especially when such deviations correspond to the guiding principles of direct impact and optimal use. There is a two-phase process for requesting a deviation from this Guidance.

Phase I: When an Operating Unit wishes to deviate from USAID guidance, the OU must hold a technical consultation, organized by the Office Director of GH/SPBO, which must include representatives from the relevant Regional Bureau, GH, the Bureau for Legislative and Public Affairs, GC/Washington or the Regional Legal Advisor, the Office of the Chief Operating Officer, and the Office of the Director of U.S. Foreign Assistance/Investing in People. The technical consultation should be documented in an Information Memorandum to the File from the OU. Ideally, the parties will reach a consensus on technical grounds. If all parties reach consensus, then the Information Memorandum will serve as documentation and the OU is free to proceed with the requested program. See Appendix X for a sample template for documenting technical consultations.

Phase II: If and only if a mutual agreement can not be reached, then an arbitration will be held. The AA of the relevant Regional Bureau should write a split decision Action Memo to the Administrator of USAID. This action memo should include a detailed description of the activity, how it directly contributes to the relevant health area and element objectives, and the expected results. It should outline the pros and cons of moving ahead with the proposed activity, and the relevant external considerations (including political, diplomatic, and programmatic considerations). The COO's office will convene an intra-agency committee with the appropriate policy, technical, program, and budget personnel to review the request and recommend approval or disapproval.



APPENDICES TO THE

GUIDANCE ON THE DEFINITION AND USE OF THE

GLOBAL HEALTH AND CHILD SURVIVAL ACCOUNT

UPDATE

JANUARY 2009

APPENDICES

<i>APPENDIX I: Excerpts from Relevant Legislation and Congressional Reports</i>	4
<i>APPENDIX II: HIV/AIDS ABC Guidance</i>	33
<i>APPENDIX III: HIV/AIDS Palliative Care Guidance</i>	47
<i>APPENDIX IV: Preventive Care Guidance</i>	66
<i>APPENDIX V: HIV Prevention among Drug Users Guidance</i>	79
<i>APPENDIX VI: Executive Message on President's Malaria Initiative, December 23, 2005</i>	82
<i>APPENDIX VII: Executive Message on Avian Influenza, September 26, 2005</i>	85
<i>APPENDIX VIII: Executive Message on Avian Influenza, November 3, 2005</i>	88
<i>APPENDIX IX: USAID Family Planning Requirements, Statutory and Policy</i>	89
<i>APPENDIX X: Sample Template for Documenting Technical Consultations</i>	93

Relevant Excerpt from Foreign Assistance Act of 1961, as amended

Section 104 (b)

ASSISTANCE FOR POPULATION PLANNING.—In order to increase the opportunities and motivation for family planning and to reduce the rate of population growth, the President is authorized to furnish assistance, on such terms and conditions as he may determine, for voluntary population planning. In addition to the provision of family planning information and services, including also information and services which relate to and support natural family planning methods,¹ and the conduct of directly relevant demographic research, population planning programs shall emphasize motivation for small families.

Section 104 (c)(2)

In carrying out the purposes of this subsection, the President shall promote, encourage, and undertake activities designed to deal directly with the special health needs of children and mothers. Such activities should utilize simple, available technologies that can significantly reduce childhood mortality, such as improved and expanded immunization programs, oral rehydration to combat diarrheal diseases, and education programs aimed at improving nutrition and sanitation and at promoting child spacing. In carrying out this paragraph, guidance shall be sought from knowledgeable health professionals from outside the Agency primarily responsible for administering this part. In addition to government-to-government programs, activities pursuant to this paragraph should include support for appropriate activities of the types described in this paragraph which are carried out by international organizations (which may include international organizations receiving funds under chapter 3 of this part) and by private and voluntary organizations, and should include encouragement to other donors to support such types of activities.

Section 104A (c)(1)

(c) AUTHORIZATION.—

(1) IN GENERAL.—Consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for HIV/AIDS, including to prevent, treat, and monitor HIV/AIDS, and carry out related activities, in countries in sub-Saharan Africa, the Caribbean, and other countries and areas.

Section 104B (c)

(c) AUTHORIZATION.—To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of tuberculosis.

Section 104C (c)

(c) AUTHORIZATION.—To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of malaria.

**Appropriations Act, 2008
DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED
PROGRAMS APPROPRIATIONS ACT, 2008**

As noted below, the FY 2008 Appropriations language defines the Global Health and Child Survival Account and delineates notwithstanding provisions.

[Excerpt 1]

For necessary expenses to carry out the provisions of chapters 1 and 10 of part I of the Foreign Assistance Act of 1961, for global health activities, in addition to funds otherwise available for such purposes, \$1,843,150,000, to remain available until September 30, 2009, and which shall be apportioned directly to the United States Agency for International Development: Provided, That this amount shall be made available for such activities as: (1) child survival and maternal health programs; (2) immunization and oral rehydration programs; (3) other health, nutrition, water and sanitation programs which directly address the needs of mothers and children, and related education programs; (4) assistance for children displaced or orphaned by causes other than AIDS; (5) programs for the prevention, treatment, control of, and research on HIV/AIDS, tuberculosis, polio, malaria, and other infectious diseases, and for assistance to communities severely affected by HIV/AIDS, including children infected or affected by AIDS; and (6) family planning/reproductive health: Provided further, That none of the funds appropriated under this paragraph may be made available for nonproject assistance, except that funds may be made available for such assistance for ongoing health activities: Provided further, That of the funds appropriated under this paragraph, not to exceed \$350,000, in addition to funds otherwise available for such purposes, may be used to monitor and provide oversight of child survival, maternal and family planning/reproductive health, and infectious disease programs: Provided further, That of the funds appropriated under this paragraph the following amounts should be allocated as follows: \$450,150,000 for child survival and maternal health; \$15,000,000 for vulnerable children; \$350,000,000 for HIV/AIDS; \$633,000,000 for other infectious diseases, including \$153,000,000 for tuberculosis control, of which \$15,000,000 shall be used for the Global TB Drug Facility; and \$395,000,000 for family planning/reproductive health, including in areas where population growth threatens biodiversity or endangered species: Provided further, That of the funds appropriated under this paragraph, \$72,500,000 should be made available for a United States contribution to The GAVI Fund, and up to \$6,000,000 may be transferred to and merged with funds appropriated by this Act under the heading "Operating Expenses of the United States Agency for International Development" for costs directly related to global health, but funds made available for such costs may not be derived from amounts made available for contribution under this and preceding provisions. Provided further, That of the funds appropriated under this paragraph, \$115,000,000 shall be made available to combat avian influenza, of which

\$15,000,000 shall be made available, notwithstanding any other provision of law except section 551 of Public Law 109-102, to enhance the preparedness of militaries in Asia and Africa to respond to an avian influenza pandemic, subject to the regular notification procedures of the Committees on Appropriations: Provided further, That none of the funds made available in this Act nor any unobligated balances from prior appropriations may be made available to any organization or program which, as determined by the President of the United States, supports or participates in the management of a program of coercive abortion or involuntary sterilization: Provided further, That any determination made under the previous proviso must be made no later than six months after the date of enactment of this Act, and must be accompanied by a comprehensive analysis as well as the complete evidence and criteria utilized to make the determination: Provided further, That none of the funds made available under this Act may be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions: Provided further, That nothing in this paragraph shall be construed to alter any existing statutory prohibitions against abortion under section 104 of the Foreign Assistance Act of 1961: Provided further, That none of the funds made available under this Act may be used to lobby for or against abortion: Provided further, That in order to reduce reliance on abortion in developing nations, funds shall be available only to voluntary family planning projects which offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services; and that any such voluntary family planning project shall meet the following requirements: (1) service providers or referral agents in the project shall not implement or be subject to quotas, or other numerical targets, of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning (this provision shall not be construed to include the use of quantitative estimates or indicators for budgeting and planning purposes); (2) the project shall not include payment of incentives, bribes, gratuities, or financial reward to: (A) an individual in exchange for becoming a family planning acceptor; or (B) program personnel for achieving a numerical target or quota of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning; (3) the project shall not deny any right or benefit, including the right of access to participate in any program of general welfare or the right of access to health care, as a consequence of any individual's decision not to accept family planning services; (4) the project shall provide family planning acceptors comprehensible information on the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method; and (5) the project shall ensure that experimental contraceptive drugs and devices and medical procedures are provided only in the context of a scientific study in which participants are advised of potential risks and benefits; and, not less than 60 days after the date on which the Administrator of the United States Agency for International Development determines that there has been a violation of the requirements contained in paragraph (1), (2), (3), or (5) of this proviso, or a pattern or practice of violations of the requirements contained in paragraph (4) of this proviso, the Administrator shall submit to the Committees on Appropriations a report containing a description of such violation and the corrective action taken by the Agency: Provided further, That in awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant's religious or conscientious commitment to offer only natural family planning; and, additionally, all such applicants shall comply with the requirements of the previous proviso: Provided further, That for purposes of this or any other Act authorizing or appropriating funds

for foreign operations, export financing, and related programs, the term "motivate", as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options: Provided further, That to the maximum extent feasible, taking into consideration cost, timely availability, and best health practices, funds appropriated in this Act or prior appropriations Acts that are made available for condom procurement shall be made available only for the procurement of condoms manufactured in the United States: Provided further, That information provided about the use of condoms as part of projects or activities that are funded from amounts appropriated by this Act shall be medically accurate and shall include the public health benefits and failure rates of such use: Provided further, That of the amount provided by this paragraph, \$115,000,000 is designated as described in section 5 (in the matter preceding division A of this consolidated Act).

In addition, for necessary expenses to carry out the provisions of the Foreign Assistance Act of 1961 for the prevention, treatment, and control of, and research on, HIV/AIDS, \$4,700,000,000, to remain available until expended, and which shall be apportioned directly to the Department of State: Provided, That of the funds appropriated under this paragraph, \$550,000,000 shall be made available, notwithstanding any other provision of law, except for the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (Public Law 108-25) for a United States contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria, and shall be expended at the minimum rate necessary to make timely payment for projects and activities: Provided further, That up to 5 percent of the aggregate amount of funds made available to the Global Fund in fiscal year 2008 may be made available to the United States Agency for International Development for technical assistance related to the activities of the Global Fund: Provided further, That of the funds appropriated under this paragraph, up to \$13,000,000 may be made available, in addition to amounts otherwise available for such purposes, for administrative expenses of the Office of the Global AIDS Coordinator: Provided further, That funds made available under this heading shall be made available notwithstanding the second sentence of section 403(a) of Public Law 108-25.

[Excerpt 2]

GLOBAL HEALTH AND CHILD SURVIVAL ACTIVITIES

SEC. 622. Up to \$13,500,000 of the funds made available by this Act in title III for assistance under the heading "Global Health and Child Survival", may be used to reimburse United States Government agencies, agencies of State governments, institutions of higher learning, and private and voluntary organizations for the full cost of individuals (including for the personal services of such individuals) detailed or assigned to, or contracted by, as the case may be, the United States Agency for International Development for the purpose of carrying out activities under that heading: Provided, That up to \$3,500,000 of the funds made available by this Act for assistance under the heading "Development Assistance" may be used to reimburse such agencies, institutions, and organizations for such costs of such individuals carrying out other development assistance activities: Provided further, That funds appropriated by titles III and IV of this Act that are made available for bilateral assistance for child survival activities or disease programs including activities relating to research on, and the prevention, treatment and control of,

HIV/AIDS may be made available notwithstanding any other provision of law except for the provisions under the heading "Global Health and Child Survival" and the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (117 Stat. 711; 22 U.S.C. 7601 et seq.), as amended: Provided further, That of the funds appropriated under title III of this Act, not less than \$461,000,000 shall be made available for family planning/reproductive health.

[Excerpt 3]

SEC. 634

(c) PERSONAL SERVICES CONTRACTORS.-Funds appropriated by this Act to carry out chapter 1 of part I, chapter 4 of part II, and section 667 of the Foreign Assistance Act of 1961, and title II of the Agricultural Trade Development and Assistance Act of 1954, may be used by the United States Agency for International Development to employ up to personal services contractors in the United States, notwithstanding any other provision of law, for the purpose of providing direct, interim support for new or expanded overseas programs and activities managed by the agency until permanent direct hire personnel are hired and trained: Provided, That not more than 10 of such contractors shall be assigned to any bureau or office: Provided further, That such funds appropriated to carry out title II of the Agricultural Trade Development and Assistance Act of 1954, may be made available only for personal services contractors assigned to the Office of Food for Peace.

[Excerpt 4]

PROHIBITION OF PAYMENT OF CERTAIN EXPENSES

SEC. 648. None of the funds appropriated or otherwise made available under titles III or IV of this Act under the heading "International Military Education and Training" or "Foreign Military Financing Program" for Informational Program activities or under the headings "Global Health and Child Survival", "Development Assistance", and "Economic Support Fund" may be obligated or expended to pay for

- (1) alcoholic beverages; or
- (2) entertainment expenses for activities that are substantially of a recreational character, including but not limited to entrance fees at sporting events, theatrical and musical productions, and amusement parks.

Joint Resolution, Making further continuing appropriations for the fiscal year 2007, and for other purposes, H. J. Res. 20

CHAPTER 4—FOREIGN OPERATIONS, EXPORT FINANCING, AND RELATED PROGRAMS

SEC. 20403. Notwithstanding section 101, the level for each of the following accounts shall be as follows: 'Bilateral Economic Assistance, Department of State, Global HIV/AIDS Initiative', \$3,246,500,000, of which \$377,500,000 shall be made available, notwithstanding any other

provision of law, except for the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108–25) for a United States contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria; and ‘Bilateral Economic Assistance, Funds Appropriated to the President, United States Agency for International Development, Child Survival and Health Programs Fund’, \$1,718,150,000, of which \$248,000,000 shall be made available for programs and activities to combat malaria.

**Appropriations Act, 2006
FOREIGN OPERATIONS, EXPORT FINANCING,
AND RELATED PROGRAMS APPROPRIATIONS ACT, 2006**

As noted below, the FY 2006 Appropriations language defines the Child Survival and Health (CSH) Programs Fund (Account) and delineates notwithstanding provisions.

[Excerpt 1]

For necessary expenses to carry out the provisions of chapters 1 and 10 of part I of the Foreign Assistance Act of 1961, for child survival, health, and family planning/reproductive health activities, in addition to funds otherwise available for such purposes, \$1,585,000,000, to remain available until September 30, 2007: Provided, That this amount shall be made available for such activities as: (1) immunization programs; (2) oral rehydration programs; (3) health, nutrition, water and sanitation programs which directly address the needs of mothers and children, and related education programs; (4) assistance for children displaced or orphaned by causes other than AIDS; (5) programs for the prevention, treatment, control of, and research on HIV/AIDS, tuberculosis, polio, malaria, and other infectious diseases, and for assistance to communities severely affected by HIV/AIDS, including children displaced or orphaned by AIDS; and (6) family planning/reproductive health: Provided further, That none of the funds appropriated under this heading may be made available for nonproject assistance, except that funds may be made available for such assistance for ongoing health activities: Provided further, That of the funds appropriated under this heading, not to exceed \$350,000, in addition to funds otherwise available for such purposes, may be used to monitor and provide oversight of child survival, maternal and family planning/reproductive health, and infectious disease programs: Provided further, That the following amounts should be allocated as follows: \$360,000,000 for child survival and maternal health; \$30,000,000 for vulnerable children; \$350,000,000 for HIV/AIDS; \$220,000,000 for other infectious diseases; and \$375,000,000 for family planning/reproductive health, including in areas where population growth threatens biodiversity or endangered species: Provided further, That of the funds appropriated under this heading, and in addition to funds allocated under the previous proviso, not less than \$250,000,000 shall be made available, notwithstanding any other provision of law, except for the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (Public Law 108-25), for a United States contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (the ‘Global Fund’), and shall be expended at the minimum rate necessary to make timely payment for projects and activities: Provided further, That up to 5 percent of the aggregate amount of funds made available to the Global Fund in fiscal year 2006 may be made available to the United States Agency for International

Development for technical assistance related to the activities of the Global Fund: Provided further, That of the funds appropriated under this heading, \$70,000,000 should be made available for a United States contribution to The Vaccine Fund, and up to \$6,000,000 may be transferred to and merged with funds appropriated by this Act under the heading `Operating Expenses of the United States Agency for International Development' for costs directly related to international health, but funds made available for such costs may not be derived from amounts made available for contribution under this and preceding provisos

[Excerpt 2]

UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT HIRING AUTHORITY

SEC. 577. (a) **AUTHORITY-** Up to \$75,000,000 of the funds made available in this Act to carry out the provisions of part I of the Foreign Assistance Act of 1961, including funds appropriated under the heading `Assistance for Eastern Europe and the Baltic States', may be used by the United States Agency for International Development (USAID) to hire and employ individuals in the United States and overseas on a limited appointment basis pursuant to the authority of sections 308 and 309 of the Foreign Service Act of 1980.

(b) **RESTRICTIONS-**

(1) The number of individuals hired in any fiscal year pursuant to the authority contained in subsection (a) may not exceed 175.

(2) The authority to hire individuals contained in subsection (a) shall expire on September 30, 2008.

(c) **CONDITIONS-** The authority of subsection (a) may only be used to the extent that an equivalent number of positions that are filled by personal services contractors or other nondirect-hire employees of USAID, who are compensated with funds appropriated to carry out part I of the Foreign Assistance Act of 1961, including funds appropriated under the heading `Assistance for Eastern Europe and the Baltic States', are eliminated.

(d) **PRIORITY SECTORS-** In exercising the authority of this section, primary emphasis shall be placed on enabling USAID to meet personnel positions in technical skill areas currently encumbered by contractor or other nondirect-hire personnel.

(e) **CONSULTATIONS-** The USAID Administrator shall consult with the Committees on Appropriations at least on a quarterly basis concerning the implementation of this section.

(f) **PROGRAM ACCOUNT CHARGED-** The account charged for the cost of an individual hired and employed under the authority of this section shall be the account to which such individual's responsibilities primarily relate. Funds made available to carry out this section may be transferred to and merged and consolidated with funds appropriated for `Operating Expenses of the United States Agency for International Development'.

(g) **MANAGEMENT REFORM PILOT-** Of the funds made available in subsection (a), USAID may use, in addition to funds otherwise available for such purposes, up to \$10,000,000 to fund overseas support costs of members of the Foreign Service with a Foreign Service rank of four or below: Provided, That such authority is only used to reduce USAID's reliance on overseas personal services contractors or other nondirect-hire employees compensated with funds appropriated to carry out part I of the Foreign Assistance Act of 1961, including funds appropriated under the heading `Assistance for Eastern Europe and the Baltic States'.

(h) DISASTER SURGE CAPACITY- Funds appropriated by this Act to carry out part I of the Foreign Assistance Act of 1961, including funds appropriated under the heading 'Assistance for Eastern Europe and the Baltic States', may be used, in addition to funds otherwise available for such purposes, for the cost (including the support costs) of individuals detailed to or employed by the United States Agency for International Development whose primary responsibility is to carry out programs in response to natural disasters.

**Relevant Excerpt From House Report 107-142 on the
Child Survival and Health Programs Fund**

**DEFINITION OF THE BUDGET CATEGORIES WITHIN THE CHILD SURVIVAL
AND HEALTH PROGRAMS FUND**

In order to clarify the range of activities categorized in the above allocations, the Committee, in consultation with AID, provides the following explanation:

1) CHILD SURVIVAL AND MATERNAL HEALTH

Primary causes of morbidity and mortality for children and mothers

- Supporting key child health and survival interventions that focus on prevention, treatment, and control of the five primary childhood killers: diarrheal disease, acute respiratory infection, malnutrition, malaria (directed primarily at children) and vaccine preventable diseases;
- Introducing environmental health interventions to prevent the spread of childhood diseases from environmental factors such as contaminated water; and
- Improving maternal health to protect the outcome of pregnancy, neonatal and young infants, and to save the lives of mothers, by improving maternal nutrition, promoting birth preparedness, improving safe delivery and postpartum care, and managing and treating life-threatening complications of pregnancy and childbirth.

Micronutrients

- Supplementing, fortifying and modifying dietary behaviors to increase intake of key micronutrients, particularly vitamin A, iron, iodine, folic acid, and zinc.

Polio eradication

- Partnering to strengthen polio eradication and vaccination programs;
- Supplemental polio immunization campaigns and improving routine immunization; and
- Improving acute flaccid paralysis surveillance, response and linkages with other disease control programs.

2) VULNERABLE CHILDREN

Care and protection of children who are displaced or vulnerable with an emphasis on strengthening family and community capacity in identifying and responding to special physical, social, educational, and emotional needs including:

- [Other accounts (e.g., Development Assistance and Economic Support Fund) support programs addressing the issues of children affected by violence and/or trafficked for illicit purposes.]
- Under the Displaced Children and Orphans Fund, children affected by war, including child soldiers, as well as orphaned, abandoned and street children;
- Blind children;
- Orphanages in Europe and Eurasia;
- Trafficking of young women and children; and
- Abusive child labor.

3) HIV/AIDS

Prevention

- Expanding behavior change interventions to prevent and mitigate the impact of HIV/AIDS;
- Preventing and managing sexually transmitted diseases (STDs);
- Preventing and managing TB and other opportunistic diseases related to HIV/AIDS; and
- Reducing mother-to-child transmission of HIV/AIDS.

Care and Treatment

- Increasing the capacity of public and private sector organizations, particularly at the home and community level, to prevent HIV transmission and support persons living with HIV/AIDS, their caregivers, families and survivors;
- Treating opportunistic infections, primarily tuberculosis, in persons living with HIV/AIDS;
- Conducting pilot programs for the care and treatment of persons living with HIV/AIDS;
- Entering into cooperative agreements and parallel financing alliances with the private sector to obtain needed commodities for sustained treatment of persons living with HIV/AIDS; and
- Establishing microcredit programs designed for communities with a high incidence of persons living with HIV/AIDS.
- Caring for infected children, and for communities severely affected by HIV/AIDS.

Surveillance

- Increasing the quality, availability, and use of evaluation and surveillance information.

4) OTHER INFECTIOUS DISEASES

Tuberculosis (TB)

- Improving control of tuberculosis at the country level by expanding the application of the Directly Observed Therapy Short Course (DOTS) strategy and strengthening local capacity;
- Developing and testing alternative approaches for TB control;
- Improving surveillance of TB and of multi-drug resistant TB strains;

- Conducting research to identify improved technologies/methods for TB diagnosis and treatment; and
- Preventing and treating TB in persons with HIV/AIDS and their caregivers.

Malaria

- Improving prevention, control and treatment of malaria and other infectious diseases that are not currently vaccine preventable.

Antimicrobial resistance and infectious diseases surveillance

- Improving interventions to reduce the spread of antimicrobial resistance; and
- Improving capacity for surveillance and response for infectious diseases, including at the local level.

5) REPRODUCTIVE HEALTH/VOLUNTARY FAMILY PLANNING

- Expanding access to, and improving the quality of Family Planning programs;
- Supporting related reproductive health services such as integrating family planning with antenatal, neonatal, and postpartum care, integrating family planning with HIV/AIDS and Sexually Transmissible Disease [STD] programs, eliminating female genital cutting, and supporting post-abortion care;
- Providing information and services for families experiencing difficulty in conceiving children, including programs to treat non-infectious diseases that impede fertility;
- Forecasting, purchasing, and supplying contraceptive commodities and other materials necessary for reproductive health programs; and
- Fostering conditions to create favorable policy environments, improve quality, strengthen systems, and contribute to the sustainability of family planning and other reproductive health programs.

