APPENDICES TO THE

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

UPDATE

JANUARY 2009

APPENDICES

APPENDIX I: Excerpts from Relevant Legislation and Congressional Reports

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 deter-mine, for voluntary population planning. In addition to the provision of family planning information and services, including also in-formation and services which relate to and support natural family planning methods,[1] and the conduct of directly relevant demo-graphic 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 deter-mine, 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 deter-mine, 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 provisos. 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

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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 county 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 #1For 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

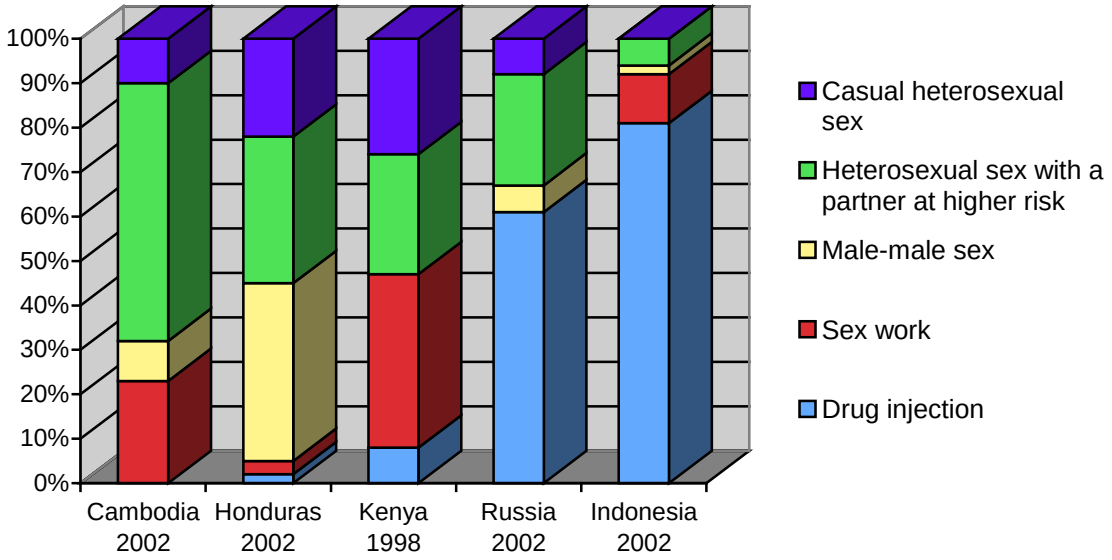
interventions that are believed to have contributed to Uganda's success originated from pre-existing structures, organizations, and networks. This type of information is often collected through observation and experience, but reviewing local media and conducting strategic interviews with key local and 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?

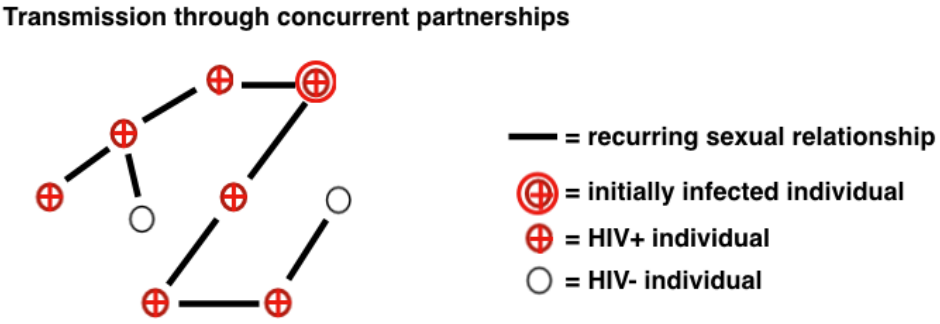
These diagnostic questions are all critical for empowering a grassroots/community-level response to the epidemic. U.S. missions should collaborate with local experts to foster a local perspective that is culturally appropriate and sensitive. Creating a strong community-level response will aid rapid scale-up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