NOTE: Child Survival and Health Programs Funds used for family planning/reproductive health are not to be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions, or to pay for biomedical research which relates to the performance of abortion as a method of family planning (although epidemiological or descriptive research to assess the incidence, extent or consequences of abortions is permitted).

**Relevant Excerpt from the House Report 107-142 on
Promoting the Integrity of the Child Survival Fund**

The Committee expects the current Administrator to appoint a coordinator for all child survival and health programs managed by AID, or, alternatively, to establish a separate bureau to manage central programs, provide technical support to child survival and health programs in the field, and to act as liaison with the Committee on all child survival and health programs and activities managed by AID, regardless of the funding source. ...The Committee is again including bill language that prohibits the use of certain funds in this account for nonproject assistance, or cash grants, to governments. The provision of cash grants as general budget support for governments

is no longer an appropriate development tool, given current funding constraints. To the extent that cash grants are necessary for countries in transition or for specific foreign policy goals, funds are available through the 'Economic Support Fund'.

Excerpts from the United States Leadership Against HIV/AIDS Tuberculosis, and Malaria Act of 2003, as amended by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008

[Excerpt 1]

SEC. 4. PURPOSE.

The purpose of this Act is to strengthen and enhance United States leadership and the effectiveness of the United States response to the HIV/AIDS, tuberculosis, and malaria pandemics and other related and preventable infectious diseases as part of the overall United States health and development agenda by--

(1) establishing comprehensive, coordinated, and integrated 5-year, global strategies to combat HIV/AIDS, tuberculosis, and malaria by—

(A) building on progress and successes to date;

(B) improving harmonization of United States efforts with national strategies of partner governments and other public and private entities; and

(C) emphasizing capacity building initiatives in order to promote a transition toward greater sustainability through the support of country-driven efforts;

(2) providing increased resources for bilateral and multilateral efforts to fight HIV/AIDS, tuberculosis, and malaria as integrated components of United States development assistance;

(3) intensifying efforts to—

(A) prevent HIV infection;

(B) ensure the continued support for, and expanded access to, treatment and care programs;

(C) enhance the effectiveness of prevention, treatment, and care programs; and

(D) address the particular vulnerabilities of girls and women;

(4) encouraging the expansion of private sector efforts and expanding public-private sector partnerships to combat HIV/AIDS, tuberculosis, and malaria;

(5) reinforcing efforts to—

(A) develop safe and effective vaccines, microbicides, and other prevention and treatment technologies; and

(B) improve diagnostics capabilities for HIV/AIDS, tuberculosis, and malaria; and

(6) helping partner countries to--

(A) strengthen health systems;

(B) expand health workforce; and

(C) address infrastructural weaknesses."

[Excerpt 2]

SEC. 102. HIV/AIDS RESPONSE COORDINATOR.

(f) HIV/AIDS RESPONSE COORDINATOR.—

(1) IN GENERAL.—There shall be established within the Department of State in the immediate office of the Secretary of State a Coordinator of United States Government Activities to Combat HIV/AIDS Globally, who shall be appointed by the President, by and with the advice and consent of the Senate. The Coordinator shall report directly to the Secretary.

(2) AUTHORITIES AND DUTIES; DEFINITIONS.—

(A) AUTHORITIES.—The Coordinator, acting through such nongovernmental organizations (including faith-based and community-based organizations) and relevant executive branch agencies as may be necessary and appropriate to effect the purposes of this section, is authorized—

(i) to operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities for combatting HIV/AIDS;

(ii) to transfer and allocate funds to relevant executive branch agencies; and

(iii) to provide grants to, and enter into contracts with, nongovernmental organizations (including faithbased and community-based organizations) to carry out the purposes of section.

(B) DUTIES.—

(i) IN GENERAL.—The Coordinator shall have primary responsibility for the oversight and coordination of all resources and international activities of the United States Government to combat the HIV/AIDS pandemic, including all programs, projects, and activities of the United States Government relating to the HIV/AIDS pandemic under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 or any amendment made by that Act.

(ii) SPECIFIC DUTIES.—The duties of the Coordinator shall specifically include the following:

(I) Ensuring program and policy coordination among the relevant executive branch agencies and nongovernmental organizations, including auditing, monitoring, and evaluation of all such programs.

(II) Ensuring that each relevant executive branch agency undertakes programs primarily in those areas where the agency has the greatest expertise, technical capabilities, and potential for success.

(III) Avoiding duplication of effort.

(IV) Ensuring coordination of relevant executive branch agency activities in the field.

(V) Pursuing coordination with other countries and international organizations.

(VI) Resolving policy, program, and funding disputes among the relevant executive branch agencies. “(VII) Directly approving all activities of the United States (including funding) relating to combatting HIV/AIDS in each of Botswana, Cote d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, and other countries designated by the President, which other designated countries may include those countries in which the United States is implementing HIV/AIDS programs as of the date of the enactment of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003.

(VIII) Establishing due diligence criteria for all recipients of funds section and all

activities subject to the coordination and appropriate monitoring, evaluation, and audits carried out by the Coordinator necessary to assess the measurable outcomes of such activities.

[Excerpt 3]

TITLE III—BILATERAL EFFORTS

SEC. 104A. ASSISTANCE TO COMBAT HIV/AIDS.

(c) Authorization.--

(1) In general.--Consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for HIV/AIDS, including to prevent, treat, and monitor HIV/AIDS, and carry out related activities, in countries in sub-Saharan Africa, the Caribbean, Central Asia, Eastern Europe, Latin America, and other countries and areas, particularly with respect to refugee populations or those in postconflict settings in such countries and areas with significant or increasing HIV incidence rates.

(d) Activities Supported.--Assistance provided under subsection (c) shall, to the maximum extent practicable, be used to carry out the following activities

(1) Prevention.--Prevention of HIV/AIDS through activities including—

(A) 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, including integration of such programs into health programs and the inclusion in counseling programs of information on methods of avoiding infection of HIV, including delaying sexual debut, abstinence, fidelity and monogamy, reduction of casual sexual partnering and multiple concurrent sexual partnering, reducing sexual violence and coercion, including child marriage, widow inheritance, and polygamy, and where appropriate, use of male and female condoms;

(B) assistance to establish and implement culturally appropriate HIV/AIDS education and prevention programs that are designed with local input and focus on helping individuals avoid infection of HIV/AIDS, implemented through nongovernmental organizations, including faith-based and community-based organizations, particularly those locally based organizations that utilize both professionals and volunteers with appropriate skills, experience, and community presence;

(C) assistance for the purpose of encouraging men to be responsible in their sexual behavior, child rearing, and to respect women;

(D) assistance for the purpose of providing voluntary testing and counseling (including the incorporation of confidentiality protections with respect to such testing and counseling) and promoting the use of provider-initiated or ‘opt-out’ voluntary testing in accordance with World Health Organization guidelines;

(E) assistance for the purpose of preventing mother-to-child transmission of the

HIV infection, including medications to prevent such transmission and access to infant formula and other alternatives for infant feeding;

(F) assistance to—

(i) achieve the goal 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

(ii) promote infant feeding options and treatment protocols that meet the most recent criteria established by the World Health Organization;

(G) medical male circumcision programs as part of national strategies to combat the transmission of HIV/AIDS;

(H) assistance to ensure a safe blood supply and sterile medical equipment;

(I) assistance to help avoid substance abuse and intravenous drug use that can lead to HIV infection; and

(J) assistance for the purpose of increasing women's access to employment opportunities, income, productive resources, and microfinance programs, where appropriate.

(K) assistance for counseling, testing, treatment, care, and support programs, including—

(i) counseling and other services for the prevention of reinfection of individuals with HIV/AIDS;

(ii) counseling to prevent sexual transmission of HIV, including—

(I) life skills development for practicing abstinence and faithfulness;

(II) reducing the number of sexual partners;

(III) delaying sexual debut; and

(IV) ensuring correct and consistent use of condoms;

(iii) assistance to engage underlying vulnerabilities to HIV/AIDS, especially those of women and girls;

(iv) assistance for appropriate HIV/AIDS education programs and training targeted to prevent the transmission of HIV among men who have sex with men;

(v) assistance to provide male and female condoms;

(vi) diagnosis and treatment of other sexually transmitted infections;

(vii) strategies to address the stigma and discrimination that impede HIV/AIDS prevention efforts; and

(viii) assistance to facilitate widespread access to microbicides for HIV prevention, if safe and effective products become available, including financial and technical support for culturally appropriate introductory programs, procurement, distribution, logistics management, program delivery, acceptability studies, provider training, demand generation, and postintroduction monitoring.”

(2) Treatment.--The treatment and care of individuals with HIV/AIDS, including—

(A) assistance to establish and implement programs to strengthen and broaden indigenous health care delivery systems and the capacity of such systems to

deliver HIV/AIDS pharmaceuticals and otherwise provide for the treatment of individuals with HIV/AIDS, including clinical training for indigenous organizations and health care providers;

(B) assistance to strengthen and expand hospice and palliative care programs to assist patients debilitated by HIV/AIDS, their families, and the primary caregivers of such patients, including programs that utilize faith-based and community-based organizations;

(C) assistance for the purpose of the care and treatment of individuals with HIV/AIDS through the provision of pharmaceuticals, including antiretrovirals and other pharmaceuticals and therapies for the treatment of opportunistic infections, pain management, nutritional support, and other treatment modalities.;

(D) as part of care and treatment of HIV/AIDS, assistance (including prophylaxis and treatment) for common HIV/AIDS-related opportunistic infections for free or at a rate at which it is easily affordable to the individuals and populations being served;

(E) as part of care and treatment of HIV/AIDS, assistance or referral to available and adequately resourced service providers for nutritional support, including counseling and where necessary the provision of commodities, for persons meeting malnourishment criteria and their families;

(3) Preventative intervention education and technologies.—

(A) With particular emphasis on specific populations that represent a particularly high risk of contracting or spreading HIV/AIDS, including those exploited through the sex trade, victims of rape and sexual assault, individuals already infected with HIV/AIDS, and in cases of occupational exposure of health care workers, assistance with efforts to reduce the risk of HIV/AIDS infection including post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(B) Bulk purchases of available test kits, condoms, and, when proven effective, microbicides that are intended to reduce the risk of HIV/AIDS transmission and for appropriate program support for the introduction and distribution of these commodities, as well as education and training on the use of the technologies.

(4) Monitoring.--The monitoring of programs, projects, and activities carried out pursuant to paragraphs (1) through (3), including—

(A) monitoring to ensure that adequate controls are established and implemented to provide HIV/AIDS pharmaceuticals and other appropriate medicines to poor individuals with HIV/AIDS;

(B) appropriate evaluation and surveillance activities;

(C) monitoring to ensure that appropriate measures are being taken to maintain the sustainability of HIV/AIDS pharmaceuticals (especially antiretrovirals) and ensure that drug resistance is not compromising the benefits of such pharmaceuticals;

(D) monitoring to ensure appropriate law enforcement officials are working to ensure that HIV/AIDS pharmaceuticals are not diminished through illegal counterfeiting or black market sales of such pharmaceuticals.;

(E) carrying out and expanding program monitoring, impact evaluation research and analysis, and operations research and disseminating data and findings through mechanisms to be developed by the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, in coordination with the Director of the Centers for Disease Control, in order to—

- (i) improve accountability, increase transparency, and ensure the delivery of evidence-based services through the collection, evaluation, and analysis of data regarding gender-responsive interventions, disaggregated by age and sex;
- (ii) identify and replicate effective models; and
- (iii) develop gender indicators to measure outcomes and the impacts of interventions; and

(F) establishing appropriate systems to—

- (i) gather epidemiological and social science data on HIV; and
- (ii) evaluate the effectiveness of prevention efforts among men who have sex with men, with due consideration to stigma and risks associated with disclosure.

(5) Pharmaceuticals.—

(A) Procurement.--The procurement of HIV/AIDS pharmaceuticals, antiviral therapies, and other appropriate medicines, including medicines to treat opportunistic infections.

(B) Mechanisms for quality control and sustainable supply.--Mechanisms to ensure that such HIV/AIDS pharmaceuticals, antiretroviral therapies, and other appropriate medicines are quality-controlled and sustainably supplied.

(C) Mechanism to ensure cost-effective drug purchasing.—Subject to subparagraph (B), mechanisms to ensure that safe and effective pharmaceuticals, including antiretrovirals and medicines to treat opportunistic infections, are purchased at the lowest possible price at which such pharmaceuticals may be obtained in sufficient quantity on the world market, provided that such pharmaceuticals are approved, tentatively approved, or otherwise authorized for use by—

- (i) the Food and Drug Administration;
- (ii) a stringent regulatory agency acceptable to the Secretary of Health and Human Services; or
- (iii) a quality assurance mechanism acceptable to the Secretary of Health and Human Services.

(D) Distribution.--The distribution of such HIV/AIDS pharmaceuticals, antiviral therapies, and other appropriate medicines (including medicines to treat opportunistic infections) to qualified national, regional, or local organizations for the treatment of individuals with HIV/AIDS in accordance with appropriate HIV/AIDS testing and monitoring requirements and treatment protocols and for the prevention of mother-to-child transmission of the HIV infection.

(6) Related and coordinated activities.--The conduct of related activities, including—

(A) the care and support of children who are orphaned by the HIV/AIDS pandemic, including services designed to care for orphaned children in a family environment which rely on extended family members;

(B) improved infrastructure and institutional capacity to develop and manage education, prevention, and treatment programs, including training and the resources to collect and maintain accurate HIV surveillance data to target programs and measure the effectiveness of interventions; and

(C) vaccine research and development partnership programs with specific plans of action to develop a safe, effective, accessible, preventive HIV vaccine for use throughout the world.;

(D) coordinated or referred activities to—

- (i) enhance the clinical impact of HIV/AIDS care and treatment; and
- (ii) ameliorate the adverse social and economic costs often affecting AIDS-impacted families and communities through the direct provision, as necessary, or through the referral, if possible, of support services, including—
 - (I) nutritional and food support;
 - (II) safe drinking water and adequate sanitation;
 - (III) nutritional counseling;
 - (IV) income-generating activities and livelihood initiatives;
 - (V) maternal and child health care;
 - (VI) primary health care;
 - (VII) the diagnosis and treatment of other infectious or sexually transmitted diseases;
 - (VIII) substance abuse and treatment services; and
 - (IX) legal services;

(E) coordinated or referred activities to link programs addressing HIV/AIDS with programs addressing gender-based violence in areas of significant HIV

prevalence to assist countries in the development and enforcement of women's health, children's health, and HIV/AIDS laws and policies that—

- (i) prevent and respond to violence against women and girls;
- (ii) promote the integration of screening and assessment for gender-based violence into HIV/AIDS programming;
- (iii) promote appropriate HIV/AIDS counseling, testing, and treatment into gender-based violence programs; and
- (iv) assist governments to develop partnerships with civil society organizations to create networks for psychosocial, legal, economic, or other support services;

(F) coordinated or referred activities to—

- (i) address the frequent coinfection of HIV and tuberculosis, in accordance with World Health Organization guidelines;
- (ii) promote provider-initiated or 'opt-out' HIV/AIDS counseling and testing and appropriate referral for treatment and care to individuals with tuberculosis or its symptoms, particularly in areas with significant HIV prevalence; and
- (iii) strengthen programs to ensure that individuals testing positive for HIV receive tuberculosis screening and to improve laboratory capacities, infection control, and adherence; and

(G) activities to—

- (i) improve the effectiveness of national responses to HIV/AIDS;
- (ii) 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; and
- (iii) encourage fair and transparent procurement practices among partner countries; and
- (iv) promote in-country or intra-regional pediatric training for physicians and other health professionals, preferably through public-private partnerships involving colleges and universities, with the goal of increasing pediatric HIV workforce capacity.

(7) Comprehensive hiv/aids public-private partnerships.—The establishment and operation of public-private partnership entities within countries in sub-Saharan Africa, the Caribbean, and other countries affected by the HIV/AIDS pandemic that are dedicated to supporting the national strategy of such countries regarding the prevention, treatment, and monitoring of HIV/AIDS. Each such public-private partnership should-

(A) support the development, implementation, and management of comprehensive HIV/AIDS plans in support of the national HIV/AIDS strategy;

(B) operate at all times in a manner that emphasizes efficiency, accountability,

and results-driven programs;

(C) engage both local and foreign development partners and donors, including businesses, government agencies, academic institutions, nongovernmental organizations, foundations, multilateral development agencies, and faith-based organizations, to assist the country in coordinating and implementing HIV/AIDS prevention, treatment, and monitoring programs in accordance with its national HIV/AIDS strategy;

(D) provide technical assistance, consultant services, financial planning, monitoring and evaluation, and research in support of the national HIV/AIDS strategy; and

(E) establish local human resource capacities for the national HIV/AIDS strategy through the transfer of medical, managerial, leadership, and technical skills.

(8) Compacts and framework agreements.—The development of compacts or framework agreements, tailored to local circumstances, with national governments or regional partnerships in countries with significant HIV/AIDS burdens to promote host government commitment to deeper integration of HIV/AIDS services into health systems, contribute to health systems overall, and enhance sustainability, including—

(A) cost sharing assurances that meet the requirements under section 110; and

(B) 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.

[Excerpt 4]

(e) LIMITATION.—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. Nothing in the preceding sentence shall 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.

(f) LIMITATION.—No funds made available to carry out this Act, or any amendment made by this Act, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.

[Excerpt 5]

SEC. 302. ASSISTANCE TO COMBAT TUBERCULOSIS.

(a) Amendment of the Foreign Assistance Act of 1961.—Chapter 1 of part I of the Foreign Assistance Act of 1961 (22 U.S.C. 2151 et seq.), as amended by section 301 of this Act, is

further amended by inserting after section 104A the following new section:

SEC. 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.

(a) Findings.--Congress makes the following findings:

(1) Congress recognizes the growing international problem of tuberculosis and the impact its continued existence has on those countries that had previously largely controlled the disease.

(2) Congress further recognizes that the means exist to control and treat tuberculosis through expanded use of the DOTS (Directly Observed Treatment Short-course) treatment strategy, including DOTS-Plus to address multi-drug resistant tuberculosis, and adequate investment in newly created mechanisms to increase access to treatment, including the Global Tuberculosis Drug Facility established in 2001 pursuant to the Amsterdam Declaration to Stop TB and the Global Alliance for TB Drug Development.

(b) Policy.—It is a major objective of the foreign assistance program of the United States to control tuberculosis. In all countries in which the Government of the United States has established development programs, particularly in countries with the highest burden of tuberculosis and other countries with high rates of tuberculosis, the United States should support the objectives of the Global Plan to Stop TB, including through achievement of the following goals:

(1) Reduce by half the tuberculosis death and disease burden from the 1990 baseline.

(2) Sustain or exceed the detection of at least 70 percent of sputum smear-positive cases of tuberculosis and the successful treatment of at least 85 percent of the cases detected in countries with established United States Agency for International Development tuberculosis programs.

(3) In support of the Global Plan to Stop TB, the President shall establish a comprehensive, 5-year United States strategy to expand and improve United States efforts to combat tuberculosis globally, including a plan to support—

(A) the successful treatment of 4,500,000 new sputum smear tuberculosis patients under DOTS programs by 2013, primarily through direct support for needed services, commodities, health workers, and training, and additional treatment through coordinated multilateral efforts; and

(B) the diagnosis and treatment of 90,000 new multiple drug resistant tuberculosis cases by 2013, and additional treatment through coordinated multilateral efforts.

(c) Authorization.--To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of tuberculosis.

(d) Coordination.--In carrying out this section, the President shall coordinate with the World

Health Organization, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and other organizations with respect to the development and implementation of a comprehensive tuberculosis control program.

(e) Priority To Stop TB Strategy.—In furnishing assistance under subsection (c), the President shall give priority to—

(1) direct services described in the Stop TB Strategy, including expansion and enhancement of Directly Observed Treatment Short-course (DOTS) coverage, rapid testing, treatment for individuals infected with both tuberculosis and HIV, and treatment for individuals with multi-drug resistant tuberculosis (MDR–TB), strengthening of health systems, use of the International Standards for Tuberculosis Care by all providers, empowering individuals with tuberculosis, and enabling and promoting research to develop new diagnostics, drugs, and vaccines, and program-based operational research relating to tuberculosis; and

(2) funding for the Global Tuberculosis Drug Facility, the Stop Tuberculosis Partnership, and the Global Alliance for TB Drug Development.”.

(f) Assistance for the World Health Organization and the Stop Tuberculosis Partnership.—In carrying out this section, the President, acting through the Administrator of the United States Agency for International Development, is authorized to provide increased resources to the World Health Organization and the Stop Tuberculosis Partnership to improve the capacity of countries with high rates of tuberculosis and other affected countries to implement the Stop TB Strategy and specific strategies related to addressing multiple drug resistant tuberculosis (MDR–TB) and extensively drug resistant tuberculosis (XDR–TB).

(g) Annual report.—The President shall submit an annual report to Congress that describes the impact of United States foreign assistance on efforts to control tuberculosis, including—

(1) the number of tuberculosis cases diagnosed and the number of cases cured in countries receiving United States bilateral foreign assistance for tuberculosis control purposes;

(2) a description of activities supported with United States tuberculosis resources in each country, including a description of how those activities specifically contribute to increasing the number of people diagnosed and treated for tuberculosis;

(3) in each country receiving bilateral United States foreign assistance for tuberculosis control purposes, the percentage provided for direct tuberculosis services in countries receiving United States bilateral foreign assistance for tuberculosis control purposes;

(4) a description of research efforts and clinical trials to develop new tools to combat tuberculosis, including diagnostics, drugs, and vaccines supported by United States bilateral assistance;

(5) the number of persons who have been diagnosed and started treatment for multidrug-resistant tuberculosis in countries receiving United States bilateral foreign assistance for tuberculosis control programs;

(6) a description of the collaboration and coordination of United States anti-tuberculosis efforts with the World Health Organization, the Global Fund, and other major public and private entities within the Stop TB Strategy;

(7) the constraints on implementation of programs posed by health workforce shortages and capacities;

(8) the number of people trained in tuberculosis control; and

(9) a breakdown of expenditures for direct patient tuberculosis services, drugs and other commodities, drug management, training in diagnosis and treatment, health systems strengthening, research, and support costs

(h) Definitions.--In this section:

(1) DOTS.--The term 'DOTS' or 'Directly Observed Treatment Short-course' means the World Health Organization-recommended strategy for treating tuberculosis. including—

- (A) low-cost and effective diagnosis, treatment, and monitoring of tuberculosis;
- (B) a reliable drug supply;
- (C) a management strategy for public health systems;
- (D) health system strengthening;
- (E) promotion of the use of the International Standards for Tuberculosis Care by all care providers;
- (F) bacteriology under an external quality assessment framework;
- (G) short-course chemotherapy; and
- (H) sound reporting and recording systems.

(2) DOTS-plus.--The term 'DOTS-Plus' means a comprehensive tuberculosis management strategy that is built upon and works as a supplement to the standard DOTS strategy, and which takes into account specific issues (such as use of second line anti-tuberculosis drugs) that need to be addressed in areas where there is high prevalence of multi-drug resistant tuberculosis.

(3) Global alliance for tuberculosis drug development.--The term 'Global Alliance for Tuberculosis Drug Development' means the public-private partnership that brings together leaders in health, science, philanthropy, and private industry to devise new approaches to tuberculosis and to ensure that new medications are available and affordable in high tuberculosis burden countries and other affected countries.

(4) Global tuberculosis drug facility.--The term 'Global Tuberculosis Drug Facility (GDF)' means the new initiative of the Stop Tuberculosis Partnership to increase access to high-

quality tuberculosis drugs to facilitate DOTS expansion.

(5) Stop TB strategy.—The term ‘Stop TB Strategy’ means the 6-point strategy to reduce tuberculosis developed by the World Health Organization, which is described in the Global Plan to Stop TB 2006–2015: Actions for Life, a comprehensive plan developed by the Stop TB Partnership that sets out the actions necessary to achieve the millennium development goal of cutting tuberculosis deaths and disease burden in half by 2015.

(6) Stop tuberculosis partnership.--The term ‘Stop Tuberculosis Partnership’ means the partnership of the World Health Organization, donors including the United States, high tuberculosis burden countries, multilateral agencies, and nongovernmental and technical agencies committed to short- and long-term measures required to control and eventually eliminate tuberculosis as a public health problem in the world.’

(b) Authorization of Appropriations.—

(1) In general.--In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, a total of \$4,000,000,000 for the 5-year period beginning on October 1, 2008 to carry out section 104B of the Foreign Assistance Act of 1961, as added by subsection (a).

(2) Availability of funds.--Amounts appropriated pursuant to the authorization of appropriations under paragraph (1) are authorized to remain available until expended.

(3) Transfer of prior year funds.--Unobligated balances of funds made available for fiscal year 2001, 2002, or 2003 under section 104(c)(7) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)(7) (as in effect immediately before the date of enactment of this Act) shall be transferred to, merged with, and made available for the same purposes as funds made available for fiscal years 2009 through 2013 under paragraph (1).

[Excerpt 6]

SEC. 303. ASSISTANCE TO COMBAT MALARIA.

(a) Amendment of the Foreign Assistance Act of 1961.--Chapter 1 of part I of the Foreign Assistance Act of 1961 (22 U.S.C. 2151 et seq.), as amended by sections 301 and 302 of this Act, is further amended by inserting after section 104B the following new section:

SEC. 104C. ASSISTANCE TO COMBAT MALARIA.

(a) Finding.--Congress finds that malaria kills more people annually than any other communicable disease except tuberculosis, that more than 90 percent of all malaria cases are in sub-Saharan Africa, and that children and women are particularly at risk. Congress recognizes that there are cost-effective tools to decrease the spread of malaria and that malaria is a curable disease if promptly diagnosed and adequately treated.

(b) Policy.--It is a major objective of the foreign assistance program of the United States to

provide assistance for the prevention, control, treatment and cure of malaria.

(c) Authorization.--To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of malaria.

(d) Coordination.--In carrying out this section, the President shall coordinate with the World Health Organization, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the Department of Health and Human Services (the Centers for Disease Control and Prevention and the National Institutes of Health), and other organizations with respect to the development and implementation of a comprehensive malaria control program."

(b) Authorization of Appropriations.—

(1) In general.--In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, \$5,000,000,000 during the 5-year period beginning on October 1, 2008 to carry out section 104C of the Foreign Assistance Act of 1961, as added by subsection (a), including for the development of anti-malarial pharmaceuticals by the Medicines for Malaria Venture.

(2) Availability of funds.--Amounts appropriated pursuant to paragraph (1) are authorized to remain available until expended.

(3) Transfer of prior year funds.--Unobligated balances of funds made available for fiscal year 2001, 2002, or 2003 under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) (as in effect immediately before the date of enactment of this Act) and made available for the control of malaria shall be transferred to, merged with, and made available for the same purposes as funds made available for fiscal years 2009 through 2013 under paragraph (1).

(c) Conforming Amendment.--Section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)), as amended by section 301 of this Act, is further amended by adding after paragraph (3) the following:

(4) Relationship to other laws.--Assistance made available under this subsection and sections 104A, 104B, and 104C, and assistance made available under chapter 4 of part II to carry out the purposes of this subsection and the provisions cited in this paragraph, may be made available notwithstanding any other provision of law that restricts assistance to foreign countries, except for the provisions of this subsection, the provisions of law cited in this paragraph, subsection (f), section 634A of this Act, and provisions of law that limit assistance to organizations that support or participate in a program of coercive abortion or involuntary sterilization included under the Child Survival and Health Programs Fund heading in the Consolidated Appropriations Resolution, 2003 (Public Law 108-7)."

(c) Statement of policy.—Providing assistance for the prevention, control, treatment, and the ultimate eradication of malaria is—

(1) a major objective of the foreign assistance program of the United States; an

(2) 1 component of a comprehensive United States global health strategy to reduce disease burdens and strengthen communities around the world.

(d) Development of a Comprehensive 5-Year Strategy.—The President shall establish a comprehensive, 5-year strategy to combat global malaria that—

(1) strengthens the capacity of the United States to be an effective leader of international efforts to reduce malaria burden;

(2) maintains sufficient flexibility and remains responsive to the ever-changing nature of the global malaria challenge;

(3) includes specific objectives and multisectoral approaches and strategies to reduce the prevalence, mortality, incidence, and spread of malaria;

(4) describes how this strategy would contribute to the United States’ overall global health and development goals;

(5) clearly explains how outlined activities will interact with other United States Government global health activities, including the 5-year global AIDS strategy required under this Act;

(6) expands public-private partnerships and leverage of resources;

(7) coordinates among relevant Federal agencies to maximize human and financial resources and to reduce duplication among these agencies, foreign governments, and international organizations;

(8) coordinates with other international entities, including the Global Fund;

(9) maximizes United States capabilities in the areas of technical assistance and training and research, including vaccine research; and

(10) establishes priorities and selection criteria for the distribution of resources based on factors such as—

(A) the size and demographics of the population with malaria;

(B) the needs of that population;

(C) the country’s existing infrastructure; and

(D) the ability to closely coordinate United States Government efforts with national malaria control plans of partner countries.”

[Excerpt 7]

SEC. 304. MALARIA RESPONSE COORDINATOR.

(a) In General.--There is established within the United States Agency for International Development a Coordinator of United States Government Activities to Combat Malaria Globally (referred to in this section as the `Malaria Coordinator'), who shall be appointed by the President.

(b) Authorities.--The Malaria Coordinator, acting through nongovernmental organizations (including faith-based and community-based organizations), partner country finance, health, and other relevant ministries, and relevant executive branch agencies as may be necessary and appropriate to carry out this section, is authorized to—

(1) operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities to reduce the prevalence, mortality, and incidence of malaria;

(2) provide grants to, and enter into contracts and cooperative agreements with, nongovernmental organizations (including faith-based organizations) to carry out this section; and

(3) transfer and allocate executive branch agency funds that have been appropriated for the purposes described in paragraphs (1) and (2).

(c) Duties.--

(1) In general.--The Malaria Coordinator has primary responsibility for the oversight and coordination of all resources and international activities of the United States Government relating to efforts to combat malaria.

(2) Specific duties.--The Malaria Coordinator shall--

(A) facilitate program and policy coordination of antimalarial efforts among relevant executive branch agencies and nongovernmental organizations by auditing, monitoring, and evaluating such programs;

(B) ensure that each relevant executive branch agency undertakes antimalarial programs primarily in those areas in which the agency has the greatest expertise, technical capability, and potential for success;

(C) coordinate relevant executive branch agency activities in the field of malaria prevention and treatment;

(D) coordinate planning, implementation, and evaluation with the Global AIDS Coordinator in countries in which both programs have a significant presence;

(E) coordinate with national governments, international agencies, civil society, and the private sector; and

(F) establish due diligence criteria for all recipients of funds appropriated by the Federal Government for malaria assistance.

[Excerpt 8]

TITLE IV--AUTHORIZATION OF APPROPRIATIONS

SEC. 401. AUTHORIZATION OF APPROPRIATIONS.

(a) In General.--There are authorized to be appropriated to the President to carry out this Act and the amendments made by this Act \$48,000,000,000 for the 5-year period beginning on October 1, 2008.

(b) Availability.--Amounts appropriated pursuant to the authorization of appropriations in subsection (a) are authorized to remain available until expended.

(b) Sense of Congress.—It is the sense of the Congress that the appropriations authorized under section 401(a) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, as amended by subsection (a), should be allocated among fiscal years 2009 through 2013 in a manner that allows for the appropriations to be gradually increased in a manner that is consistent with program requirements, absorptive capacity, and priorities set forth in such Act, as amended by this Act.

(c) Availability of Authorizations.--Authorizations of appropriations under subsection (a) shall remain available until the appropriations are made.

SEC. 402. SENSE OF CONGRESS.

(a) Increase in HIV/AIDS Antiretroviral Treatment.--It is a sense of the Congress that an urgent priority of United States assistance programs to fight HIV/AIDS should be the rapid increase in distribution of antiretroviral treatment so that—

(1) by the end of fiscal year 2004, at least 500,000 individuals with HIV/AIDS are receiving antiretroviral treatment through United States assistance programs;

(2) by the end of fiscal year 2005, at least 1,000,000 such individuals are receiving such treatment; and

(3) by the end of fiscal year 2006, at least 2,000,000 such individuals are receiving such treatment.

(b) Effective Distribution of HIV/AIDS Funds.--It is the sense of Congress that, of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance, 10 percent should be used for orphans and vulnerable children.

SEC. 403. ALLOCATION OF FUNDS.

(a) Therapeutic Medical Care.--For fiscal years 2006 through 2008, not less than 55 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for therapeutic medical care of individuals infected with HIV, of which such amount at least 75 percent should be expended for the purchase and distribution of antiretroviral pharmaceuticals and at least 25 percent should be expended for related care. For fiscal years 2006 through 2008, not less than 33 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS prevention consistent with section 104A(d) of the Foreign Assistance Act of 1961 (as added by section 301 of this Act) for each such fiscal year shall be expended for abstinence-until-marriage programs.

(a) Balanced funding requirement.—

(1) In general.—The Global AIDS Coordinator shall—

(A) provide balanced funding for prevention activities for sexual transmission of HIV/AIDS; and

(B) ensure that activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction are implemented and funded in a meaningful and equitable way in the strategy for each host country based on objective epidemiological evidence as to the source of infections and in consultation with the government of each host country involved in HIV/AIDS prevention activities.

(2) Prevention strategy.—

(A) Establishment.—In carrying out paragraph (1), the Global AIDS Coordinator shall establish an HIV sexual transmission prevention strategy governing the expenditure of funds authorized under this Act to prevent the sexual transmission of HIV in any host country with a generalized epidemic.

(B) Report.—In each host country described in subparagraph (A), if the strategy established under subparagraph (A) provides less than 50 percent of the funds described in subparagraph (A) for activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction, the Global AIDS Coordinator shall, not later than 30 days after the issuance of this strategy, report to the appropriate congressional committees on the justification for this decision.

(3) Exclusion.—Programs and activities that implement or purchase new prevention technologies or modalities, such as medical male circumcision, public education about risks to acquire HIV infection from blood exposures, promoting universal precautions, investigating suspected nosocomial infections, pre-exposure pharmaceutical prophylaxis to prevent transmission of HIV, or microbicides and programs and activities that provide counseling and testing for HIV or prevent mother-to-child prevention of HIV, shall not be included in determining compliance with paragraph (2).

(4) Report.—Not later than 1 year after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and annually thereafter as part of the annual report required under section 104A(e) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2(e)), the President shall—

(A) submit a report on the implementation of paragraph (2) for the most recently concluded fiscal year to the appropriate congressional committees; and

(B) make the report described in subparagraph (A) available to the public.

(b) Orphans and Vulnerable Children.—For fiscal years 2009 through 2013, not less than 10 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for assistance for

orphans and other children affected by, or vulnerable to HIV/AIDS, of which such amount at least 50 percent shall be provided through non-profit, nongovernmental organizations, including faith-based organizations, that implement programs on the community level.

(c) Funding allocation.—For each of the fiscal years 2009 through 2013, more than half of the amounts appropriated for bilateral global HIV/AIDS assistance pursuant to section 401 shall be expended for—

- (1) antiretroviral treatment for HIV/AIDS;
- (2) clinical monitoring of HIV-seropositive people not in need of antiretroviral treatment;
- (3) care for associated opportunistic infections;
- (4) nutrition and food support for people living with HIV/AIDS; and
- (5) other essential HIV/AIDS-related medical care for people living with HIV/AIDS.

(d) Treatment, prevention, and care goals.—For each of the fiscal years 2009 through 2013—

(1) the treatment goal under section 402(a)(3) shall be increased above 2,000,000 by at least the percentage increase in the amount appropriated for bilateral global HIV/AIDS assistance for such fiscal year compared with fiscal year 2008

(2) any increase in the treatment goal under section 402(a)(3) above the percentage increase in the amount appropriated for bilateral global HIV/AIDS assistance for such fiscal year compared with fiscal year 2008 shall be based on long-term requirements, epidemiological evidence, the share of treatment needs being met by partner governments and other sources of treatment funding, and other appropriate factors;

(3) the treatment goal under section 402(a)(3) shall be increased above the number calculated under paragraph (1) by the same percentage that the average United States Government cost per patient of providing treatment in countries receiving bilateral HIV/AIDS assistance has decreased compared with fiscal year 2008; and

(4) the prevention and care goals established in clauses (i) and (iv) of section 104A(b)(1)(A) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2(b)(1)(A)) shall be increased consistent with epidemiological evidence and available resources.

APPENDIX II: HIV/AIDS ABC Guidance

ABC Guidance #1 For United States Government In-Country Staff and Implementing Partners Applying the ABC Approach To Preventing Sexually-Transmitted HIV Infections Within The President's Emergency Plan for AIDS Relief



**The President's Emergency Plan for AIDS Relief
Office of the U.S. Global AIDS Coordinator**

Final Guidance

Introduction

With the President’s Emergency Plan for AIDS Relief U.S. Five-Year Global HIV/AIDS Strategy as its starting point, this document provides further guidance on implementing the “ABC” - Abstinence, Be Faithful, and correct and consistent Condom use—approach to HIV/AIDS prevention, including definitions, implementation considerations, and clarification of activities the Emergency Plan will fund.

To limit the progression of the HIV/AIDS pandemic, there must be a dramatic reduction in new infections. The Emergency Plan is committed to evidence-based best practices in prevention interventions to achieve the Plan’s prevention objectives. Interventions in countries such as Kenya, the Dominican Republic, Thailand, Cambodia, and most notably, Uganda, indicate that promoting behaviors aimed at risk avoidance and risk reduction will likely avert the largest proportion of new infections and reduce the spread of HIV.^(1,2)

The measurable declines achieved through local behavior change efforts in these countries, and elsewhere, highlight another commitment of the Emergency Plan—that interventions be informed by, and responsive to, local needs, local epidemiology, and distinctive social and cultural patterns, as well as coordinated with the HIV/AIDS strategies of host governments. It is with these two principles in mind that the Emergency Plan applies the ABC approach in its HIV prevention strategy.

Defining the ABC Approach

The ABC approach employs population-specific interventions that emphasize abstinence for youth and other unmarried persons, including delay of sexual debut; mutual faithfulness and partner reduction for sexually active adults; and correct and consistent use of condoms by those whose behavior places them at risk for transmitting or becoming infected with HIV. It is important to note that ABC is not a program; it is an approach to infuse throughout prevention programs. The ABC approach is distinctive in its targeting of specific populations, the circumstances they face, and behaviors within those populations for change. This targeted approach results in a comprehensive and effective prevention strategy that helps individuals personalize risk and develop tools to avoid risky behaviors under their control.

Abstinence programs encourage unmarried individuals to abstain from sexual activity as the best and only certain way to protect themselves from exposure to HIV and other sexually transmitted infections. Abstinence until marriage programs are particularly important for young people, as approximately half of all new infections occur in the 15- to 24-year-old age group.⁽³⁾ Delaying first sexual encounter can have a significant impact on the health and well-being of adolescents and on the progress of the epidemic in communities.⁽⁴⁾ In many of the countries hardest hit by HIV/AIDS, sexual activity begins early and prior to marriage. Surveys show that, on average,

slightly more than 40 percent of women in sub-Saharan Africa have had premarital sex before age 20; among young men, sex before marriage is even more common.⁽⁵⁾ A significant minority of youth experience first sex before age 15. Internationally, a number of programs have proven successful in increasing abstinence until marriage, delaying first sex, and achieving “secondary abstinence”—returning to abstinence—among sexually experienced youth. These programs promote the following:

- Abstaining from sexual activity as the most effective and only certain way to avoid HIV infection;
- The development of skills for practicing abstinence;
- The importance of abstinence in eliminating the risk of HIV transmission among unmarried individuals;
- The decision of unmarried individuals to delay sexual debut until marriage; and
- The adoption of social and community norms that support delaying sex until marriage and that denounce cross-generational sex; transactional sex; and rape, incest, and other forced sexual activity.

Be faithful programs encourage individuals to practice fidelity in marriage and other sexual relationships as a critical way to reduce risk of exposure to HIV. Once a person begins to have sex, the fewer lifetime sexual partners he or she has, the lower the risk of contracting or spreading HIV or another sexually transmitted infection. Some of the most significant gains in Uganda’s fight against HIV are a result of specific emphasis on, and funding of, programs to promote changes in behavior related to fidelity in marriage, monogamous relationships, and reducing the number of sexual partners among sexually active unmarried persons.^(6,7) Uganda’s President Museveni, along with local religious groups and other NGOs, promoted a consistent message of partner reduction and fidelity, which contributed to a significant decline in the number of sexual partners among both men and women in Uganda. Between 1989 and 1995 the proportion of men who reported one or more “casual” partners in the past year fell from 35 percent to 15 percent; the proportion of women with one or more casual partners in the past year fell from 16 percent to 6 percent, and the proportion of men reporting 3 or more “nonregular” partners in past year fell from 15 percent to 3 percent. This significant level of behavior change contributed to a reduction in estimated adult HIV prevalence in Uganda from 15 percent in the early 1990s to about 4 percent today.⁽⁸⁾ Be faithful programs promote the following:

- The elimination of casual sexual partnerships;
- The development of skills for sustaining marital fidelity;
- The importance of mutual faithfulness with an uninfected partner in reducing the transmission of HIV among individuals in long-term sexual partnerships;
- HIV counseling and testing with their partner for those couples that do not know their HIV status;
- The endorsement of social and community norms supportive of refraining from sex outside of marriage, partner reduction, and marital fidelity, by using strategies that respect and respond to local cultural customs and norms; and
- The adoption of social and community norms that denounce crossgenerational sex; transactional sex; and rape, incest, and other forced sexual activity.

Correct and consistent Condom use programs support the provision of full and accurate information about correct and consistent condom use reducing, but not eliminating, the risk of HIV infection; and support access to condoms for those most at risk for transmitting or becoming infected with HIV. Behaviors that increase risk for HIV transmission include engaging in casual sexual encounters, engaging in sex in exchange for money or favors, having sex with an HIV-positive partner or one whose status is unknown, using drugs or abusing alcohol in the context of sexual interactions, and using intravenous drugs. Women, even if faithful themselves, can still be at risk of becoming infected by their spouse, regular male partner, or someone using force against them. Other high-risk persons or groups include men who have sex with men and workers who are employed away from home. Existing research demonstrates that the correct and consistent use of condoms significantly reduces, but does not eliminate, risk of HIV infection. Studies of sexually active couples for example, in which one partner is infected with HIV and the other partner is not, demonstrate that latex condoms provide approximately 80-90 percent protection, *when used consistently*.^(9, 10, 11) To achieve the protective effect of condoms, people must use them *correctly and consistently, at every sexual encounter*. Failure to do so diminishes the protective effect and increases the risk of acquiring a sexually transmitted infection (STI) because transmission can occur with even a single sexual encounter. Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV. In addition, correct and consistent use of latex condoms can reduce the risk of other sexually transmitted diseases (STDs), including gonorrhea, chlamydia, and genital ulcer diseases.⁽¹²⁾ While the effect of condoms in preventing human papillomavirus (HPV) infection is unknown, condom use has been associated with a lower rate of cervical cancer. Persistent infection with “high-risk” types of HPV is the main risk factor for cervical cancer. Condom use programs promote the following:

- The understanding that abstaining from sexual activity is the most effective and only certain way to avoid HIV infection;
- The understanding of how different behaviors increase risk of HIV infections;
- The importance of risk reduction and a consistent risk-reduction strategy when risk elimination is not practiced;
- The importance of correctly and consistently using condoms during every sexual encounter with partners known to be HIV-positive (discordant couples), or partners whose status is unknown;
- The critical role of HIV counseling and testing as a risk-reduction strategy;
- The development of skills for obtaining and correctly and consistently using condoms, including skills for vulnerable persons; and
- The knowledge that condoms do not protect against all STIs.

Implementing the ABC Approach

Overarching Considerations

Effective implementation of the ABC approach requires careful evaluation of risk behaviors that fuel local epidemics. Although prevention interventions are most successful when locally driven and responsive to local cultural values, epidemiological evidence can identify risky behaviors within populations and guide specific behavioral messages. For example, in some communities, as many as 20 percent of girls aged 15 to 19 are infected, compared to 5 percent of boys the same

age.⁽¹³⁾ Coupled with high prevalence among older men, such data can point to transmission that is fueled by cross-generational sex.^(14, 15) Prevention approaches must then address the risks of cross-generational and transactional sex through abstinence programs for youth and be faithful programs for men that foster collective social norms that emphasize avoiding risky sexual behavior.⁽¹⁶⁾

Every country program must include all three elements of the “ABCs,” promoted strategically to appropriate populations and drivers of disease. Thus, the optimal balance of ABC activities will vary across countries according to the patterns of disease transmission, the identification of core transmitters (i.e., those at highest risk of transmitting HIV), cultural and social norms, and other contextual factors.⁽¹⁷⁾ In addition, prevention messages are most effective when they are accurate and consistent, and all implementing partners must harmonize them at the community level. The A, B, and C components must not undermine or compete with each other, and therefore program partners must not disseminate incorrect information about any health intervention or device. Implementing partners must not promote condoms in a way that implies that it is acceptable to engage in risky sex. Whenever condoms are discussed, information about them must be accurate and not misleading, and must include both the public health benefits and failure rates of condoms as they apply to preventing HIV and other diseases. Likewise, abstinence and faithfulness programs and messages must be medically sound and based on best practices that indicate effectiveness.

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. As stated above, ABC must be balanced at the portfolio level, i.e., all three components must be represented in the country’s prevention strategy, but individual programs must be appropriately designed to meet the needs of the target audience.

Priority Interventions: Abstinence and Behavior Change for Youth

Young people are the most important asset to any community or nation. Protecting them from contracting HIV is unquestionably one of the most important missions of the Emergency Plan. Young people who have not had their sexual debut must be encouraged to practice abstinence until they have established a lifetime monogamous relationship. For those youth who have initiated sexual activity, returning to abstinence must be a primary message of prevention programs. Implementing partners must take great care not to give a conflicting message with regard to abstinence by confusing abstinence messages with condom marketing campaigns that appear to encourage sexual activity or appear to present abstinence and condom use as equally viable, alternative choices. Thus, marketing campaigns that target youth and encourage condom use as the primary intervention are not appropriate for youth, and the Emergency Plan will not fund them. (For this same reason, Emergency Plan funds may not be used to actively promote or provide condoms in school settings, but may be used in schools to support programs that deliver *age-appropriate* “ABC” information for youth.) This means the following:

1. For 10-to-14-year-olds, the Emergency Plan will fund age-appropriate and culturally appropriate “AB” programs that include promoting (1) dignity and self-worth; (2) the importance of abstinence in reducing the transmission of HIV; (3) the importance of delaying sexual debut until marriage; and (4) the development of skills for practicing abstinence.
2. For older youth (above age 14) the Emergency Plan will fund ABC programs that promote (1) dignity and self worth; (2) the importance of abstinence in reducing the transmission of HIV; (3) the importance of delaying sexual activity until marriage; (4) the development of skills for practicing abstinence, and where appropriate, secondary abstinence; (5) the elimination of casual sexual partnerships; (6) the importance of marriage and mutual faithfulness in reducing the transmission of HIV among individuals in long-term relationships; (7) the importance of HIV counseling and testing; and (8) provide full and accurate information about correct and consistent condom use as a way to significantly reduce—but not eliminate—the risk of HIV infection for those who engage in risky sexual behaviors.