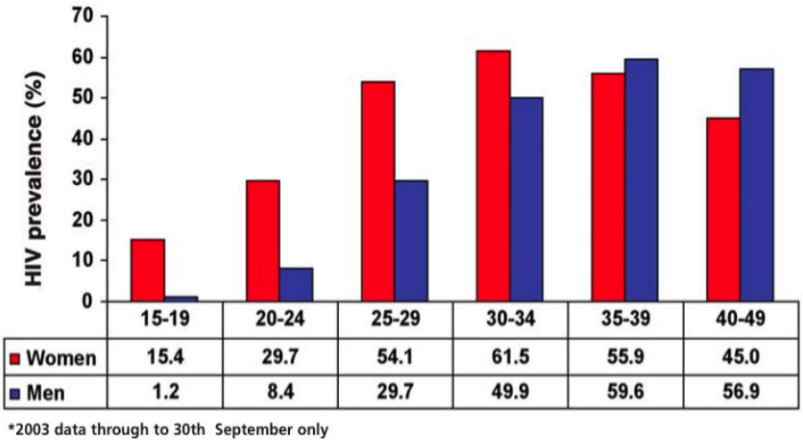


This diagram illustrates how the efficiency of HIV transmission is dramatically increased in the presence of frequent sexual contact if such contacts are "concurrent" (overlapping). Since population-level survey data from many countries indicates that regular and "low-risk" (marital or cohabitating) 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*



	15-19	20-24	25-29	30-34	35-39	40-49
Women	15.4	29.7	54.1	61.5	55.9	45.0
Men	1.2	8.4	29.7	49.9	59.6	56.9

*2003 data through to 30th September only

For More Information
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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
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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 opiods and non-opiods); 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 ladder[2]]. 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.

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[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 broaden0 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.

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[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 medications[4], 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 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

[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.

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. PLHWA 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 Care[5] 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.
- Establish integrated programs and networks of service providers, including community health associations and organizations.
- Establish evidence-based care standards and care packages.

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

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/

[7] **WHO (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 paracetemol 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, 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 1989[8] 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/µl.[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/µl,[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

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[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, Swingler, 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 presons 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/µl.[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.

<u>Emergency Plan funds may support</u>:

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 immunosupression 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 Africa[25] and elsewhere[26] 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.

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[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, Schecter 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, Horsburgn 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 are. 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 diarrhea 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 andsanitation 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, Kaharuza 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

Malaria is a life-threatening parasitic disease transmitted from person-to-person through the bite

[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.

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

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[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 are 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 malaria transmission in western Kenya. Am J Trop Med Hyg. 2003 Apr;68(4 Suppl):68-77.

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 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]

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[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.

[48] Fawzi WW, Msamanga GI, Spiegelman D, Urassa EJ, McGrath N, Mwakagile D,

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 HIV transmission.[52,53] In the Democratic Republic of Congo, condom use among HIV discordant

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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, Spielgeman 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.

[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.

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 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.

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[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.

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:

- 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;

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[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.

- 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. <u>All medication-assisted substance abuse therapy will require prior O/GAC approval</u>.

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

Provision	Applies To	Statutory Text from Foreign Assistance Act and/or Appropriations Act for FY 2007
Helms (1973) [1]	All assistance[2] All entities[4] All instruments[5]	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.[6][7]
Leahy (1994) [1]	All assistance[2] All entities[4] All instruments[5]	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.[7][8]
Biden (1981) [1]	All assistance[2] All entities[4] All instruments[5]	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.[6][7]
Siljander (1981) [1]	All assistance[2] All entities[4] All instruments[5]	None of the funds made available under this Act may be used to lobby for or against abortion.[7]
Kemp-Kasten (1985) [1]	All assistance[2] All entities[4] All instruments[5]	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.[7]
DeConcini (1985) [1]	FP assistance[3] All entities[4] All instruments[5]	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.[7]
Tiahrt (1998) [1]	FP assistance[3] All entities[4] All instruments[5]	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.[7]
Livingston-Obey (1986) [1]	FP assistance[3] All entities[4] All instruments[5]	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].[7]
Additional Provisions (1977) [1] (1986) [1]	All assistance[2] All entities[4] All instruments[5]	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.[6][7] 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"].[7]

USAID FAMILY PLANNING REQUIREMENTS – POLICY

Provision	Applies To	Executive and USAID Policies
USAID Policy on Voluntarism and Informed Choice	FP assistance [3] All entities[4] All instruments[5]	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.
PD-3 (1977) [1]	FP assistance[3] All entities[4] All instruments[5]	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. 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. 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. More detailed information on PD-3 can be found at: http://www.usaid.gov/our_work/global_health/pop/populat.pdf.

(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 to all instruments (e.g., grants, cooperative agreements, contracts, and SOAGs).
(6) Text from Section 104(f) of the Foreign Assistance Act of 1961, as amended.
(7) Text from FY 2008 Foreign Operations Appropriations Act, Title III, "Bilateral Economic Assistance—Global Health and Child Survival" and/or Title VI, Section 618.
(8) 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]