It must be recognized that certain young people will, either by choice or coercion, engage in sexual activity. In these cases an integrated “ABC” approach is necessary. When individual students are identified as engaging in or at high risk for engaging in risky sexual behaviors, they should be appropriately referred to integrated “ABC” programs. Such programs should have the following characteristics: (1) be located in communities where youth engaging in high-risk behaviors congregate; (2) be coordinated with school-based abstinence programs so that high risk in-school youth can be easily referred, and (3) be targeted to specific high-risk individuals or groups (i.e., not involve the marketing of condoms to broad audiences of young people). Again, for programs that include a “C” component, information about 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. In summary:

1. Emergency Plan funds may be used in schools to support programs that deliver age-appropriate “AB” information to young people age 10-14;
2. Emergency Plan funds may be used in schools to support programs that deliver age-appropriate “ABC” information for young people above age 14;
3. Emergency Plan funds may be used to support integrated ABC programs that include condom provision in out-of-school programs for youth identified as engaging in or at high risk for engaging in risky sexual behaviors;
4. Emergency Plan funds may not be used to physically distribute or provide condoms in school settings;
5. Emergency Plan funds may not be used in schools for marketing efforts to promote condoms to youth; and
6. Emergency Plan funds may not be used in any setting for marketing campaigns that target youth and encourage condom use as the primary intervention for HIV prevention.

Priority Interventions: Promoting Healthy Norms and Behaviors

Communities must mobilize to address the norms, attitudes, values, and behaviors that increase vulnerability to HIV, including the acceptance or tolerance of multiple casual sex partnerships, cross-generational and transactional sex, forced sex, the unequal status of women, and the sexual coercion and exploitation of young people. To stimulate such mobilization, there is an urgent need to help communities identify the ways in which they contribute to establishing and reinforcing norms that contribute to risk, vulnerability, and stigma, and to help communities identify interventions that can change norms, attitudes, values, and behaviors that increase vulnerability to HIV. In addition, mobilization and change are most likely when messages are reinforced through a variety of fora; social and cultural networks; leaders and personal relationships, including parents, grandparents, religious and other leaders, and peers.

Emergency Plan funds can be used to support activities that will generate public discussion and problem solving about harmful social and sexual behaviors through a variety of means at both the community and national levels. Suggested activities include the following:

1. Educating parents to improve parent-child communication on HIV, sexuality, and broader issues such as limit-setting through parent-teacher groups, local associations, and faith-based groups;
2. Training local religious and other traditional leaders in HIV concerns and supporting them in publicizing the risks of early sexual activity, sex outside of marriage, multiple partners, and cross-generational sex;
3. Supporting youth-led community programs to help youth, their parents, and the broader community personalize the risk associated with early sexual activity, sex outside of marriage, multiple partnerships, and crossgenerational sex;
4. Supporting media campaigns that reinforce and make abstinence, fidelity, partner reduction, HIV counseling and testing, and other safer behaviors legitimate options and standards of behavior for both youth and adults;
5. Developing and training mentors for youth who lack sufficient parental or other adult supervision, including training in messages for HIV prevention;
6. Organizing campaigns and events to educate local communities about sexual violence against youth and strengthen community sanctions against such behaviors;
7. Implementing workplace programs for older men to stress male sexual and familial responsibility, and school-based programs for younger males to provide education about preventing sexual violence;
8. Promoting the use of testing and counseling services, including developing innovative strategies to encourage and increase HIV testing, such as routine testing where appropriate;
9. Training health care providers, teachers, and peer educators to identify, counsel, and refer young victims of rape, incest, or other sexual abuse for other health care; and
10. Coordinating with governments and NGOs to eliminate gender inequalities in the civil and criminal code and enforce existing sanctions against sexual abuse and sexual violence.

Priority Interventions: Prevention of HIV Infection in the Most At-Risk Populations

Following the ABC model, and recognizing that correct and consistent condom use is an essential means of reducing, but not eliminating, the risk of HIV infection for populations who engage in risky behavior, the Emergency Plan will fund those activities that target at-risk populations with specific outreach, services, comprehensive prevention messages, and condom information and provision. As defined above, these populations 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.

Some of the populations most affected by HIV/AIDS are also the most difficult to reach through conventional health care programs. Sex workers and their clients, men who have sex with men, and injecting drug users have the least access to basic health care. These populations are generally at higher risk of infection and in greatest need of prevention services. The experiences of Thailand, Cambodia, the Dominican Republic, Senegal, and other countries illustrate that targeted efforts to promote correct and consistent condom use with specific high-risk groups can prevent concentrated epidemics from maturing into generalized epidemics.^(18, 19) In generalized epidemics, such targeted approaches remain crucial but must be augmented by balanced ABC approaches that can reach broader audiences in order to provide information to those who may be having sex with a partner whose status is unknown.⁽²⁰⁾

First and foremost, the Emergency Plan will support approaches directed at ending risky behavior. In addition, the Emergency Plan supports effective new approaches to serve groups at high risk through a combination of the following:

1. Interpersonal approaches to behavior change, such as counseling, mentoring, and peer outreach;
2. Community and workplace interventions to eliminate or reduce risky behaviors;
3. Initiatives to promote the use of testing and counseling services, including developing innovative strategies to encourage and increase HIV testing, such as routine testing where appropriate;
4. Promoting and supporting substance abuse prevention and treatment targeting HIV-infected individuals;
5. Promoting a comprehensive package for sex workers and other high-risk groups, including HIV counseling and testing, STI screening and treatment, targeted condom promotion and distribution, and other risk reduction education;
6. Promoting correct and consistent condom use during high-risk sexual activity; and
7. Media interventions with specially tailored messages appropriately targeted to specific populations.

Conclusion

Prevention activities under the Emergency Plan will be driven by best practices, sensitivity to the dynamics of the local epidemic, and the national strategy of host governments. Therefore, the Emergency Plan will use the ABC approach for prevention of the sexual transmission of HIV. Technical assistance is available to support the implementation of ABC programs. By strengthening our prevention efforts, the Emergency Plan will support the efforts of the nations

in which we work to prevent HIV infection and preserve health and families as, together, we turn the tide against HIV/AIDS.

Appendix: Determining the Appropriate Mix of ABC Interventions

To identify the most strategic prevention interventions, countries must first gain an understanding of the types and degrees of risk behavior that fuel the epidemic locally. It is recommended that countries develop their prevention strategies through a two-step situation analysis that addresses questions of “who is doing what, with whom, where, and why.”

In the first step, available epidemiological data should be applied to estimate the proportion of new infections that are associated with specific behaviors such as prostitution, early onset of sexual activity among youth, transmission through sexual networks, etc. Efforts should be made to review prevalence data available through national serosurveys, antenatal clinic surveillance, and/or voluntary counseling and testing clinics, to assess different infection burdens by age and by gender. For example, high HIV prevalence among young women, and among older men, may point to transmission that is fueled by cross-generational sex. Population-level surveys featuring behavioral indicators, such as demographic health surveys and behavioral surveillance surveys should also be carefully reviewed to assess the extent to which certain types of behaviors represent important opportunities for preventing new infections. In Botswana, for example, reported levels of condom use are quite high, but so are reported numbers of concurrent sex partners, suggesting that approaches emphasizing partner reduction could have strategic benefits over those that prioritize additional condom promotion.

It is recommended that this first step produce information relevant to each of the following considerations:

- Who are the core transmitters?
- What are the specific behaviors through which HIV is transmitted?
- What are the specific behaviors that represent the most strategic targets for averting new infections?
- What are some of the specific prevention/intervention needs of women, youth, and “vulnerable” populations?
- What are some of the specific prevention/intervention needs of people living with HIV/AIDS (PLWHAs)?
- How can the “ABCs” be applied appropriately? (Note: ABC must be balanced at the portfolio level, i.e., all three components must be represented in the country’s prevention strategy, but individual programs must be appropriately designed to meet the needs of the target audience.)
- What are the priorities for abstinence?
- Partner reduction is a critical behavioral determinant in many cases; how is it being addressed?
- In what circumstances are condoms critical?

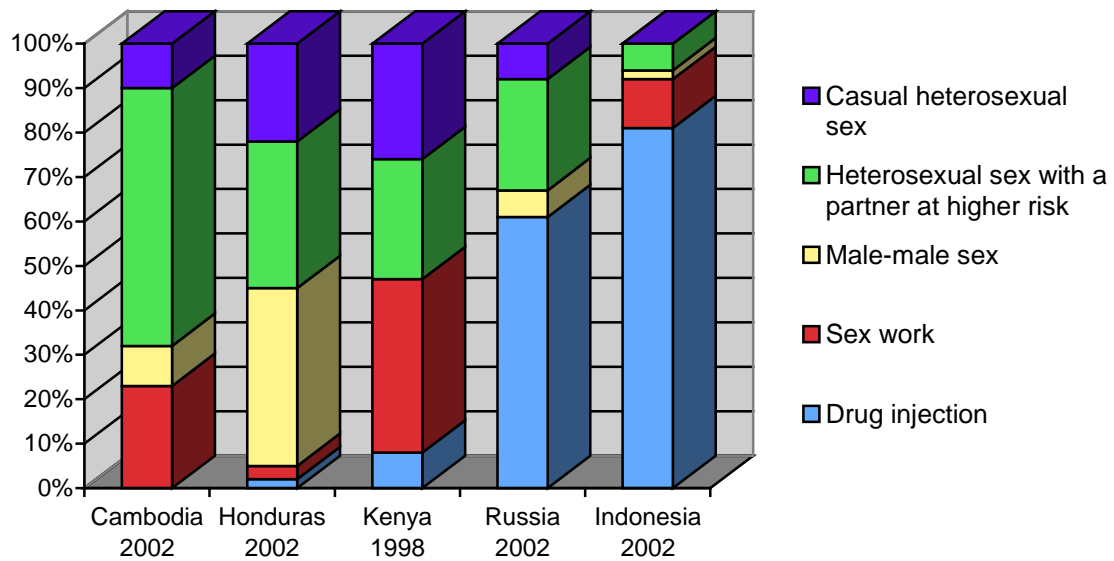
Having identified these behavior change priorities, the second step should seek to understand more specifically who is engaging in risk-related activities, where to reach these people, and what individual and structural factors could be leveraged to promote change. Participatory and/or rapid assessment approaches, employing qualitative and/or quantitative methods, can help to characterize transmission risk among specific groups or in specific settings. In addition, one of the most important components of this step involves developing a better sense of the supporting environment for specific kinds of initiatives and prevention opportunities. Many of the interventions that are believed to have contributed to Uganda's success originated from pre-existing structures, organizations, and networks. This type of information is often collected through observation and experience, but reviewing local media and conducting strategic interviews with key local and national stakeholders from a variety of backgrounds can help to generate a good picture of the supporting environment. Some other critical questions to consider in this stage include:

- What is national political, social, and cultural leadership saying or doing (or not) about AIDS and about behavior change and prevention?
- What networks or institutions are engaged (or not) in HIV prevention? (Schools, churches, NGOs, local government units, workplaces, etc.)
- What are community leaders doing or saying (or not) about HIV prevention?
- How is information about HIV/AIDS being shared within personal networks? Are people talking about HIV/AIDS? To what extent does stigma present a barrier to effective action?
- What are the gender inequities that foster the spread of HIV?
- What are the other social inequities and local practices that foster the spread of HIV?
- How is the media treating HIV prevention and behavior change?
- What additional issues are impacting the country and its HIV epidemic (e.g. war, famine, refugees, other diseases)?
- How are local experts engaged in assessing the supporting environment, including women and PLWHA?

These diagnostic questions are all critical for empowering a grassroots/community-level response to the epidemic. U.S. missions should collaborate with local experts to foster a local perspective that is culturally appropriate and sensitive. Creating a strong community-level response will aid rapid scale-up and ensure long-term sustainability.

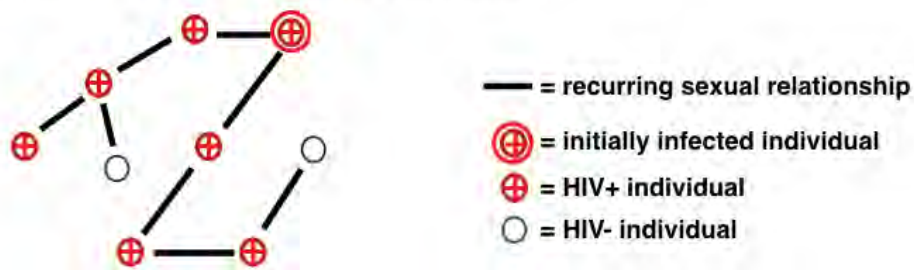
ABC and Local Transmission Dynamics

Program planners should recognize that the relative prevention benefits associated with “A”, “B” and “C” programs will vary across epidemic contexts with differing transmission dynamics. In the absence of this recognition, programmers risk responding to a “generalized” epidemic with a “generalized” response – one that lacks strategic focus in terms of both its target audiences and its behavioral objectives. This point is illustrated in the following figure, which highlights large differences in the types of exposures that are significantly contributing to new infections in five countries. The transmission dynamics that contribute to infection across these different "exposure" types helps to highlight the strategic benefits of prioritizing different ABC objectives in different settings.



In the majority of the Emergency Plan focus countries, a large proportion of new HIV infections is attributable to heterosexual transmission fueled by casual sex and concurrent partnerships. Whether or not an HIV epidemic escalates depends on the existence of secondary networks that facilitate further HIV transmission to individuals who may not have direct contact with perceived “high-risk” partners.⁽²¹⁾

Transmission through concurrent partnerships

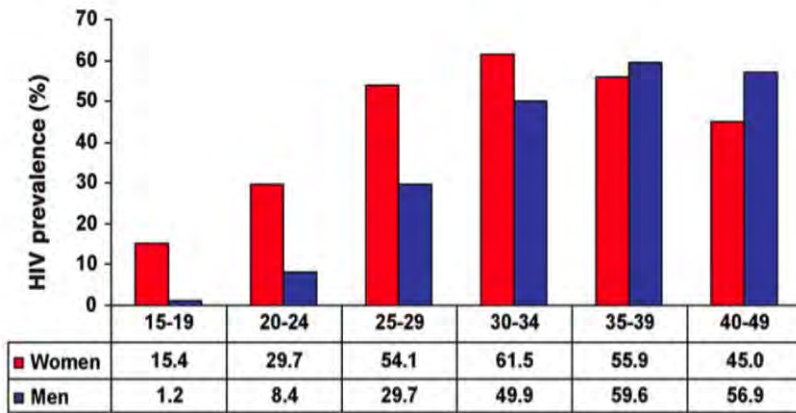


This diagram illustrates how the efficiency of HIV transmission is dramatically increased in the presence of frequent sexual contact if such contacts are “concurrent” (overlapping). Since population-level survey data from many countries indicates that regular and “low-risk” (marital or cohabitating) partnerships have low levels of condom use, the “B” or partner reduction component of the ABC approach in a “generalized” epidemic is especially important.^(6,16)

A lesson learned from successful country programs is that the most effective prevention interventions are ones that focus on changing the specific behaviors likely to avert the largest proportion of new infections.^(2,19) In other words, the selection of intervention activities cannot

be divorced from identifying the most strategic behavior change objectives at a country level, and country programs should not simply devote funding to generic behavior change activities in categories such as school programs, community-based programs, and mass media. The figure below depicts age and gender-specific HIV prevalence in Botswana and illustrates why activities must be associated with prioritized behavioral objectives. From the figure one can conclude that programs to reduce new infections in young women should focus on promotion of abstinence among young females, on reducing cross-generational sexual relationships, and on encouraging faithfulness and correct and consistent condom use among older males.

HIV prevalence by age group among men and women aged 15-49. Tebelopele VCT Centres, 2003, Botswana*



*2003 data through to 30th September only

For More Information

Please contact:

Caroline Ryan, M.D., M.P.H; Acting Senior Technical Advisor—Prevention Office of the Global AIDS Coordinator

Email: cryan@cdc.gov

References:

1. Green E. Rethinking AIDS Prevention. Westport, Ct: Praeger, 2003.
2. Pisani E, Garnett GP, Grassly NC, et al. Back to basics in HIV prevention: focus on exposure. *BMJ* 2003;326:1384-87 (bmj.bmjournals.com/cgi/content/full/326/7403/1384).
3. UNAIDS. 2004 Report of the Global AIDS Epidemic: 4th global report.
4. Pettifor AE, van der Straten A, Dunbar MS, Shiboski SC, Padian NS. Early age of first sex: a risk factor for HIV infection among women in Zimbabwe. *AIDS* 2004;18:1435–42.
5. Measure Evaluation. Sexual behavior, HIV and fertility trends: a comparative analysis of six countries. USAID: 2003 (www.cpc.unc.edu/measure/publications/special/abc.pdf).
6. Shelton J, Halperin D, Nantulya V, Potts M, Gayle H, Holmes K. Partner reduction is crucial for balanced "ABC" approach to HIV prevention. *Brit Med J* 2004;328:891-3 (<http://bmj.bmjournals.com/cgi/content/full/bmj;328/7444/891>).
7. Cohen S. Beyond slogans: lessons from Uganda's experience with ABC and HIV/AIDS. Alan Guttmacher Institute report (www.agi-usa.org/pubs/journals/gr060501.pdf).
8. Stoneburner R, Low-Beer D. Population-level HIV declines and behavioral risk avoidance in Uganda. *Science* 2004; 304:714-18.
9. Hearst N, Chen S. Condom promotion for AIDS prevention in the developing world: is it working? *Stud Fam Plann* 2004;35:39-47 (www.usp.br/nepaids/condom.pdf).
10. Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. Oxford: The Cochrane Library, Issue 2, 2002 (www.cochrane.org/cochrane/revabstr/ab003255.htm).
11. Pinkerton SD, Abramson PR. Effectiveness of condoms in preventing HIV transmission. *Social Science and Medicine* 1997; 44:1303-12.
12. Holmes KK, Levine R, Weaver M. Effectiveness of condoms in preventing sexually transmitted infections. *Bull World Health Organ.* 2004 June 82(6):454-61

13. Kelly RJ, Gray RH, Sewankambo NK, et al. Age differences in sexual partners and risk of HIV-1 infection in rural Uganda. *J Acq Immune Def Synd* 2003;32:446–51.
14. Glynn et al. (2001). Why do young women have a much higher prevalence of HIV than young men? A study in Kisumu, Kenya and Ndola, Zambia. *AIDS*, 15(Suppl. 4):S51–60.
15. Luke N, Kurz K (2002). *Cross-generational and transactional sexual relations in sub-Saharan Africa*. Washington, AIDSmark. Available at www.icrw.org/docs/crossgensex_Report_902pdf
16. Wilson D. Partner reduction and the prevention of HIV/AIDS: the most effective strategies come from communities. *BMJ* 2004;328:848-49 (bmj.bmjournals.com/cgi/content/full/328/7444/848).
17. Cates W. The "ABC to Z" approach: condoms are one element in a comprehensive approach to STI/HIV prevention. Network, Family Health Int., June 2003 (www.fhi.org/en/RH/Pubs/Network/v22_4/nt2241.htm).
18. Merson M H, Dayton J M, O'Reilly K (2000). Effectiveness of HIV prevention interventions in developing countries. *AIDS*, 14 (Suppl. 2):S68–84.
19. Stover J, Walker N, Garnett G P et al. (2002). Can we reverse the HIV/AIDS pandemic with an expanded response. *Lancet*, 360:73–77. ([http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=12114060](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt= Citation&list_uids=12114060))
20. Cote AM, Sobela F, Dzokoto A, et al. Transactional sex is the driving force in the dynamics of HIV in Accra, Ghana. *AIDS* 2004,18:917–25.
21. Morris M, Kretzschmar M. Concurrent partnerships and the spread of HIV. *AIDS* 1997;11:681-83.

APPENDIX III: HIV/AIDS Palliative Care Guidance

HIV/AIDS Palliative Care Guidance#1For the United States Government in–Country Staff And
Implementing Partners



The President's Emergency Plan for AIDS Relief
Office of the U.S. Global AIDS Coordinator

Final

HIV/AIDS Palliative Care Guidance #1
An Overview of Comprehensive HIV/AIDS Care Services in the
President's Emergency Plan for AIDS Relief
February 3, 2006
U.S. Department of State
Office of the U.S. Global AIDS Coordinator

Introduction

Comprehensive palliative care is essential to the health and well-being of people living with HIV/AIDS (PLWHA) and is an integral part of the President's Emergency Plan for AIDS Relief (the Emergency Plan). Palliative care has traditionally been associated with terminal or end-of-life care. However, current thought and practice and Emergency Plan policy take the broader view that palliative care encompasses care provided from the time that HIV is diagnosed and throughout the continuum of HIV infection.

The Emergency Plan envisions a comprehensive, holistic, interdisciplinary approach to HIV care. It recognizes that different types and intensity of comprehensive palliative care interventions are needed, depending upon the stage and progression of disease and the needs of the individual and family.

This document provides initial guidance on the development HIV/AIDS palliative care programs, including definitions and activities be funded under the Emergency Plan. Guidance on many issues will evolve as new information and experience emerge from the field.

This document summarizes key elements related to the development, implementation, and support of palliative care programs necessary to achieve the Emergency Plan goals.

These elements include:

- 1.1 Definition of Palliative Care
- 1.2 Types of Palliative Care
- 1.3 Packages of Care
- 1.4 Palliative Care Delivery Sites
- 1.5 Networks, Linkages and Integration
- 1.6 Food and Nutritional Support
- 1.7 Tuberculosis and HIV/AIDS
- 1.8 Wrap-around Care
- 1.9 Pediatric Care
- 1.10 Gender Issues
- 1.11 Human Capacity Development and Provider Education and Training

- 1.12 Policy Development
- 1.13 Supply Chain Management and the Procurement of Drugs.
- 1.14 Reference Guide

1.1 Definition of Palliative Care

Palliative care, as stated in the *U.S. Five-Year Global HIV/AIDS Strategy*, aims to achieve optimal quality of life for PLWHA and their families and minimize suffering through mobilizing clinical, psychological, spiritual, and social care throughout the entire course of HIV infection. It also provides the routine monitoring that is essential to determining the optimal time to initiate anti-retroviral therapy (ART), and it continues during and after the initiation of treatment. Palliative care includes and goes beyond the medical management of infectious, neurological or oncological complications of HIV/AIDS to comprehensively address symptoms and suffering throughout the continuum of HIV disease. Routine, confidential counseling and testing is an essential component of palliative care to identify those who need or will need palliative care, family members who could also be infected and in need of care and, family members and partners not infected and in need of prevention.

Principles of an effective HIV/AIDS care program include the following.

- Respect for patient autonomy and choice and provision of adequate access to information.
- Respectful and trusting relationships between the HIV-positive person and the caregivers.
- Support of the family, child, and community caregivers in delivering palliative care.
- Integration and respect for cultural values, beliefs and customs.
- Enhanced quality of life throughout the continuum of disease.

1.2 Types of Palliative Care Interventions

Palliative care for HIV-infected individuals becomes increasingly important as the disease progresses. The Emergency Plan can support all areas of comprehensive palliative care offered throughout the course of HIV disease but what individual country programs provide can vary in type, scope, and intensity, based on the progression of the disease, availability of anti-retrovirals (ARVs), and the needs of the individual and family.

The Emergency Plan can support

The Emergency Plan can support the following four categories of essential palliative care, where compatible with national guidelines:

Clinical care is generally provided by nurses, midwives, clinical officers, community and volunteer health workers, traditional healers and physicians. It includes a wide range of treatment and care including: routine, confidential HIV counseling and testing; routine follow-up to determine the optimal time to initiate ART; prevention and treatment of opportunistic infections (OIs) such as tuberculosis (TB); HIV prevention and behavior-change counseling, alleviation of HIV-related symptoms and pain; time-limited support for clinically malnourished PLWHA; and support for

adherence to anti-retroviral therapy (ART). Illustrated below are types of interventions that Emergency Plan programs should provide, based on the presence or absence of clinical symptoms:

Asymptomatic clinical care is toward persons who are not experiencing specific signs or symptoms of HIV disease. These interventions include: routine clinical monitoring and assessments, including those that assist in determining the optimal time to initiate ART (including laboratory and clinical evaluations); services to prevent TB, other OIs and malaria, such as the use of isoniazid prophylaxis, cotrimoxazole; impregnated mosquito bed nets (preferably long-lasting); safe-water systems; nutritional assessment and counseling; HIV prevention counseling, promotion of good personal and household hygiene; and the assessment and management of HIV-related psychosocial problems. Additional guidance will be forthcoming on the elements of basic preventive care for PLWHAs and their families.

Symptomatic clinical care is directed toward individuals who are experiencing progressive immunological impairment and related HIV symptoms. These interventions include: treatment of symptomatic illness; pain control (with opioids and non-opioids); prevention of TB, other OIs, and malaria using medications such as isoniazid prophylaxis, cotrimoxazole, and/or the use of (preferably long-lasting) impregnated mosquito bed nets; safe-water systems; nutritional assessment and counseling; promotion of good hygiene; the assessment and management of HIV-related psychosocial problems; basic nursing care (including but not limited to assessment and monitoring of symptoms and adherence to medications; assistance with bathing, mobility, mouth care and skin and wound care); preparation and support prior to and throughout ART; and time-limited nutrition rehabilitation and supplementation for clinically malnourished PLWHA.

Future guidance will provide details on food and nutrition programs the Emergency Plan can support. United States Government (USG) teams in Emergency Plan countries that are also part of the President's Malaria Initiative should coordinate closely and use both funding streams creatively to serve HIV-affected individuals in the distribution of (long-lasting) insecticide-impregnated bednets.

End-of-Life and bereavement care is directed toward the individual and family members in need of intensive management of symptoms and pain [using non-opioids and/or opioids and directed by the World Health Organization (WHO) analgesic ladder²]. They include culturally appropriate end-of-life care and bereavement interventions, as well as appropriate succession planning and referrals for orphans and vulnerable children.

Psychological care addresses the non-physical suffering of individuals and family members, and can include: mental health counseling; family care and support groups; support for disclosure of HIV status; bereavement care; development and implementation of culture- and age-specific initiatives for psychological care; and treatment of HIV-related psychiatric illnesses, such as depression and related anxieties.

² In countries where national legislation or government regulation or policy prohibits or severely restricts the use of opioids for palliative care, including end-of-life care, USG teams should advocate for changes in statute, regulations or policy to broaden access to pain medication in ways that will increase the ability of providers to alleviate suffering while continuing to maintain appropriate safeguards against abuse of medications.

Spiritual care addresses the major life events that cause people to question themselves, their purpose and their meaning in life. The interventions should be sensitive to the culture, religion(s) and rituals of the individual and community, and can include (but are not limited to): life review and assessment; counseling related to hopes and fears, meaning and purpose, guilt and forgiveness; and life-completion tasks.

Social care assists individuals and family members in maintaining linkages to and use of care, preventing HIV infection, and ensuring adherence to treatment. These can include: community-based support groups; community mobilization and leadership development of PLWHA; efforts to reduce stigma; legal services to assist with succession planning, inheritance rights, and legal documentation (such as a living will or power of attorney); assistance to secure government grants, housing, or health care; linkages to food support and income-generating programs; efforts to increase community awareness of HIV care, treatment, and prevention; and other activities to strengthen affected households and communities.

Prevention for HIV-infected persons has been shown to be both effective and efficient at preventing new infections. Emergency Plan programs should incorporate prevention for positives into palliative care and treatment. Models to provide these interventions can include: interventions for sero-discordant couples, including confidential testing and ongoing counseling; community and clinic-based support groups; case-management and provider-delivered prevention messages focused on disclosure; partner testing; correct and consistent condom use for populations engaged in high-risk behavior and mutual fidelity.³

1.3 Packages of Care

Participating USG agencies have discussed extensively the concept of providing a minimum set of evidenced-based care interventions, or a “package of care” for HIV-infected persons in recent months. The Emergency Plan palliative care programs should provide this set of interventions regardless of stage of HIV disease or clinical condition. Additional guidance on Preventive Care Packages for Adults and Children will be forthcoming.

The Emergency Plan recognizes that a “package of care” cannot be standardized for all countries. Each USG team should adapt the basic package and support care packages in a way that is appropriate for the country in which it works.

1.4 Palliative Care Delivery Sites

Comprehensive care includes a wide range of interventions to improve the quality of life for the individual and family. These interventions are not specific to any one setting or location. Delivery sites for care generally are home-, community-, and/or facility-based. As discussed below, it is essential that Emergency Plan programs link these interventions and sites to ensure coordinated access to a comprehensive array of primary, secondary and tertiary care and hospice care.

³ Office of the Global AIDS Coordinator ABC Guidance

Home-Based Care

Home-based programs deliver various types of HIV/AIDS care in the patient's home. Given the relative availability and affordability of home-based care programs for most resource-poor settings, these programs play a significant role in providing access to comprehensive palliative and supportive care for a large proportion of individuals and families affected by HIV disease. However, many home-based programs either do not include or are missing key palliative care interventions. The introduction of comprehensive care into home-based programs requires the training and education of medical providers (e.g. nurses, clinical officers, and physicians, including pediatricians and pediatric nurses) and community-care providers in the following areas:

- Clinical diagnosis and care, including pain, symptom and OI-assessment and -management.
- The delivery of medications (including pain medications) and other clinical interventions within the community and home.
- Basic nursing care, including client and household hygiene and promotion of disease prevention in the home.
- The use of established patient management protocols and standards.
- Procedures for referring patients for diagnostic, care, and treatment.
- Communication skills, including patient education in local languages on HIV/AIDS and HIV prevention messages, counseling on disclosure of HIV status, and grief, anxiety, and bereavement care.
- The establishment of interdisciplinary teams to address physical, psychosocial support, and spiritual needs of clients.
- Other standards and procedures for providing quality care.

Community-based Care

Community-based care is provided in a variety of community settings including free-standing outpatient clinics, day care centers, school or university-based clinics, community health centers, workplace clinics or stand-alone hospices. These delivery sites often provide a wide range of interventions, including primary care, management of acute and chronic medical conditions and supportive care. Emergency Plan programs should also link them with inpatient facilities, such as provincial or district hospitals.

Facility-Based Care

Hospital-based outpatient clinics and inpatient facilities provide direct and more advanced clinical care in the facility and are essential sites for the delivery of HIV palliative care. Both types of delivery sites provide access to health and basic social-service providers trained in the diagnosis and

management of acute and chronic medical conditions and supportive care needs and are often linked to home- and community-based care providers for patient follow-up.

Hospice Care

Hospice is an approach to delivering end-of-life care, often provided in the home by trained nurses and or community care-givers, in community-based and hospital-based facilities, or in a free-standing hospice. Hospice care includes intensive end-of-life care, such as severe pain control with opioids and other medications⁴, as well as support in the last months of life for individuals with a terminal illness. Hospice also provides intensive family and bereavement support.

1.5 Networks, Linkages and Integration

As stated in the *U.S. Five-Year Global HIV/AIDS Strategy*, the Emergency Plan works to integrate the delivery of prevention, treatment, and care across facilities, clinics, communities, and homes, to build and sustain comprehensive HIV/AIDS care systems. USG teams should develop network systems, foster linkages, and establish and strengthen referral to care at various levels. Network systems represent formal relationships among providers to create a comprehensive system of care, and include the following:

- **Linkages between delivery sites** to support referrals among and within HIV prevention, orphan and vulnerable children programs, palliative care, and treatment sites.
- **Integration of care** to allow for incorporation of new interventions into existing delivery sites, for example, locating palliative care in existing ART-delivery sites.

Networking should include close coordination and collaboration with other groups and organizations that provide complementary care. These may include hospitals, clinics, hospices, schools, universities, home- and community-care programs, government and international partner programs in other sectors, community groups, legal services, food and nutritional support providers, transportation between and among referral sites and home, PLWHA support groups, orphans and vulnerable children programs and advocacy organizations. USG teams in Emergency Plan countries should also coordinate closely with the President's Malaria Initiative and programs funded by the Global Fund to Fight AIDS, Malaria and Tuberculosis.

Networks

A health network consists of a system of clinical and non-clinical programs for the care of PLWHA and families. Governments (particularly Ministries of Health), community-based and faith-based organizations (CBOs and FBOs), non-governmental organizations (NGOs), private companies, or

⁴ In countries where national legislation or government regulation or policy prohibits or severely restricts the use of opioids for palliative care, including end-of-life care, USG teams should advocate for changes in statute, regulations or policy to broader access to pain medication in ways that will increase the ability of providers to alleviate suffering while continuing to maintain appropriate safeguards against abuse of medications.

consortiums composed of some or all of the above entities. A network is a system of care that includes primary, secondary, tertiary, and home-based care—for example, a regional treatment center that is associated with a district clinic, a health post, and a home-based treatment program. In such a system, patients are able to access each service within the network based on need. Components may be both facility- and non facility-based.

In optimal circumstances, comprehensive care is provided across various delivery sites and through an integrated model of community care which emphasizes a continuum of care between the community care provider and all sectors of the formal health care system.

Building Networks through Program Linkages and Integration

Linkages and integration provide for the coordination and collaboration of multiple provider groups through referrals and co-location.

For example, a linkage model could consist of an HIV/AIDS clinic linked with a palliative care provider, an orphan and vulnerable children (OVC) program, a TB clinic, a voluntary family planning program, and a food assistance program, with the client being referred among programs for access to comprehensive care. An integrated model could include the establishment of ART within an existing home- and community-based care program.

Networks may be built through the integration of palliative care into all existing HIV prevention, treatment, and care programs, or through linkage of home-based, outpatient, hospital, and hospice providers. Examples of network development in specific program areas the Emergency Plan can support appear below.

- **Prevention** – Care programs should include prevention for all PLWHA, their families and partners should integrate or link with prevention programs, including those with a particular focus on behavioral interventions. As appropriate, care programs should include counseling on risk of transmission and measures to avoid infection, including ABC (see Emergency Plan ABC guidance document), prevention for maternal-to-child transmission, prevention between sero-discordant partners, among intravenous drug users and through medical procedures to ensure safe injections and blood transfusions. All care programs should incorporate provision or referral for routine, confidential counseling and testing. HIV-infected individuals should receive prevention counseling at every treatment visit, and through all palliative care interventions.
- **Treatment** - Care programs should integrate or link with treatment programs. Programs prepare and support HIV-infected individuals and families prior to and throughout ART. Services may include symptom management (including pain control, adherence counseling, and prevention and treatment of TB and other OIs), psychological and spiritual care, nutrition counseling, and support for the family and caregivers of those who are on ART.
- **Orphans and Vulnerable Children (OVC)** - A comprehensive care program addresses the needs of HIV-positive children, children whose parent/s or principal caregivers have HIV/AIDS, and children whose parents have died. Programs include early identification of

these children and appropriate interventions to support them and their families. Program providers at all levels need to have the communication skills necessary for working with HIV-positive family members and the clinical skills needed to identify HIV infection in OVC. Providers should also have the capacity to provide case management for children and families, as well as referrals to other OVC care.

Care providers should coordinate and collaborate with other government and donor programs including the President's Malaria Initiative and the Global Fund to Fight AIDS, Tuberculosis, and Malaria, to maximize efficiency and effectiveness of service delivery and minimize duplication of effort.

1.6 Food and Nutritional Support

Food and nutritional support can be an important component of palliative care. It must also be noted, however that the Emergency Plan works in many communities that food insecurity broadly affects. Larger issues of food security are extremely complex, and other organizations and international partners have a strong comparative advantage in the area of food assistance. Thus a key precept of interventions supported by the Emergency Plan is to remain focused on HIV/AIDS, and to provide support for food only in limited circumstances and leverage other resources whenever possible. Further guidance on the limited circumstance in which the Emergency Plan can support food and nutrition interventions is in preparation and the Office of the Global AIDS Coordinator will disseminate it shortly.

1.7 Tuberculosis and HIV/AIDS

TB is the most common OI in HIV-infected persons in sub-Saharan Africa, and in some facilities up to 70 percent of TB patients are HIV-infected. It is also a leading cause of death in individuals with AIDS in developing countries, and accounts for 15 percent of deaths in PLWHA in Africa. Therefore, interventions that target TB in HIV-infected persons have a significant public health and individual clinical impact.

Prevention and treatment of TB are thus an integral part of comprehensive palliative care, and the Emergency Plan clearly defines care as including treatment and prevention of OIs, including TB. Emergency Plan goals relating to TB are the following: 1) to diagnose, care and treat all PLWHA with active TB disease; 2) to provide HIV counseling and testing for all patients who are seeking care in TB programs; and 3) consistent with local guidelines to provide preventive TB care for HIV-positive persons who are not diagnosed with active TB, and to ensure that all eligible co-infected PLWHAs receive ART.

Resources must be allocated to achieve these goals, and Emergency Plan programs should test all persons with TB for HIV. Successful prevention and treatment of TB in HIV-infected individuals can mitigate TB-associated morbidity in patients and significantly reduce TB-associated risk of death. Treatment of TB also reduces TB transmission in the community and in care settings. Programs should seek all opportunities to improve coordination of TB and HIV/AIDS interventions.

1.8 Wrap-around Interventions

Wrap-around programs are programs not funded by the Emergency Plan, but can improve the quality of life for people infected and affected by HIV/AIDS and complement the programs of the Emergency Plan. These programs include those funded by the USG (e.g. USAID Development Assistance, etc.), other international partners including the Global Fund, the United Nations (World Food Program, UNICEF, etc) and other partners. They include, but are not limited to initiatives that:

- Strengthen household livelihoods;
- Build local governance and democracy;
- Improve access to education and skills development;
- Promote gender equity;
- Strengthen economic capacity and generate income;
- Stabilize communities in crisis;
- Enhance food supply including community/home gardens;
- Improve sanitation in communities;
- Provide clean water in communities; and
- Strengthen non-HIV health, including voluntary family planning, child health and nutrition.

1.9 Pediatrics and Palliative Care

Palliative care for children mirrors that of adults, inasmuch as it includes clinical, psychological, spiritual, and social care implemented by a multi-disciplinary team. There are, however, important differences between adults and children that affect providers' decisions related to palliative care. Children are growing, and have different metabolisms and different manifestations of HIV disease. Palliative care for children begins when an infant is exposed to HIV (in utero, in labor, and/or through breastfeeding). It continues through diagnosis, care, and treatment, and extends to end-of-life care. Further discussion of this topic is included in Appendix I.

It is important to recognize that the “family” is the unit of care when it comes to addressing the needs of children. Working with families can be an entry point for identifying HIV-infected children. Programs should be established to provide access to a coordinated system of both adult and pediatric care. The goal is to identify all HIV-infected family members and to provide (directly or through referral) access to a wide range of comprehensive care. These include HIV prevention, treatment and other support such as family mental health and bereavement counseling and voluntary family planning.

1.10 Gender Issues

Gender is a critical issue in palliative care. HIV/AIDS has increased the palliative care burden on women and girls in developing countries, as they are often responsible for those living with HIV in their families and communities. Women and girls are usually not remunerated for the care they provide, which has social, economic, and health implications for themselves and their families.

Efforts are needed to involve men in community care giving for PLWHA. Palliative care programs supported by the Emergency Plan should pay special attention to this issue, and work to facilitate dialogue and policies that improve support for women and girls who are caregivers, and to foster the involvement of men.

The equitable distribution of medications to ensure inclusion of women and girls must receive high priority. Programs should also work with men on the issues of gender power imbalance and domestic violence as they relate to care, as well as their roles in home-based care. More attention must also be given to creating legal protections and creating linkages to legal services for women and girls. Palliative care programs need to act as instruments of change, highlighting the need for effective efforts to ensure gender-sensitive access to treatment and care issues.

1.11 Human Capacity Development and Provider Education and Training

In many developing countries, inadequate human resources and palliative care training policies and weak or non-existent institutions contribute to the insufficient supply of health care professionals and other caregivers. Limited support for caregivers also deteriorates the human capacity which is essential to delivery quality care, and it is important for programs and policies to consider the extraordinary physical, psychological, practical (food and housing), and spiritual demands caregivers face. Support for all caregivers is important to maintaining a viable and effective health-care team. This support should address economic and subsistence needs of caregivers, education and skills development, caregiver recognition and access to HIV care for caregivers who are living with HIV/AIDS.

Several categories of health care providers are necessary for an effective palliative care program. Each has a unique role and training needs.

Medical Providers

The role of medical providers (physicians, clinical officers, and cadres of nurses) includes assessment, prevention, diagnosis, treatment, and management of pain and suffering experienced by PLWHA and their families. To fulfill their role, providers need training in the use of standard protocols for assessing pain, symptoms, and TB and other OIs. They must be able either to directly diagnose and treat the patient, or to refer the individual for appropriate care. Given the severe shortage of physicians, nurses must be trained in aspects of diagnosis and management as appropriate under local professional standards of practice and licensure. Access to continued training for all clinicians is essential.

Traditional Healers

The Emergency Plan acknowledges the important role of traditional healers in delivering health care to many individuals and families. They are often the link between the community and the health care system and are important partners in improving access to care. When appropriate, they should be included in the palliative care team. It is also important to recognize the critical cultural, supportive, psychological, and spiritual role of the traditional healer when patients and their families are

searching for meaning in illness and death. To support the participation of traditional healers in the palliative care team, training should be made available to them.

Community Health Workers

The use of trained community health care workers such as volunteers, medical assistants, counselors, and family members could provide opportunities to expand the delivery of palliative care in the community setting. Trained community health workers can provide basic nursing care, support for treatment adherence and HIV prevention, monitoring and assessment of medication impact (including symptom improvement and adverse drug reactions), referrals, pain and symptom assessment and management, psychosocial and nutrition counseling, and determination of need for, and provision of, social support (such as referrals to community-based support groups and income-generating activities).

People Living with HIV/AIDS

The success of palliative care programs depends on the involvement and leadership of PLWHA. As a result of their personal experiences, PLWHA can contribute to better understanding of the true needs of other PLWHA and best practices in HIV care programs. PLWHA are often the best counselors and educators for others who are HIV-positive and their families, particularly in regards to treatment literacy and symptom and pain management. All care and treatment programs must make a concerted effort to recruit PLWHA and support leadership roles for them.

Program staff who are PLWHA must receive the same level of palliative care as the program recipients to ensure full PLWHA participation in program leadership.

Interdisciplinary Teams

Given the many ways in which HIV disease affects individuals, communities, and families, it is important to establish interdisciplinary teams able to address the physical, psychological, supportive, and spiritual needs of the individual, family, and orphans. This collaboration allows for a more integrated and holistic approach to complex and interrelated problems and needs of adults and children infected or affected by HIV/AIDS. These teams should consist of professional health care workers such as palliative care nurses, community volunteers, clergy or religious leaders, family members, mental health counselors, traditional healers when appropriate, and other health care and support service providers and community workers.

The actions listed below promote human-resource capacity development. Each offers a unique opportunity to increase the capacity of the overall health care system:

- Support pre-service and in-service training and education in palliative care for professionals and community health workers (several countries have already developed comprehensive curricula).
- Ensure that the full range of providers, including physicians, nurses, traditional healers, community and volunteer health workers, PLWHA, pharmacists, social workers, and spiritual

counselors are available and trained appropriately. It is important to utilize the various types of nursing professionals and their varied competencies and skill levels.

- Ensure care resources and tools for health workers (e.g., availability to first level health workers of the WHO IMAI modules: Acute Care, Chronic HIV Care, General Principles of Chronic Care, and Palliative Care⁵ on symptom management and end-of-life care).
- Train program staff in fiscal accounting and management practices, including identification of diverse funding streams.
- Develop accreditation standards and support achievement of competencies in palliative care.
- Provide resources and technical assistance to develop quality standards, including the monitoring and evaluating of such standards from in-country or regional palliative care experts.
- Provide mentorship, twinning, and support for South-to-South exchanges among palliative care organizations.
- Develop and strengthen initiatives to care for caregivers (including professionals, community health workers, and family caregivers).
- Support the formation of interdisciplinary teams.
- Provide training and other support for family members and community caregivers to provide basic health care.
- Support regional training centers in palliative care.

Each of these options provides opportunities to expand human-resource capacity for delivering palliative care. It is important that these and other activities be considered elements in establishing sustainable care programs.

1.12 Policy Development

Public policies that advance development and implementation of palliative care are critical to the success of the Emergency Plan. Policies can be generated from various levels of government and public and private institutions, such as medical and nursing schools, public and private health care facilities, and CBOs and FBOs. Policies often prevent scale-up of care because of legal or regulatory restrictions on who can deliver care. Many types of providers can provide excellent quality care by including, but not limited to, trained doctors, various cadres of nurses, paramedicals, medical assistants, clinical officers, traditional birth attendants, community volunteers and health workers, etc.. Key actions for policy development include the following, among others:

- Recognize other cadres of health workers and expand roles of nurses, community health workers and other health care providers to provide palliative care and medications.
- Train, supervise and develop capacity of health care providers.
- Offer equitable access to a wide range of medications to prevent and control pain and symptoms, and to prevent and treat TB and other OIs.

⁵ WHO (2004). *Palliative care: symptom management and end-of-life care*
<http://www.who.int/3by5/publications/documents/en/genericpalliativecare082004.pdf>

- Establish integrated programs and networks of service providers, including community health associations and organizations.
- Establish evidence-based care standards and care packages.

The advancement of these policies is often accomplished through a well-organized effort to bring together leaders and practitioners in the field of palliative care with senior administrators and decision-makers in government and institutions. This type of collaboration promotes development of policies that reflect both the existing capacity within the government and health care system and the socio-cultural conditions of persons living in the community, and that respond to the specific health and supportive needs of PLWHA.

The following are among the actions that can be taken to develop appropriate policies:

- Support the establishment of national standards, regulations, guidelines and oversight.
- Work with governments to expand prescribing privileges and training for clinical officers, midwives and nurses to safely prescribe OI treatment and pain/symptom control medications.
- Develop the capacity of national palliative care organizations and associations to conduct policy advocacy for palliative care.
- Support training, skill development and supervision for volunteers or community health workers to provide home and community- based palliative care.
- Work with key government officials to help them understand and integrate comprehensive palliative care (not limited to home-based or hospice care) into national health strategic plans and national HIV/AIDS strategies.
- Establish policies to ensure access to HIV care and treatment for HIV-infected health care providers – professionals, community health workers, and caregivers.
- Work with key government officials to promote policies and programs to expand and enhance access to appropriate pain- and symptom-control medications, including the availability and prescribing of opioids, the integration of pain and symptom control and other palliative care into existing home-based care policies, and the adoption of professional curricula in academic training programs.

1.13 Supply-Chain Management

The *U.S. Five-Year Global HIV/AIDS Strategy* defines supply-chain management as a systematic process to “create, enhance, and promote an uninterrupted supply of high-quality, low-cost products that flow through an accountable system.” The goal of supply management is to eliminate drug diversion, counterfeiting, waste, and gaps in distribution systems to ensure an efficient and sustainable delivery of essential drugs, supplies, and equipment. The Strategy identifies these four key areas for developing supply chain management:

1. Rapid scale-up of logistic systems to manage supplies and products.
2. Build-up of sustainable procurement and distribution mechanisms.
3. Establishment of quality-control standards for drugs, test kits, and other supplies.

4. Protection of intellectual property laws at national and international levels.

Each of these strategies has implications for the delivery of palliative care and program management.

Palliative care providers at all levels of the health system need access to specific drugs and supplies. In addition to medications for pain and symptom relief and OI management, providers need access to items necessary for managing clinical conditions (e.g., drug-dispensing equipment, gloves, wound-care and mouth-care supplies, HIV test kits, sterile needles). Product selection procedures, distribution systems and networks, and information-management systems are needed to provide these products. Centralized procurement mechanisms, demand forecasting procedures, and coordination between supply-chain managers and program-service managers are needed to ensure patient enrollment and continual product availability. An accountable system is necessary to protect against the misuse or diversion of opioids used for pain control. The development of a supply management system with accountability is needed to increase service capacity to deliver effective care.

1.14 Reference Guide

The USG has published a *Clinical Guide to Supportive and Palliative Care for HIV/AIDS*⁶ and, in collaboration with African care experts, is developing a similar clinical guide for sub-Saharan Africa. The WHO Secretariat has developed guidelines for symptom management and end of life care.⁷ USG, the WHO, Ministries of Health, and other academic bodies around the world have developed guidelines addressing OIs, acute care, and other aspects of palliative care. Additionally, the USG is delineating a menu of evidence-based care interventions for PLWHA, HIV-infected children and pregnant/post-partum women and newborns. Below are additional palliative care resources:

- *U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention, Global AIDS Program. Strategies: Palliative Care.*
http://www.cdc.gov/nchstp/od/gap/strategies/4_3_palliative_care.htm
- *The World Health Organization:* <http://www.who.int/cancer/palliative/definition/en/>
- *The African Palliative Care Association: APCA, PO Box 7757, Kampala, Uganda Email: apca@hospiceafrica.or.ug http://www.theworkcontinues.org/docs/news/apca_newsletter.pdf*
- *The U.S. National Hospice and Palliative Care Organization* <http://www.nhpco.org/>
- The Diana Fund: <http://www.theworkcontinues.org/causes/palliative.asp>
- *Center for Advanced Palliative Care* <http://www.capc.org/>

⁶ The Health Resources and Service Administration (HRSA) HIV/AIDS Bureau (2003). A Clinical Guide on Supportive and Palliative Care for People with HIV/AIDS <http://hab.hrsa.gov/tools/palliative/>

⁷WHO (2004). Palliative care: symptom management and end-of-life care
<http://www.who.int/3by5/publications/documents/en/genericpalliativecare082004.pdf>

Annex I

Pediatric Palliative Care

Issues related to the delivery of HIV palliative care for pediatric clients include the following:

- The clinical course of HIV is more rapid in children, and mortality for infected babies is as high as 40 percent in the first year of life.
- Maternal antibodies make serologic diagnosis of HIV difficult in the first 18 months. Unless virologic diagnostic tools are available, this means that interventions such as cotrimoxazole prophylaxis and safe infant feeding must be initiated before diagnosis is confirmed.
- The appropriate interventions and methods of administration change with the age of the child. The infant and adolescent have very specific and age-dependent needs. Drug dosages also change with age, and child-friendly formulations are required.
- Children are dependent on adults for their care. These adults need to be identified, recruited, and educated as to how to care for the child. Family-centered care need to be supported, and caregivers encouraged to seek care and treatment interventions for the child, including ART when appropriate. Such caregivers are critical for adherence support for ART and other interventions.
- Certain symptoms are more common in children, including skin disorders, sore mouth, and convulsions. Some, such as pain, are more difficult to diagnose in children.
- Nutrition and growth are critical indicators of well-being, and of response to care and treatment. Failure to thrive is a key indicator of clinical deterioration. Safe infant feeding is a critical issue both for prevention and for care.
- If a child is infected, it means that one or both of his/her parents are or will likely become sick as a result of HIV/AIDS. Other siblings could also be infected. The family must therefore be assessed and supported as a unit.
- Disclosure of HIV status for children living with HIV/AIDS needs to be tailored to the child's understanding, and approached gradually and with parental consent, and preferably communicated by the parents.
- Communicating with children requires creativity and sensitivity, and often the use of stories, make-believe, drawing, dance and drama.
- Bereavement counseling and succession planning should be an intrinsic part of psychosocial support for children living with HIV/AIDS, and their families.

The Office of the U.S. Global AIDS Coordinator is finalizing the specific care package for children living with HIV/AIDS. Emergency Plan programs also need to consider the needs of the non-infected or asymptomatic child living with HIV/AIDS. These include immunizations, monitoring of growth and development, safe infant feeding, hand-washing and personal and household hygiene, and malaria prevention in endemic areas.

Pain management for children also follows the principles of the WHO analgesic ladder. Non-opioids, such as paracetamol and ibuprofen, can be used, but aspirin should be avoided because of the risk of Reye's Syndrome. Because young children might not be able to complain of pain or describe its intensity, it is important to observe for signs such as listlessness, irritability, poor

appetite, changes in sleep patterns, and loss of interest in play.

Emergency Plan programs must ensure several important linkages to providers. OVC programs should help identify the small proportion of orphans that are HIV-positive for referral to health care. Adult home-based care programs should help identify children who are single or double orphans or whose parents are very sick, and enroll them in OVC programs. PMTCT programs need to ensure follow-up of infants and children at the community level and refer children for diagnosis and treatment and commence co-trimoxazole and infant feeding interventions. HIV/TB programs must inquire about children in the home who may have been exposed to TB (regardless of HIV status), and provide treatment or INH prophylaxis as appropriate. Emergency Plan programs must support specific provider training and other human-capacity development strategies for the expansion of pediatric palliative care. Finally, Emergency Plan programs should integrate wrap-around programs, including child health and nutrition programs that are operating at the community level, particularly in high-prevalence countries.

APPENDIX IV: Preventive Care Guidance

**Guidance for United States Government In-Country Staff and Implementing Partners for
a Preventive Care Package for Adults* - #1**

**The President's Emergency Plan for AIDS Relief
Office of the U.S. Global AIDS Coordinator**

April 2006

***Please refer to companion Emergency Plan guidance for children aged 0-14 years of age**

I. Introduction

A key objective of the Emergency Plan is to reduce HIV-related morbidity and mortality rates and slow the progression of HIV disease in affected communities. A specific Emergency Plan goal is to support the provision of care for 10 million people infected and affected by HIV/AIDS. To address these priorities, it is necessary to identify and implement interventions targeted at the primary causes of HIV-related illness and death.

The use of antiretroviral treatment (ART) is one approach to slowing the progression of disease. However, it is also important to provide adults and children with interventions that prevent the onset of conditions such as *Pneumocystis carinii* pneumonia (PCP), tuberculosis (TB), malaria, malnutrition, and others, regardless of stage of HIV disease or eligibility for antiretroviral treatment. Each of these conditions can be complicated, severe, and even fatal to persons with HIV disease. Provision of preventive care interventions may also augment counseling and testing and HIV prevention programs by attracting more clients who will perhaps be more receptive to behavioral change messages. Counseling HIV-infected persons to refrain from high-risk behaviors offers an opportunity to prevent exposure to additional sexually-transmitted infections and to reduce transmission of HIV to others. Similarly, counseling and testing of family members and other contacts of HIV-infected persons offer an opportunity to identify additional HIV-infected persons and to refer them to appropriate care and prevention.

Emergency Plan countries should consider implementation of a standard “preventive care package” as part of their palliative care programs. Funding for the Preventive Care Package should be requested in Country Operational Plans, in appropriate program areas such as: Laboratory; Orphans and Vulnerable Children (OVCs); Palliative Care; TB/HIV; Treatment; and Strategic Information. United States Government (USG) teams in countries that are also part of the President’s Malaria Initiative (PMI) and/or are recipients of grants for the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), should work closely to integrate Emergency Plan work with activities funded by these two programs.

There is ongoing discussion regarding which interventions should be included in a preventive care package. Recognizing that a package cannot be standardized for all situations and countries, components of a care package are likely to vary within regions, and even within countries, depending on the setting and the capacity of the partners who are implementing such programs. However, it is valuable to offer a “menu” of interventions that should be considered. Emergency Plan programs should link the preventive components within this document to other key health care, such as routine medical care and voluntary family planning, which play a key role in reducing morbidity and mortality. Those interventions for people living with HIV/AIDS (PLWHA) and their families that cannot be funded directly should be considered for “wrap-around” funding from other sources including the PMI, the GFATM, and family planning programs. “Wrap-around” services may benefit non-HIV-infected, as well as HIV-infected, persons in the household or elsewhere in the community. An example of such an activity is the construction of latrines, which have been shown to prevent diarrheal disease in resource-constrained settings. This intervention is mentioned under “Safe water and personal hygiene,” but is not included in the recommendations, since latrine construction is not currently supported

by PEPFAR. Prioritization and selection of the components of a preventive care package must be performed locally, and should be consistent with national guidelines and those sponsored by the World Health Organization (WHO) operative within the country.

The following sections provide the scientific basis for the interventions that could be included in a “preventive care package.” Although most interventions included here are pertinent to both adults and children, HIV-infected/exposed children require additional consideration. Therefore, a separate document focusing on a preventive care package for such children has been developed. It should also be emphasized that the preventive care package described here constitutes only a fraction of palliative care to be considered by USG programs. Treatment of symptomatic conditions, alleviation of pain, and psychological, spiritual and social support are important components of palliative care but are beyond the scope of this document (see “HIV/AIDS Palliative Care Guidance #1:

An Overview of Comprehensive HIV/AIDS Care Services in the President’s Emergency Plan for AIDS Relief (section 1.5)).

II. Activities Supported by the Emergency Plan

1. *Cotrimoxazole prophylaxis*

In industrialized countries, the combination antibiotic trimethoprim-sulfamethoxazole (or cotrimoxazole) has been recommended to prevent *Pneumocystis jiroveci* (formerly *P. carinii*) pneumonia (PCP) in HIV-infected adults with CD4 counts of less than 200 cells/μl since 1989⁸ and in children born to HIV-infected mothers since 1991.⁹ Cotrimoxazole prophylaxis is standard practice in areas of the world where PCP is common in HIV-infected persons. PCP appears to be less common in sub-Saharan Africa than in other regions,¹⁰ but cotrimoxazole is also effective in African countries in preventing diarrhea and malaria and in prolonging life.

Several studies have addressed the efficacy of cotrimoxazole in HIV-infected persons in sub-Saharan Africa. A randomized placebo-controlled trial of cotrimoxazole prophylaxis for HIV-infected adults (WHO clinical stage 2 or 3) in Cote d’Ivoire demonstrated a reduction of the rate of severe events (death or hospitalization) by 43 percent in the intervention group, but did not show a decline in mortality.¹¹ Another randomized trial in Cote d’Ivoire of cotrimoxazole prophylaxis for HIV-infected adults with active pulmonary TB showed a 46 percent reduction in

⁸ CDC. Guidelines for prophylaxis against *Pneumocystis carinii* pneumonia for persons infected with human immunodeficiency virus. MMWR Morb Mortal Wkly Rep. 1989 Jun 16;38 Suppl 5:1-9.

⁹ CDC. Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia for Children Infected with Human Immunodeficiency Virus. MMWR Morb Mortal Wkly Rep. Vol 40, No RR02;001 03/15/1991.

¹⁰ Malin AS, Gwanzura LK, Klein S, Robertson VJ, Musvaire P, Mason PR. *Pneumocystis carinii* pneumonia in Zimbabwe. Lancet. 1995 Nov 11;346(8985):1258-61.

¹¹ Anglaret X, Chene G, Attia A, Toure S, Lafont S, Combe P, Manlan K, N’Dri-Yoman T, Salamon R. Early chemoprophylaxis with trimethoprim-sulphamethoxazole for HIV-1-infected adults in Abidjan, Cote d’Ivoire: a randomised trial. Cotrimo-CI Study Group. Lancet. 1999 May 1; 353(9163):1463-8.

mortality and a 43 percent reduction in hospitalization.¹² A study in South Africa found that cotrimoxazole reduced mortality by 44 percent and severe HIV-related illnesses by 48 percent in patients with WHO stage 3 or 4 disease or with CD4 counts less than 200 cells/ μ l.¹³ These findings were further supported by a meta-analysis of randomized trials in adult African HIV-infected patients, which showed that cotrimoxazole reduced death by 31 percent, morbidity by 24 percent and hospitalization by 34 percent.¹⁴ In a recent study in Uganda, cotrimoxazole, when taken daily by persons with HIV, reduced death by 46 percent, malaria by 72 percent, diarrhea by 35 percent, and hospitalizations by 31 percent. It also slowed the rate of CD4 decline and the rate of viral load increase.¹⁵ PCP appears to be more common in HIV-infected African children than in adults, and one study that evaluated the efficacy of cotrimoxazole prophylaxis in South African children documented an 89 percent reduction in PCP incidence.¹⁶

Several criteria for cotrimoxazole prophylaxis eligibility in African patients have been proposed: Wiktor et al. found the benefit of cotrimoxazole was most significant in patients with CD4 counts less than 350 cells/ μ l,¹² and Badri et al. suggested prophylaxis for patients at WHO clinical stage 3 or 4.¹³ However, Anglaret et al. found benefit at all CD4 levels,¹¹ as did Mermin et al.¹⁵ A cost-effectiveness study by Yazdanpanah also recommended prophylaxis for adults with WHO stage 2, 3 or 4;¹⁷ another by Pitter et al. reports cost-savings when cotrimoxazole is given to all HIV-infected adults in Uganda (Dr. Christian Pitter, personal communication). National recommendations in Uganda suggest cotrimoxazole for all HIV-infected persons.

Cotrimoxazole is relatively safe and available, does not require laboratory monitoring, and in the

¹² Wiktor SZ, Sassan-Morokro M, Grant AD, Abouya L, Karon JM, Maurice C, Djomand G, Ackah A, Domoua K, Kadio A, Yapi A, Combe P, Tossou O, Roels TH, Lackritz EM, Coulibaly D, De Cock KM, Coulibaly IM, Greenberg AE. Efficacy of trimethoprim-sulphamethoxazole prophylaxis to decrease morbidity and mortality in HIV-1-infected patients with tuberculosis in Abidjan, Cote d'Ivoire: a randomised controlled trial. *Lancet*. 1999 May 1; 353(9163):1469-75.

¹³ Badri M, Ehrlich R, Wood R, Maartens G. Initiating co-trimoxazole prophylaxis in HIV-infected patients in Africa: an evaluation of the provisional WHO/UNAIDS recommendations. *AIDS*. 2001 Jun 15; 15(9):1143-8.

¹⁴ Grimwade K, Swingle G. Cotrimoxazole prophylaxis for opportunistic infections in adults with HIV. *Cochrane Database Syst Rev*. 2003; (3):CD003108.

¹⁵ Mermin, J., Lule, J., Ekwaru, J.P., Malamba, S., Downing, R., Ransom, R., Kahazura, F., Culver, D.H., Kizito, F., Bunnell, R., Kigozi, A., Nakanjako, D., Wafula, W., and Quick, R. Effect of cotrimoxazole prophylaxis on morbidity, mortality, CD4 cell count, and HIV viral load among persons with HIV in rural Uganda. *Lancet*. 2004 Oct 16;364(9443):1428-34.

¹⁶ Zar HJ, Dechaboon A, Hanslo D, Apolles P, Magnus KG, Hussey G. Pneumocystis carinii pneumonia in South African children infected with human immunodeficiency virus. *Pediatr Infect Dis J*. 2000 Jul; 19(7):603-7.

¹⁷ Y. Yazdanpanah, E. Losina, X. Anglaret, S.J. Goldie, R.P. Walensky, M.C. Weinstein, S. Toure, H.E. Smith, A.D. Kimmel, H. Zhang, T.N' Dri-Yoman, R. Salamon, J. Kaplan, K.A. Freedberg. Clinical impact and cost-effectiveness of co-trimoxazole prophylaxis in patients living with HIV/AIDS in Côte d'Ivoire: a trial-based analysis. World AIDS Conference, Bangkok, July 11-14, 2004.

Ugandan study, its effect did not decrease over the 1.5-2 year follow-up period.¹⁵ The most common toxicity - skin rash - appears to be uncommon in African patients, and its severe manifestation - Stevens-Johnson syndrome - is rare.^{11,12} Cotrimoxazole is widely available in sub-Saharan Africa and when purchased in bulk costs only \$6 per person per year. Concerns remain about the generation of widespread antimicrobial resistance to cotrimoxazole, including resistance of Plasmodium species to the closely related antimalarial Fansidar. However, current data actually support a benefit to household contacts of persons receiving cotrimoxazole. Therefore, these concerns remain largely theoretical.

WHO/UNAIDS provisionally recommends cotrimoxazole for all HIV-infected adults with WHO clinical stage 2, 3 or 4 disease or with CD4 counts less than 500 cells/ μ l.¹⁸ For children, WHO/UNAIDS currently recommends cotrimoxazole for all HIV-exposed/infected infants and older children with HIV-related symptoms or with severe immunosuppression (see companion guidance - *Emergency Plan guidance for children aged 0-14 years of age*). Updated WHO recommendations on cotrimoxazole prophylaxis were discussed at an international consultation in Geneva in May 2005 and are expected to be released soon. When available, this document will be posted on the OGAC website.

Emergency Plan funds may support:

1. Technical assistance to develop national policy, guidelines and training for the utilization of cotrimoxazole in adults and children.
2. Cotrimoxazole prophylaxis for HIV-infected adults and children who are eligible based on national guidelines.

¹⁸ Provisional WHO/UNAIDS secretariat recommendations on the use of cotrimoxazole prophylaxis in adults and children living with HIV/AIDS in Africa. 2000.

2. Effective tuberculosis (TB) interventions for HIV-infected persons

TB is a leading cause of severe morbidity and mortality among persons with HIV/AIDS, especially in sub-Saharan Africa where 32 percent of TB patients are HIV-infected;¹⁹ and in some areas, the prevalence of HIV infection among TB patients can be as high as 70 percent.²⁰ In sub-Saharan Africa, approximately 39 percent of TB deaths are attributable to HIV.²¹

HIV-induced immunosuppression promotes the development of active TB in persons co-infected with HIV and *Mycobacterium tuberculosis*,²² and active TB accelerates the progression of HIV disease.²³ Therefore, in high HIV prevalence populations, the identification and treatment of active TB are high priorities not only for care of HIV-infected persons but also for control of TB.²⁴ Furthermore, operational research in Africa²⁵ and elsewhere²⁶ has shown that up to 11 percent of HIV-infected persons identified in HIV counseling and testing have undiagnosed TB. Thus, HIV care programs are very likely to include patients with undiagnosed, active TB.

After active TB has been excluded, daily isoniazid (INH) prophylaxis for 6-9 months has been associated with a reduction in the incidence of TB among HIV-infected persons. This effect is most pronounced in persons with a positive tuberculin skin test (TST), in whom a 60 percent reduction in incidence of TB has been observed.²⁷ However, this meta-analysis of seven randomized controlled trials showed that INH preventive therapy (IPT) for 6-12 months given to HIV-infected persons was associated with a 42 percent reduction in TB incidence regardless of TST result. The effect of IPT on mortality is not as clear.

¹⁹ Dye C, Scheele S, Dolin P, Pathania V, Raviglione MC. Consensus statement: Global burden of tuberculosis: estimated incidence, prevalence, and mortality by country. WHO Global Surveillance and Monitoring Project. JAMA. 1999 Aug 18;282(7):677-86.

²⁰ WHO Guidelines for implementing collaborative TB and HIV program activities. WHO 2003.

²¹ Corbett EL, Watt CJ, Walker N, Maher D, Williams BG, Raviglione MC, Dye C. The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. Arch Intern Med. 2003 May 12;163(9):1009-21.

²² Daley CL, Small PM, Schechter GF, et al. An outbreak of tuberculosis with accelerated progression among persons infected with the human immunodeficiency virus: an analysis using restriction-fragment length polymorphisms. N Engl J Med 1992;326:231-235.

²³ Whalen C, Horsburgh R, Hom D, Lahart C, Simberkoff M, Ellner J. Accelerated course of human immunodeficiency virus infection after tuberculosis. Am J Crit Care Med 1995; 151:129-135.

²⁴ World Health Organization. Strategic framework to decrease the burden of TB/HIV. WHO/CDS/TB/2002.296, WHO/HIV_AIDS/2002.2.

²⁵ Zar HJ, Cotton MF, Lombard C et al. The impact of isoniazid prophylaxis on mortality in HIV-infected children from a high tuberculosis prevalence area. Abstract in XV AIDS Conference, Bangkok July 11-15.

²⁶ Grant AD, Kaplan JE, de Cock KM. Preventing opportunistic infections among human immunodeficiency virus-infected adults in African countries. Am J Trop Med Hyg., 65(6), 2001, pp 810-21.

²⁷ Bucher HC, Griffith LE, Guyatt GH, Surde P, Naef M, Sendi P, Battega M. Isoniazid prophylaxis for tuberculosis in HIV infection: a meta-analysis of randomized trials. AIDS 1999 Mar 11; 13(4): 501-7.

Emergency Plan funds may support:

1. Technical assistance to develop national policy, guidelines and training for the implementation of TB/HIV related prevention and treatment.
2. Screening of HIV-infected persons for active TB according to national guidelines (at a minimum using a simple set of questions to identify suspected TB cases [e.g., prolonged cough, weight loss, night sweats]).
3. With a goal of performing an HIV test in all persons who access TB clinics, a referral system that links HIV counseling, testing, and care with TB diagnostic and treatment centers, consistent with national guidelines for referral, treatment, and reporting of TB.
4. Tuberculin skin testing to identify HIV-infected persons at highest risk.
5. INH preventive therapy for persons living with HIV/AIDS once active TB has been excluded.
6. INH for HIV-exposed and HIV-infected children who have been exposed to a case of smear-positive TB in their households, once active TB has been excluded.

3. Safe drinking water and personal hygiene

People living in resource-poor settings often have limited access to safe water and basic methods of hygiene and sanitation (*e.g.* hand washing with soap). Most research on the impact of safe water, sanitation, and hygiene interventions on diarrheal disease has focused on children under 5 years of age because most diarrhea-associated mortality has been associated with this group. Use of a safe water supply was shown to reduce diarrhea by 20 percent in children in a study in Malawi.²⁸ In a review of 144 studies, water treatment and safe storage at the point-of-use (typically the household) were effective in reducing diarrheal prevalence by 26 percent;²⁹ in another review, Gundry et al. estimated a 65 percent reduction in diarrhea from such household-level interventions.³⁰ A study of HIV-infected persons and their families in Uganda showed that use of a simple, home-based safe water system reduced the incidence of diarrheal episodes by 25 percent, the number of days with diarrhea by 33 percent, and the frequency of visible blood or pus in stool.³¹ The cost of the intervention was less than \$5 per family per year. Provision of safe water at the household level in resource-constrained settings is consistent with WHO

²⁸ Young B, Brisco J. A case control study of the effect of environmental sanitation on diarrheal morbidity in Malawi. *J Epidemiol Community Health*. 1988 Mar; 42(1): 83-8.

²⁹ Esrey SA, Potash JB, Roberts L, Shiff C 1991 Effects of improved water supply and sanitation on ascariasis, diarrhea, dracunculiasis, hookworm infection, schistosomiasis, and trachoma *Bulletin of the World Health Organization* 69(5):609-621

³⁰ Gundry S, Wright S, Conroy R 2004 A systematic review of the health outcomes related to household water quality in developing countries *Journal of Water and Health* 2(1): 1-13

³¹ Lule JR, Mermin J, Ekwaru JP, Malamba S, Downing R, Ransom R, Nakanjako D, Wafula W, Hughes P, Bunnell R, Kaharuzza F, Coutinho A, Kigozi A, Quick R. Effect of home-based water chlorination and safe storage on diarrhea among persons with human immunodeficiency virus in Uganda. *Am J Trop Med Hyg*. 2005 Nov;73(5):926-33.

policies.

A recent review by Curtis showed that hand washing with soap was associated with a 43 percent reduction in diarrheal disease.³² The benefit of hand washing was further supported by a reduction in diarrhea by 62 percent in people in rural Bangladesh,³³ and by 53 percent in a randomized controlled trial of children in Pakistan.³⁴ Reviews by Esrey *et al.* and Huttly *et al.* of the effect of hygiene promotion interventions on diarrhea morbidity found a median reduction of roughly one-third.^{29,35} However, the HIV status of the subjects of all of these studies was unknown.

Protecting the water supply by use of latrines has also been associated with a reduction in incidence of diarrheal disease. Latrine construction is currently beyond the scope of PEPFAR funding but should be considered for “wrap-around” support by other funding sources.

Diarrhea incidence, duration, severity, and mortality are all higher in children with HIV/AIDS than in HIV-uninfected children, and chronic diarrhea is also a major cause of morbidity and mortality in HIV-infected adults. Therefore, interventions that reduce diarrheal episodes should be considered for use in all HIV-infected persons.

Emergency Plan funds may support:

1. Home-based, safe drinking water interventions, (*e.g.*, dilute sodium hypochlorite (bleach) water treatment, water vessels, etc.) for HIV-infected persons in communities where there is not a reliable source of safe water.
2. Soap and hand washing instructions for HIV-infected persons.

4. Insecticide-treated nets

³² Curtis V, Cairncross S. 2003. Effect of washing hands with soap on diarrhea risk in the community: a systematic review. *Lancet Infectious Diseases* 3 (5) :275-81.

³³ Shahid NS, Greenough WB 3rd, Samadi AR, Huq MI, Rahman N. Hand washing with soap reduces diarrhoea and spread of bacterial pathogens in a Bangladesh village. *J Diarrhoeal Dis Res.* 1996 Jun; 14(2):85-9.

³⁴ Luby SP, Agboatwalla M, Painter J, Altaf A, Billhimer WL, Hoekstra RM. Effect of intensive handwashing promotion on childhood diarrhea in high-risk communities in Pakistan: a randomized controlled trial. *JAMA.* 2004 Jun 2; 291(21):2547-54.

³⁵ Huttly SRA, Moriss SS, Pisni V 1997. Prevention of diarrhea in young children in developing countries. *Bulletin of the World Health Organization* 75 (2): 165-174.

Malaria is a life-threatening parasitic disease transmitted from person-to-person through the bite of a mosquito. The disease exerts its heaviest toll in Africa, where about 90 percent of the more than one million deaths from malaria worldwide occur each year. Prevalence of parasitemia ranges from 22-61 percent in the general population and can be as high as 82 percent in children 5-10 years of age.³⁶ In a study in Uganda, the prevalence of parasitemia and clinical malaria in HIV-infected persons was found to be almost twice that in HIV-uninfected persons.³⁷ In another study, malaria was found to be 1.7-fold more common in HIV-infected children compared to HIV-uninfected children.¹⁵ HIV was also associated with more severe manifestations of malaria.^{38,39}

Insecticide-treated nets (ITN) have proven to be effective in reducing the risk of malaria in children living in areas with high transmission: 27.8 percent reduction in malaria parasitemia,⁴⁰ 17 percent reduction in mortality in children under 5 years of age,⁴¹ and 25 percent reduction in all-cause mortality in children 1-9 years old.⁴² In randomized controlled trials in Kenya, bednets reduced symptomatic malaria in children by 52 percent, placental malaria by 35 percent and the prevalence of low birth weight by 28 percent.^{43,44} ITNs also had a protective effect on persons in

³⁶ Koram KA, Owusu-Agyei S, Fryauff DJ, Anto F, Atuguba F, Hodgson A, Hoffman L, Nkrumah FK. Seasonal profiles of malaria infection, anaemia, and bed net use among age groups and communities in northern Ghana. *Trop Med Int Health*. 2003 Sep;8(9):793-802.

³⁷ Whitworth J, Morgan D, Quigley M, Smith A, Mayanja B, Eotu H, Omoding N, Okongo M, Malamba S, Ojwiya A. Effect of HIV-1 and increasing immunosuppression on malaria parasitaemia and clinical episodes in adults in rural Uganda: a cohort study. *Lancet*. 2000 Sep 23; 356 (9235):1051-6.

³⁸ Grimwade K, French N, Mbatha DD, Zungu DD, Dedicoat M, Gilks CF. Childhood malaria in a region of unstable transmission and high human immunodeficiency virus prevalence. *Pediatr Infect Dis J*. 2003 Dec;22(12):1057-63.

³⁹ Grimwade K, French N, Mbatha DD, Zungu DD, Dedicoat M, Gilks CF. HIV infection as a cofactor for severe falciparum malaria in adults living in a region of unstable malaria transmission in South Africa. *AIDS*. 2004 Feb 20;18(3):547-54.

⁴⁰ Holtz TH, Marum LH, Mkandala C, Chizani N, Roberts JM, Macheso A, Parise ME, Kachur SP. Insecticide-treated bed net use, anaemia, and malaria parasitaemia in Blantyre District, Malawi. *Trop Med Int Health*. 2002 Mar;7(3):220-30.

⁴¹ Lengeler C. Insecticide-treated bednets and curtains for preventing malaria. *Cochrane Database Syst Rev*. 2000; (2): CD000363.

⁴² D'Alessandro U, Olaleye BO, McGuire W, Langerock P, Bennett S, Aikins MK, Thomson MC, Cham MK, Cham BA, Greenwood BM. Mortality and morbidity from malaria in Gambian children after introduction of an impregnated bed net programme. *Lancet*. 1995 Feb 25;345(8948):479-83.

⁴³ ter Kuile FO, Terlouw DJ, Kariuki SK, Phillips-Howard PA, Mirel LB, Hawley WA, Friedman JF, Shi YP, Kolczak MS, Lal AA, Vulule JM, Nahlen BL. Reduction of malaria during pregnancy by permethrin-treated bednets in an area of intense perennial malaria transmission in western Kenya. *Am J Trop Med Hyg*. 2003 Apr; 68 (4 Suppl): 50-60.

⁴⁴ ter Kuile FO, Terlouw DJ, Kariuki SK, Phillips-Howard PA, Mirel LB, Hawley WA, Friedman JF, Shi YP, Kolczak MS, Lal AA, Vulule JM, Nahlen BL. Impact of permethrin-treated bed nets on malaria, anemia, and growth in infants in an area of intense perennial

nearby homes.⁴⁵ Mermin et al. recently addressed the effects of ITNs on malaria in HIV-positive persons.⁴⁶ They found that the combination of co-trimoxazole, antiretroviral therapy, and ITNs substantially reduced the frequency of malaria in adults with HIV. Compared with a baseline malaria incidence of 50.8 episodes per 100 person-years, co-trimoxazole prophylaxis was associated with 9.0 episodes per 100 person-years (adjusted incidence rate ratio [IRR] 0.24, 95% CI 0.15-0.38); ART and co-trimoxazole with 3.5 episodes per 100 person-years (0.08, 0.04-0.17); and co-trimoxazole, ART, and ITNs with 2.1 episodes per 100 person-years (0.05, 0.03-0.08).

The currently recommended bednet is the long-lasting, insecticide-treated net. The insecticide in these nets lasts for 3-5 years - the life of the net. The average cost of an ITN is about \$5, making it a low-cost public health intervention.

Emergency Plan funds may support:

USG teams in Emergency Plan countries that are also part of the President's Malaria Initiative should coordinate closely and use both funding streams creatively to serve HIV-affected individuals in the distribution of (long-lasting) insecticide-impregnated nets. Emergency Plan support can be used for insecticide-treated nets to cover the sleeping areas of households of HIV-infected persons in areas in which malaria is endemic.

5. Nutrition and micronutrient supplementation

Micronutrients, including vitamins, have gained increasing interest as a preventive measure for HIV-infected persons. Several studies have shown positive benefits of daily high-dose multiple micronutrient supplements for HIV-positive adults. In one trial of HIV-infected men and women in Thailand, a daily supplement containing 21 vitamins and minerals was associated with a 47 percent reduction in mortality, primarily among those with CD4 counts <200 who would normally be eligible for HAART, but were not on antiretroviral drugs during this study.⁴⁷ Multi-vitamins (doses of vitamins B, C, E from 6-23 times the recommended daily allowance) administered to HIV-infected pregnant women reduced fetal death by 39 percent, and decreased

malaria transmission in western Kenya. *Am J Trop Med Hyg.* 2003 Apr;68(4 Suppl):68-77.

⁴⁵ Hawley WA, Phillips-Howard PA, ter Kuile FO, Terlouw DJ, Vulule JM, Ombok M, Nahlen BL, Gimnig JE, Kariuki SK, Kolczak MS, Hightower AW. Community-wide effects of permethrin-treated bed nets on child mortality and malaria morbidity in western Kenya. *Am J Trop Med Hyg.* 2003 Apr;68(4 Suppl):121-7.

⁴⁶ Mermin J, Ekwaru JP, Liechty CA, Were W, Downing R, Ransom R, Weidle P, Lule J, Coutinho A, Solberg P. Effect of co-trimoxazole prophylaxis, antiretroviral therapy, and insecticide-treated bednets on the frequency of malaria in HIV-1-infected adults in Uganda: a prospective cohort study. *Lancet.* 2006 Apr 15;367(9518):1256-61.

⁴⁷ Jiamton S, Pepin J, Suttent R, Filteau S, Mahakkanukrauh B, Hanshaoworakul W, Chaisilwattana P, Suthipinittharm P, Shetty P, Jaffar S. A randomized trial of the impact of multiple micronutrient supplementation on mortality among HIV-infected individuals living in Bangkok. *AIDS.* 2003 Nov 21;17(17):2461-9.

the risk of low birth weight (<2500 g) by 44 percent and pre-term birth (<34 weeks gestation) by 39 percent. Multi-vitamins also significantly increased maternal CD4, CD8, and CD3 counts.⁴⁸ Daily multi-vitamin supplementation improved weight gain among HIV-infected Tanzanian pregnant women.⁴⁹ In this same trial, daily vitamin A plus beta-carotene was associated with an increased risk of HIV transmission during breastfeeding.⁵⁰ Extended follow-up of these women revealed that daily multi-vitamin supplementation of high doses of vitamins B, C, E taken during pregnancy and throughout the breastfeeding period reduced progression to WHO clinical stage 4 or death by 29 percent, and resulted in higher CD4 and lower viral load; inclusion of vitamin A plus beta-carotene in the supplement attenuated its benefits.⁵¹ WHO has concluded that while these studies are promising, they do not warrant recommending higher daily micronutrient intakes for PLWHAs than those recommended for the general population.

Emergency Plan funds may support:

1. Daily multiple micronutrient supplements (1RDA) for PLWHA, especially pregnant and lactating women and children, according to national guidelines, where dietary assessment indicates inadequate intake of micronutrients from food.
2. Nutrition counseling linked to clinical- and home-based care for all HIV-infected persons, especially in areas in which malnutrition is endemic.
6. Services and counseling to prevent the transmission of HIV to others

HIV post-test counseling is the first step to introducing HIV-infected persons to appropriate prevention messages, medical care and treatment. Providing test results and appropriate counseling to HIV-infected persons has been shown to decrease high-risk sexual behavior and

⁴⁸ Fawzi WW, Msamanga GI, Spiegelman D, Urassa EJ, McGrath N, Mwakagile D, Antelman G, Mbise R, Herrera G, Kapiga S, Willett W, Hunter DJ. Randomised trial of effects of vitamin supplements on pregnancy outcomes and T cell counts in HIV-1-infected women in Tanzania. *Lancet*. 1998 May 16; 351(9114):1477-82.

⁴⁹ Villamor E, Msamanga G, Spiegelman D, Antelman G, Peterson KE, Hunter DJ, Fawzi WW. Effect of multi-vitamin and vitamin A supplements on weight gain during pregnancy among HIV-1-infected women. *Am J Clin Nutr*. 2002 Nov;76(5):1082-90.

⁵⁰ Fawzi WW, Msamanga GI, Hunter D, Renjifo B, Antelman G, Bang H, Manji K, Kapiga S, Mwakagile D, Essex M, Spiegelman D. Randomized trial of vitamin supplements in relation to transmission of HIV-1 through breastfeeding and early child mortality. *AIDS*. 2002 Sep 27;16(14):1935-44.

⁵¹ Fawzi WW, Msamanga GI, Spiegelman D, Wei R, Kapiga S, Villamor E, Mwakagile D, Mugusi F, Hertzmark E, Essex M, Hunter DJ. A randomized trial of multi-vitamin supplements and HIV disease progression and mortality. *N Engl J Med* 2004 Jul 1; 351 (1): 23-32.

HIV transmission.^{52,53} In the Democratic Republic of Congo, condom use among HIV discordant couples increased from 5 percent before counseling to 71 percent after counseling, and a low rate of HIV seroconversion was noted among this group.⁵⁴ The provision of low-cost condoms has also been associated with an 80 percent reduction in HIV transmission among discordant couples.⁵⁵ Therefore, counseling HIV-infected persons to refrain from high-risk behaviors offers an opportunity to reduce transmission of HIV to others. It will also reduce the risk to the patient of acquiring additional sexually transmitted infections.

It is important to provide ongoing prevention messages for people with HIV infection to support their maintenance of safe sexual practices using abstinence, being faithful and the correct and consistent use of condoms (ABC). Integrating prevention into care and treatment settings, including provider-delivered risk reduction information, will allow patients to receive routine access to important messages about eliminating, or decreasing frequency of, high-risk behavior.

Emergency Plan funds may support:

1. Technical assistance to develop national policy, guidelines and training for the implementation of prevention programs for PLWHA.
2. HIV counseling about high risk behavior for all HIV-infected persons based on ABC, on an ongoing basis.
3. Condoms and referral for HIV-infected persons to other preventive services, especially family planning and STD clinics.

7. HIV counseling and testing of family members and other contacts

HIV counseling and testing may also benefit family members and other contacts of HIV-infected persons by facilitating early referral of HIV-infected persons to care and prevention. As indicated above, couples counseling and testing has been demonstrated to be effective in reducing HIV transmission risk among HIV-discordant couples. Counseling and testing models within care programs may include: 1) family-based (including home-based) counseling and

⁵² Weinhardt LS, Carey MP, Johnson BT, Bickham NL. Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985-1997. *Am J Public Health.* 1999 Sep; 89(9):1397-405.

⁵³ Painter TM. Voluntary counseling and testing for couples: a high-leverage intervention for HIV/AIDS prevention in sub-Saharan Africa. *Soc Sci Med* 2001 Dec; 53(11):1397-411

⁵⁴ Kamenga M, Ryder RW, Jingu M, Mbuyi N, Mbu L, Behets F, Brown C, Heyward WL. Evidence of marked sexual behavior change associated with low HIV-1 seroconversion in 149 married couples with discordant HIV-1 serostatus: experience at an HIV counselling center in Zaire. *AIDS.* 1991 Jan; 5(1):61-7.

⁵⁵ Weller S, Davis K. Condom effectiveness reducing heterosexual HIV transmission. *Cochrane Database Syst Rev* 2001; 93)CD003255.

testing that encourages HIV counseling and testing of family members, including children; 2) couples counseling and testing in which the partner of the HIV-infected person is counseled and tested; and 3) work site-based counseling and testing.

Emergency Plan funds may support:

1. HIV counseling and testing for family members of HIV-infected persons at a single, low-cost visit using rapid testing methods and abbreviated pre-test counseling to the family unit.
2. Counseling for discordant couples to promote risk reduction behaviors (*e.g.*, discussion of ABC and, when applicable, provision of condoms).
3. HIV counseling and testing for sex partners of HIV-infected persons.
4. Referral to care and prevention for persons identified as HIV-infected.

APPENDIX V: HIV Prevention among Drug Users Guidance

The U.S. President's Emergency Plan for AIDS Relief HIV Prevention among Drug Users Guidance #1: Injection Heroin Use March 2006

Introduction

Section 104A of the Foreign Assistance Act, as amended by the U.S. Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (P.L. 108-25), authorizes HIV/AIDS prevention through activities “to help avoid substance abuse and intravenous drug use that can lead to HIV infection.” Consistent with that authorization, this document provides initial policy guidance on the development of HIV/AIDS prevention-focused programs aimed at substance abusers and users of intravenous drugs, specifically those who inject heroin. It provides examples of activities for which we may consider President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) funding and, likewise, examples of activities for which Emergency Plan funding would not be appropriate at this time. This document is not intended as a comprehensive policy for all HIV/AIDS prevention programs relating to substance abuse that could be contemplated under the Emergency Plan. We expect additional policy and programming guidance to evolve as new information emerges and we gain more field experience.

Substance Abuse and the Risk of HIV

Substance use, including injection drugs, is a major means of spreading HIV in many parts of the world. Injection-drug users (IDUs) everywhere are at great risk for infection with HIV, including risk associated with contracting hepatitis and sexually transmitted infections (STIs), because of past and continuing high-risk behaviors. The United Nations Office on Drugs and Crime estimates there will be a significant global increase in the production, transportation and consumption of opioids, mainly heroin. We can anticipate that increased access to these drugs will play a critical part in perpetuating the HIV/AIDS epidemic. As such, we intend to begin to address this issue with three approaches to HIV prevention, namely: 1) tailoring HIV prevention programs to substance abusers; 2) supporting, on a pilot basis (i.e., with approval from the Office of the U.S. Global AIDS Coordinator, or O/GAC), substance abuse therapy programs for HIV-infected individuals as an HIV prevention measure; and 3) offering HIV-infected drug users a comprehensive HIV/AIDS treatment program to reduce the risk of transmission. Comprehensive HIV/AIDS prevention programs can help substance users stop using drugs, change their risk behaviors, and reduce their risk for acquiring or transmitting HIV infection.

1. Tailoring HIV Prevention Programs to Substance Abusers

The most effective strategy for preventing HIV/AIDS and other blood-borne infections in substance-using populations and their communities is one that decreases drug use and includes information and education, community outreach, risk reduction counseling, and substance abuse treatment. Community-based outreach for drug users should address HIV prevention, risk reduction, and substance abuse with links to appropriate care and treatment services. Prevention education should address the risks of injecting drugs and sharing syringes, and provide education

and counseling on how to reduce or stop injecting drugs.

2. Supporting Substance Abuse Programs as an HIV Prevention Measure

Substance abuse programs may include behavioral models or medication-assisted treatment, or a combination of the two, and should also include case management and counseling services. Medication-assisted treatment that uses methadone, buprenorphine or naltrexone, is an effective option for treatment of heroin dependence. Heroin injectors who do not enter substance abuse treatment programs are up to six times more likely to become infected with HIV than injectors who enter and remain in treatment.^{56,57} Many substance users are not currently in substance abuse treatment programs because of multiple factors, including the limited availability of these programs. Consequently, substantial numbers of substance users continue to use, and thus continue to be at risk for HIV and hepatitis infections. These programs should include aspects that encourage making the transition from medications to abstinence. Medication-assisted treatment can be combined with other modalities as part of a comprehensive HIV/AIDS prevention program. All prevention programs that contain medication-assisted substance abuse treatment will require prior approval from O/GAC. The Emergency Plan may only support on a pilot basis prevention programs providing medication-assisted substance abuse treatment to HIV-negative individuals.

3. Offering HIV-Infected Drug Users a Comprehensive Program to Reduce Their Risk of Transmission

To reduce the risk of HIV transmission, Emergency Plan programs should offer HIV-infected heroin users a comprehensive HIV/AIDS treatment program that promotes recovery through confidential HIV counseling and testing, anti-retroviral treatment (ART), palliative care, STI and tuberculosis treatment, substance abuse treatment, and transitional services between treatment facilities and the community (e.g., care referrals, risk reduction education, job skills training, etc.). Drug users with HIV respond as well to HIV-specific therapy as do other patient groups. Studies have documented that HIV-infected drug users who receive substance abuse treatment and other health care services are more likely to reduce high-risk drug and sexual behaviors and to comply with medical regimens.

Summary

Consistent with U.S. Government policy, Emergency Plan funding may not be used to support needle or syringe exchange programs (NSEP).

Emergency Plan funds may support the following activities:

⁵⁶ Sorensen JL, Copeland AL. Drug abuse treatment as an HIV prevention strategy: a review. *Drug and Alcohol Dependence* 2000; 59(1): 17-31.

⁵⁷ Metzger DS, Navaline H, Woody GE. Drug abuse treatment as AIDS prevention. *Public Health Reports* 1998; 113(Suppl.): 97-106.

- Policy activities that encourage countries to remove barriers to medication-assisted treatment for heroin users as an important component of their national HIV/AIDS treatment and prevention plans;
- Formative research and assessments of the contribution of substance use to the HIV epidemic globally;
- Confidential, routine HIV counseling and testing in substance abuse programs;
- Community-based outreach for drug users that addresses HIV prevention, risk reduction, and substance use with links to appropriate care services;
- Prevention education on the risks of injecting drugs and sharing syringes, and education and counseling on how to reduce or stop injecting drugs;
- Education of health professionals and policymakers regarding best practices for HIV prevention strategies for substance users;
- HIV treatment or referral to treatment for the HIV-infected IDU in the context of a comprehensive prevention program; and
- Substance abuse treatment programs for HIV-infected individuals, including medication-assisted treatment with methadone, buprenorphine and naltrexone. For those who are HIV-negative, the Emergency Plan can only support these programs on a pilot basis. All medication-assisted substance abuse therapy will require prior O/GAC approval.

APPENDIX VI: Executive Message on President's Malaria Initiative, December 23, 2005

USAID/General Notice

ADMINISTRATOR

GH/AA

12/23/2005

EXECUTIVE MESSAGE

SUBJECT: President's Malaria Initiative

USAID is the lead agency for the President's \$1.2 billion, five-year initiative to control malaria in Africa. The goal of the initiative is to reduce malaria-related deaths by 50 percent in 15 countries by achieving 85 percent coverage of proven preventive and curative interventions. Activities are already underway with spraying and other high-impact interventions in the three, first-year target countries of Angola, Uganda, and Tanzania. This initiative will be focused, results-based, and will exhibit a high level of financial and programmatic accountability. A minimum of 50 percent of this funding will be devoted to the purchase and distribution of life-saving commodities.

While the President's Malaria Initiative (PMI) ramps up over the next five years to cover 175 million people, expectations of both the White House and Congress are that all malaria prevention and treatment programs will function in the same results-based and accountable fashion as the PMI. To this end, I have approved ten actions that institute fundamental changes to the structure and conduct of USAID's malaria programs. These changes take effect immediately, or as otherwise indicated, and include:

1. Pursuant to the President's instructions and subsequent interagency implementation agreements, there is established a position of Malaria Coordinator, reporting to the USAID Administrator, with direct authority over both the PMI and USAID non-PMI malaria programs and policy. The authorities, roles, and responsibilities of the Malaria Coordinator include:

- * All malaria policies, planning, and budgeting;
- * Direct supervision over, and hiring authority for, all USAID/Washington malaria staff;
- * All malaria budget allocations to bureaus and countries, as well as malaria staffing levels in bureaus and countries;
- * Approval of all malaria-related acquisition and assistance plans, with the authority to approve or disapprove any proposed malaria-related acquisition and assistance action or obligations within countries and by USAID/W bureaus, subject to governing laws and procurement regulations;
- * Approval of all malaria-related Monitoring and Evaluation (M&E) requirements and reporting requirements, with the authority to approve or disapprove any specific malaria-related M&E and reporting plans;
- * Approval of all direct hire and non-direct hire travel to countries for malaria programs, regardless of the funding source;

* All malaria-related communication and outreach strategies and activities, in cooperation with LPA;

* Lead representation at all international malaria prevention and treatment fora and meetings, including those sponsored by Roll Back Malaria, the World Bank, the World Health Organization, and UNICEF;

* Consult and work closely with bureaus and missions on policy, programming, and budget matters affecting the implementation of the program. The Africa Bureau will be the main implementing entity for the PMI and a majority of non-PMI programs.

* The Coordinator may delegate any authorities, roles, and responsibilities to senior staff, to the fullest extent permitted by law and USAID policy.

2. I have designated the Assistant Administrator for Global Health, Kent R. Hill, as the Acting Malaria Coordinator, until such time as a Malaria Coordinator is appointed. In this capacity, he will exercise all roles, responsibilities, and authorities of the Coordinator.

3. Beginning in FY 06, at least 40 percent of USAID non-directed malaria sub-account is designated for a centrally-managed commodity fund, for the sole, express purpose of providing to country programs life-saving commodities: environmentally-sound insecticide-treated nets, and insecticides and equipment for spraying; artemisinin-combination therapies and diagnostics; drugs for intermittent preventive treatment of pregnant women; and drugs for severe malaria. In FY 07, the intention is for this fund to achieve at least 50 percent of non-directed malaria sub-account funds. The Malaria Coordinator or Acting Malaria Coordinator, in consultation with the appropriate bureaus, shall establish the operating procedures for the use of the commodity fund. The commodities will be procured by the GH Bureau or missions, whichever is most appropriate.

4. Proven principles of development will guide all malaria programs implemented or funded by USAID. Such principles include, but are not limited to: an emphasis on country or local ownership of the problem and the solution; a clear ability to build capacity in the affected countries, including strengthening of local institutions, transfer of technologies and skills, and adoption of appropriate policies; sustainability of programs to ensure continuation through funding or political changes in out-years; and, allocation of resources and personnel selectively and in such a way as to maximize the impact of all programs.

5. For FY 06, 25 percent of all non-PMI malaria funds (\$15 million) are designated to support exclusively indoor residual spraying activities in malaria-affected countries, as directed by the Malaria Coordinator or Acting Malaria Coordinator.

6. Beginning in FY 06, all non-PMI country and regional malaria allocations must be approved by the Acting Malaria Coordinator and, thereafter, by the Malaria Coordinator.

7. Beginning in FY 06, no country malaria program or regionally-managed country program will be funded at less than \$1.5 million of malaria funds. In FY 07, the minimum funding for country programs will rise to \$2.5 million, or any such other level as

is determined by the Malaria Coordinator. When the consequences of this requirement are not in the best interest of the malaria program, the Coordinator may make exceptions on a case-by-case basis.

8. All regional funding for USAID malaria programs is capped and shall not exceed the level of FY 05 funding.

9. All operating units will report according to the new malaria data management system, transmitted to the field by PPC and GH in November, 2005. The posting on the PMI website will include all procurement documents under the PMI (e.g., contracts, grants), after "redaction" by the contractor/grantee. GH and its support contractor are responsible for managing this process.

10. No Agency malaria funds are allowed to fund non-malaria activities, including cross-cutting programs or initiatives, "taxes" to cover non-malaria costs or common costs, or any other mechanism, regardless of past practice, without the express consent of the Malaria Coordinator or Acting Malaria Coordinator.

Once these changes have been instituted, USAID will be properly positioned to achieve the goals of the President's initiative. Thank you for your cooperation.

Andrew S. Natsios

Point of Contact: Michael Miller, GH/DAA, (202) 712-1325 and Gloria Steele, DAA/GH, (202) 712-4120.

APPENDIX VII: Executive Message on Avian Influenza, September 26, 2005

USAID/General Notice
ADMINISTRATOR ES
09/26/2005

E X E C U T I V E M E S S A G E

SUBJECT: Priority Message from the Administrator: USAID's
Response to Avian Influenza

The following is a high priority message from the Administrator regarding the need for a rapid and coordinated Agency response to the H5N1 avian influenza (AI) virus. The threat posed by avian influenza is critical and urgent; crafting an effective response is the top priority for all missions and posts worldwide.

To date, avian influenza has been responsible for 113 human infections with 58 deaths, and the death and destruction of over 140 million domestic poultry in Vietnam, Cambodia, Indonesia and Thailand. The present threat mainly stems from animal-to-human transmission and has been mostly confined to Southeast Asia and southern China. But trends are worrisome.

First, there is growing concern that this strain of the Influenza A virus could evolve and spread efficiently from human-to-human, placing millions of lives at risk. Experts estimate that the death toll from such a mutation could range from four million to over 180 million people, depending upon the effectiveness of containment and response. This virus has the ability to jump the species barrier. The most deadly flu epidemics in history have started with similar leaps, notably the Spanish Flu epidemic of 1918, which killed an estimated 20 to 50 million people.

Second, the geographic reach of avian influenza is rapidly increasing (see attachment). In the last two months, infected migratory birds have been located in Eurasia, moving the threat westward. Isolated outbreaks have been reported in places as far away as Russia, Mongolia and Kazakhstan. As of yet, no infected birds have been found in the Western Hemisphere.

Finally, it is also worth noting that economic ramifications of avian influenza have already been significant. At current levels of transmission, the economic cost associated with avian influenza and containment efforts is estimated to have already exceeded \$10 billion; in 2004, it cost the Vietnamese economy alone an estimated \$200 million. Moreover, a worldwide influenza pandemic would have a major effect on the global economy, including travel, trade, tourism, consumption and eventually, investment and financial markets.

I am communicating this information not to cause undue alarm, but to stress the importance of an early and effective response from all missions. If we take this threat seriously and pursue necessary actions now, we can mitigate a potential outbreak and potentially save millions of lives.

Already in Washington, D.C., significant steps are being taken. Last week, at the High-Level Plenary Meeting of the United Nations General Assembly, the President announced a new, U.S.-led International Partnership on Avian and Pandemic Influenza (IPAPI). The partnership will require countries to immediately share information about human infections and provide samples to the World

Health Organization to ensure a rapid response to reported outbreaks.

This complements the President's May 11, 2005 signing of an emergency appropriations bill containing \$25 million to prevent and control the spread of avian influenza in Asia, of which \$10 million was allocated to USAID. Our \$10 million program targets five countries in Southeast Asia where avian influenza is now endemic in animal populations and the risk of further outbreaks is highest. It intends to increase laboratory capacities, train and support rapid responders, and enhance nationwide disease surveillance and pandemic planning in partnership with the U.S. Department of Agriculture, the U.N. Food and Agriculture Organization and the World Health Organization. We will also work with our partners to conduct public education campaigns that will increase awareness of how to prevent the spread of avian influenza, change high-risk animal husbandry and market practices, and encourage timely reporting. Finally, the Global Development Alliance will lead efforts to involve private businesses and companies and increase the availability of technical assistance, commodities, and financial support for avian influenza containment and preparedness.

In USAID/Washington, we have put in place an Avian Flu task force to develop and coordinate response planning and regional activities in affected countries of Southeast Asia. Further, we are closely monitoring new outbreaks and are planning to engage in each country on the basis of their relative risk. In coordination with other U.S. Government agencies, we are pursuing a three-step approach:

- Strengthen Pandemic Planning & Preparedness. Prepare for future outbreaks by supporting enhanced pandemic planning, improve cross-Ministerial and donor coordination, and stockpile essential commodities for response and containment of animal and human outbreaks.
- Minimize the Risk of Avian Influenza Transmission. Limit animal infections by improving farming practices that minimize contact between wild and domestic birds. Cull diseased or exposed animals to limit further spread, support animal vaccination, and strengthen surveillance and response capacities.
- Ensure Rapid and Effective Treatment and Management of Infections. Prevent human infection by promptly responding to suspected outbreaks and using protective gear when working with infected animals and humans. Increase the capacities of local and national governments to promptly identify, confirm and isolate possible animal and human cases. Provide safe treatment and care to those infected, and conduct public awareness campaigns.

It is vital that our missions take the threat of avian influenza seriously. In a separate message, I will specifically task all Mission Directors to undertake the following actions, included here for your information:

- By September 30, identify a principal point of contact for the mission that will coordinate activities related to avian and pandemic influenza.
- By October 31, prepare and submit to your regional bureau a rapid assessment survey outlining the host country's

preparedness to respond to avian and pandemic influenza. This survey will be sent to all missions later this week and will include the following:

Assess the readiness of the country. Does a pandemic plan exist? Is there an enabling political environment that is appropriately sensitized to the avian influenza threat? Are there adequate plans for supplies of commodities for managing human outbreaks? If there is a high risk of animal infection in the country (see attached map), is there an adequate capacity for early surveillance and diagnosis, and for rapid containment of animal outbreaks?

Assess the effectiveness of the plan. If a plan exists, does it make sense? Can it be practically implemented in a rapid manner? Does the plan incorporate and clearly articulate the roles and of relevant ministries, and provide a mechanism for effective coordination? Does it identify key spokespeople and articulate strategies for rapidly and coherently disseminating information to the public?

Assess the role and engagement of the donor community. What steps are other donors playing? Where are the gaps in avian influenza readiness? What role is USAID best-suited to play in the country? Is there a role for donors in the national pandemic plan and are donors prepared to fulfill that role? Is there a mechanism for donor coordination and information-sharing?

The key to an early and rapid response is political commitment and transparency. It is critical that we raise the profile of avian influenza to host governments. I am asking missions to be creative and work within existing resource constraints. Additionally, I have instructed our regional bureaus to work with missions and identify specific levels of support and activity that would be appropriate.

Dennis Carroll in the Bureau of Global Health is coordinating the Agency's avian influenza response and can provide additional information. For further information on the USAID response please refer to:

http://www.usaid.gov/our_work/global_health/home/News/news_items/avian_influenza.html.

For regular updates on new developments and USAID actions refer to:

http://www.usaid.gov/our_work/global_health/home/News/news_items/actions.html

Andrew S. Natsios

POINT OF CONTACT: Dennis Carroll, GH/HIDN, (202) 712-5009

APPENDIX VIII: Executive Message on Avian Influenza, November 3, 2005

USAID/General Notice
ADMINISTRATOR A/AID
11/03/2005

E X E C U T I V E M E S S A G E

SUBJECT: Interim Budgetary Guidance for Reprogramming of Funds
for Urgent Avian Influenza Related Activities

Because of the urgency and importance of the Agency's planning for a possible Avian Influenza (AI) pandemic, I am personally issuing the following Interim Budget Guidance for immediate action. As I have stated previously, this is now the Agency's first priority. Please proceed accordingly. If you have any questions, contact GH and/or PPC.

The following guidance covers the reprogramming of funds for immediate AI related activities prior to the availability of FY 06 AI funds.

Missions and regions are asked to be creative and to work within existing resource constraints. This could involve reprogramming resources, if needed, to address urgent needs. However, countries/regions must consult with USAID/W prior to reprogramming. There is no plan to reimburse missions or regions for redirected funding.

Mission requests for reprogramming funds into AI activities should be passed through the designated point person in the regional bureau. The regional bureau point person will then present the request to the Avian Influenza Preparedness and Response Unit for consideration and a final determination based on the technical merit of the activity, availability of funds within existing statutes and earmarks, and its appropriateness to the level of threat in the country. Responses from USAID/W will be within 48 hours.

Any redirected funds should be tagged so that the Agency can track the AI obligations. A budget code has been established for all expenditures associated with AI. The code is "AFLU." Any approved use of supplemental or reprogrammed funds for activities associated with AI must be coded with this designation.

The following items should not be proposed to be procured with reprogrammed funds: Tamiflu or any other anti-viral medication and human influenza vaccines.

Andrew S. Natsios

Point of Contact: Any questions concerning this Notice may be directed to Dennis Carroll, GH/HIDN, (202) 712-5009 and/or Robbin Boyer, PPC/SPP/SRC, (202) 712-4489.

APPENDIX IX: USAID Family Planning Requirements, Statutory and Policy

USAID Family Planning Requirements – STATUTORY

<u>Provision</u>	<u>Applies To</u>	<u>Statutory Text from Foreign Assistance Act and/or Appropriations Act for FY 2007</u>
Helms (1973) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	None of the funds made available under this Act may be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. ⁽⁸⁾⁽⁹⁾
Leahy (1994) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	For purposes of this or any other Act authorizing or appropriating funds for foreign operations, export financing, and related programs, the term “motivate”, as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options. ⁽⁹⁾⁽¹⁰⁾
Biden (1981) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. ⁽⁸⁾⁽⁹⁾
Siljander (1981) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	None of the funds made available under this Act may be used to lobby for or against abortion. ⁽⁹⁾
Kemp-Kasten (1985) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	None of the funds made available in this Act nor any unobligated balances from prior appropriations may be made available to any organization or program which, as determined by the President of the United States, supports or participates in the management of a program of coercive abortion or involuntary sterilization. Any determination made under the previous proviso must be made no later than six months after the date of enactment of this Act, and must be accompanied by a comprehensive analysis as well as the complete evidence and criteria utilized to make the determination. ⁽⁹⁾
DeConcini (1985) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	In order to reduce reliance on abortion in developing nations, funds shall be available only to voluntary family planning projects which offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services. ⁽⁹⁾
Tiahrt (1998) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	Any such voluntary family planning project shall meet the following requirements: (1) service providers or referral agents in the project shall not implement or be subject to quotas, or other numerical targets, of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning (this provision shall not be construed to include the use of quantitative estimates or indicators for budgeting and planning purposes); (2) the project shall not include payment of incentives, bribes, gratuities, or financial reward to: (A) an individual in exchange for becoming a family planning acceptor; or (B) program personnel for achieving a numerical target or quota of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning; (3) the project shall not deny any right or benefit, including the right of access to participate in any program of general welfare or the right of access to health care, as a consequence of any individual’s decision not to accept family planning services; (4) the project shall provide family planning acceptors comprehensible information on the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method; and (5) the project shall ensure that experimental contraceptive drugs and devices and medical procedures are provided only in the context of a scientific study in which participants are advised of potential risks and benefits; and, not less than 60 days after the date on which the Administrator of the United States Agency for International Development determines that there has been a violation of the requirements contained in paragraph (1), (2), (3), or (5) of this proviso, or a pattern or practice of violations of the requirements contained in paragraph (4) of this proviso, the Administrator shall submit to the Committees on Appropriations a report containing a description of such violation and the corrective action taken by the Agency. ⁽⁹⁾
Livingston-Obey (1986) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	In awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant’s religious or conscientious commitment to offer only natural family planning; and, additionally, all such applicants shall comply with the requirements of the [DeConcini Amendment]. ⁽⁹⁾
Additional Provisions (1977) ⁽¹⁾ (1986) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be used to pay for the performance of involuntary sterilizations as a method of family planning or to coerce or provide any financial incentive to any person to undergo sterilization. ⁽⁸⁾⁽⁹⁾ None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be obligated or expended for any country or organization if the President certifies that the use of these funds by any such country or organization would violate [the Helms Amendment, the Biden Amendment, or the provision above

		listed as the first “Additional Provision”]. ⁽⁹⁾
--	--	---

All footnotes can be found on the bottom of page 2.

USAID FAMILY PLANNING REQUIREMENTS – POLICY

<u>Provision</u>	<u>Applies To</u>	<u>Executive and USAID Policies</u>
USAID Policy on Voluntarism and Informed Choice	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	USAID places highest priority on ensuring that its family planning (FP) and reproductive health activities adhere to the principles of voluntarism and informed choice. The Agency considers an individual’s decision to use a specific FP method or to use any FP method at all voluntary if based upon the exercise of free choice and not obtained by any special inducements or any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation. USAID defines informed choice to include effective access to information on FP choices and to the counseling, services, and supplies needed to help individuals choose to obtain or decline services and the option to see, obtain, or follow up on a referral or simply to consider the matter further.
Mexico City Policy (1985-1993) ⁽¹⁾ (2001) ⁽¹⁾	FP assistance ⁽³⁾ FNGOs only ⁽⁵⁾ Assistance Instruments ⁽⁷⁾	<p>President Bush restored the Mexico City Policy (MCP), which had been in place from 1985-1993, on January 22, 2001. MCP requires that foreign nongovernmental organizations (FNGOs) certify that they will not perform or actively promote abortion as a method of family planning (FP) as a condition for receiving USAID FP assistance.</p> <p>In a 2003 memorandum, the president extended MCP to “voluntary population planning” assistance provided by the State Department and excluded from MCP “foreign assistance furnished pursuant to the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003.” As a result, assistance only for HIV/AIDS activities is not subject to MCP. The president’s memorandum is available at: http://www.whitehouse.gov/news/releases/2003/08/print/20030829-3.html.</p> <p>MCP is an organizational requirement. If applicable, it applies to all activities carried out by the FNGO, regardless of the source of funds (i.e., funding from USAID and non-USAID sources).</p> <p>Under MCP, “abortion as a method of family planning” is defined as abortion for the purpose of spacing births. This definition includes abortions performed due to the physical or mental health of the mother, method failure, and menstrual regulation. Excluded from this definition are abortions performed when the life of the mother would be endangered if the fetus were carried to term, when used following rape or incest, and in situations where a pregnant woman asks specifically about abortion and states clearly that she has decided to have a legal abortion and the FP counselor reasonably believes that the ethics of the medical profession in the country require a response as to where abortion may be obtained safely.</p> <p>Under MCP, “to actively promote abortion” means that an organization commits resources, financial or other, in a substantial or continuing effort to increase the availability or use of abortion as an FP method. This may include counseling, referrals, lobbying, and public information campaigns.</p> <p>Postabortion care (PAC) is permitted under MCP. USAID will not finance the purchase or distribution of manual vacuum aspiration (MVA) equipment for any purpose, but USAID can support PAC programs that include the use of MVA equipment procured through non-USAID sources.</p> <p>More detailed information on MCP can be found in CIB 01-08 (R) at: http://www.usaid.gov/business/business_opportunities/cib/pdf/cib0108r.pdf.</p>
PD-3 (1977) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁶⁾	<p>In 1982, USAID issued a policy paper on population assistance, which clearly states its commitment to voluntarism in the provision of family planning (FP) services. Annex PD-3 of the Population Policy of 1982 includes specific requirements for USAID-supported programs that include voluntary sterilization. These requirements cover informed consent, ready access to other methods, and guidelines on incentive payments.</p> <p>PD-3 requires that informed consent be obtained in writing from every VS acceptor. Informed consent is defined as voluntary, knowing consent after being advised of the surgical procedures, the attendant discomforts and risks, the expected benefits, the availability of alternative FP options, the purpose and irreversibility of the operation, and the option to withdraw consent prior to the operation. Voluntary consent is defined as consent based upon free choice and not obtained by any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation. PD-3 further requires that potential VS acceptors have ready access to a range of FP methods whenever VS services are offered.</p> <p>PD-3 prohibits the payment of incentives to potential VS acceptors, providers, and referral agents, but permits compensation of reasonable expenses in order to make VS as equally available as other contraceptive methods.</p> <p>More detailed information on PD-3 can be found at: http://www.usaid.gov/our_work/global_health/pop/populat.pdf.</p>

⁽¹⁾ Indicates the date the amendment or policy was first enacted. Unless otherwise stated, the amendment or policy remains in effect.

⁽²⁾ Applies to all funds appropriated for any purpose under the Foreign Assistance Act of 1961, as amended.

- (3) Applies only to family planning assistance (from any account) appropriated under the Foreign Assistance Act of 1961, as amended.
- (4) Applies to all entities (e.g., U.S. non-governmental organizations (NGOs), foreign non-governmental organizations (FNGOs), public international organizations (PIOs), and foreign governments).
- (5) Applies only to FNGOs receiving family planning assistance (from any account) and does not apply to U.S. NGOs, PIOs, and governments.
- (6) Applies to all instruments (e.g., grants, cooperative agreements, contracts, and SOAGs).
- (7) Applies only to assistance instruments (e.g., grants, cooperative agreements, and grants under contract). Does not apply to contracts or SOAGs.
- (8) Text from Section 104(f) of the Foreign Assistance Act of 1961, as amended.
- (9) Text from FY 2008 Foreign Operations Appropriations Act, Title III, “Bilateral Economic Assistance—Global Health and Child Survival” and/or Title VI, Section 618.
- (10) The term “motivate” refers to language in the Helms Amendment. FNGOs receiving FP assistance are still subject to the Mexico City Policy.

APPENDIX X: Sample Template for Documenting Technical Consultations

[date]

INFORMATION MEMORANDUM FOR THE FILE

TO: The File

FROM: [NAME OF MISSION DIRECTOR], Mission Director, USAID/[MISSION NAME]

SUBJECT: Approval to use Global Health and Child Survival (GH/CS) funds for
[SUMMARIZE PRIMARY USE OF FUNDS]

This memo should indicate that a proposal for the use of funds was discussed with all parties listed for clearance, and a consensus was reached.

The memo should also include a detailed description of the activity, how it directly contributes to the relevant Agency Objective(s) (or element), and the expected results. It should outline the pros and cons of moving ahead with the proposed activity, and the relevant external considerations (including political, diplomatic, and programmatic considerations). The memo should also include the amount of funds being requested.

CLEARANCE PAGE FOR INFORMATION MEMORANDUM on approval to use GH/CS funds for [PURPOSE]

[Clearance required from AA of the relevant Regional Bureau]

[Clearance required from GH]

[Clearance required from F/IIP]

[Clearance required from LPA]

[Clearance required from GC/Washington or the Regional Legal Advisor]

[Clearance required from COO]

[Bureau]:[Drafter]:[Typist's Initials]:[Desk Phone #]:[Date]:{Document Location and Name}

Sample Template for Split Decision Action Memo

[date]

ACTION MEMORANDUM FOR THE ADMINISTRATOR

FROM: [Assistant Administrator of the relevant Regional Bureau]

SUBJECT: Approval to use Global Health and Child Survival (GH/CS) funds for
[SUMMARIZE PRIMARY USE OF FUNDS]

Bureau A recommends you approve [a specific action]. Bureau B opposes.

Approve_____ Disapprove_____

Alternatively, Bureau B recommends you approve [alternate action]. Bureau A opposes.

Approve_____ Disapprove_____

Background

This memo should indicate that a proposal for the use of funds was discussed with all parties listed for clearance, and a consensus could not be reached.

The memo should also include a detailed description of the activity, how it directly contributes to the relevant Agency Objective(s) (or element), and the expected results. It should outline the pros and cons of moving ahead with the proposed activity, and the relevant external considerations (including political, diplomatic, and programmatic considerations). The memo should also include the amount of funds being requested.

CLEARANCE PAGE FOR INFORMATION MEMORANDUM on approval to use GH/CS funds for [PURPOSE]

[Clearance required from GH]

[Clearance required from F/IIP]

[Clearance required from LPA]

[Clearance required from GC/Washington or the Regional Legal Advisor]

[Clearance required from COO]

[Bureau]:[Drafter]:[Typist's Initials]:[Desk Phone #]:[Date]:{Document Location and Name}