PEPFAR IMPLEMENTATION: PROGRESS AND PROMISE

Statement of

Helen L. Smits, M.D., M.A.C.P.

Vice-Chair, Committee on the President's Emergency Plan for AIDS Relief (PEPFAR) Implementation Evaluation
Board on Global Health
Institute of Medicine
The National Academies

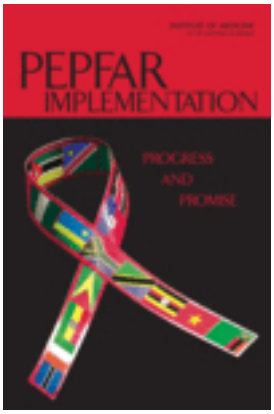
before the

Committee on Health, Education, Labor, and Pensions
U.S. Senate

December 11, 2007

PEPFAR Implementation: Progress and Promise (Free Executive Summary)
http://www.nap.edu/catalog/11905.html

Free Executive Summary



PEPFAR Implementation: Progress and Promise

Committee for the Evaluation of the President's Emergency Plan for AIDS Relief (PEPFAR) Implementation, Jaime Sepulveda, Charles Carpenter, James Curran, William Holzemer, Helen Smits, Kimberly Scott, and Michele Orza, Editors

ISBN: 978-0-309-10388-6, 400 pages, 6 x 9, paperback (2007)

This free executive summary is provided by the National Academies as part of our mission to educate the world on issues of science, engineering, and health. If you are interested in reading the full book, please visit us online at http://www.nap.edu/catalog/11905.html . You may browse and search the full, authoritative version for free; you may also purchase a print or electronic version of the book. If you have questions or just want more information about the books published by the National Academies Press, please contact our customer service department toll-free at 888-624-8373.

This executive summary plus thousands more available at www.nap.edu.

Copyright © National Academy of Sciences. All rights reserved. Unless otherwise indicated, all materials in this PDF file are copyrighted by the National Academy of Sciences. Distribution or copying is strictly prohibited without permission of the National Academies Press http://www.nap.edu/permissions/ Permission is granted for this material to be posted on a secure password-protected Web site. The content may not be posted on a public Web site.

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Abstract

The Institute of Medicine (IOM) undertook this short-term evaluation of the implementation of the President's Emergency Plan for AIDS Relief (PEPFAR) to inform Congress about the program's progress 3 years after its authorizing legislation was passed. The IOM committee found that PEPFAR has supported the expansion of HIV/AIDS prevention, treatment, and care services in the focus countries. For continued progress toward its 5-year targets and longer-term goals, PEPFAR should transition from a focus on emergency relief to an emphasis on the long-term strategic planning and capacity building necessary for sustainability. The committee identifies a number of opportunities for improvement that would support this transition, including

- Greater emphasis on prevention of HIV infection generally, and better linkage between the program planning process and improved data on prevalence and populations at risk in particular.
- Increased attention to the factors that heighten the vulnerability of women and girls to HIV infection and its consequences, such as their legal, economic, educational, and social status.
- Continued commitment to and additional emphasis on harmonization—a concept based on the importance of each country's leadership of its response to its epidemic. All three aspects of harmonization—alignment between donor and country plans, coordination with national AIDS coordinating agencies, and support for national monitoring and evaluation frameworks—need strengthening. Of particular importance is to transition

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

from the current requirement to use medications approved by the U.S. Food and Drug Administration to support for World Health Organization prequalification as the accepted global standard for assuring the quality of generic medications.

- Enhanced ability to tailor interventions to the nature of the epidemic in each country and the countries' national plans through removal of the limitations imposed by congressional budget allocations for particular activities. Alternative mechanisms that allow for spending to be directly linked with the efforts necessary to achieve performance targets would improve the necessary accountability for results.
- Expansion and better integration of services to meet the needs of all people living with HIV/AIDS, and to both improve prevention, treatment, and care interventions and capitalize on the synergy among them.
- Strengthened and expanded country capacity to provide services—particularly the necessary human resources—through implementation of HIV/AIDS programs in a manner that strengthens systems overall.
- Enhanced knowledge about what works against the pandemic, to be gained by increasing the emphasis on learning from experience with the program and on conducting operations research and program evaluations.

The Committee concludes that PEPFAR has made a promising start, but the need for U.S. leadership in the effort to control the HIV/AIDS pandemic continues.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Summary

INTRODUCTION

On May 27, 2003, the U.S. Congress passed the United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (the Leadership Act) and launched the U.S. Global AIDS Initiative. Among other things, this broad legislation required the President to establish a comprehensive, integrated 5-year strategy to combat global HIV/AIDS. The initiative is commonly known by the title of this strategy: "The President's Emergency Plan for AIDS Relief," or PEPFAR. The legislation also required the President to establish the position of U.S. Global AIDS Coordinator (the Coordinator) within the U.S. Department of State, with primary responsibility for oversight and coordination of all U.S. international activities to combat the HIV/AIDS pandemic.

As mandated by the Leadership Act, the U.S. Institute of Medicine (IOM) undertook a short-term evaluation of the implementation of PEPFAR to inform Congress about the initiative's progress 3 years after passage of the legislation. The IOM Committee for the Evaluation of PEPFAR Implementation (the Committee) began its work on this short-term evaluation in February 2005. Although the Leadership Act was passed in May 2003, Congress first appropriated funds for the program in January 2004, and the majority of the first year's funding was not obligated until September 2004. Thus at the close of the Committee's short-term evaluation, PEPFAR had been supporting the implementation of programs in the focus countries for less than 2 years.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

The U.S. Global AIDS Initiative is working in more than 120 countries around the world, but concentrates resources in 15 focus countries so as to have an impact on their epidemics at the national level.[1] The scope of this evaluation is limited to the implementation of PEPFAR in the focus countries and does not include the U.S. contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria, which is also overseen by the Coordinator. Although direct evaluation of the Leadership Act was beyond its scope, the Committee examined and reached conclusions about factors that appeared to be having a pronounced effect on the implementation of PEPFAR, some of which have their roots in the legislation.

PEPFAR's 5-year performance targets for the focus countries are to support the prevention of 7 million HIV infections; treatment for 2 million people with HIV/AIDS with antiretroviral therapy (ART); and care for 10 million people infected with and affected by HIV/AIDS, including orphans and other vulnerable children (United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25, 108th Cong., 1st Sess.; OGAC, 2004). The Committee intended its evaluation to be appropriate for a program early in its implementation, and to provide insight into whether PEPFAR is making reasonable progress toward meeting these targets and positioning the U.S. Global AIDS Initiative to achieve the ultimate goal of the Leadership Act—sustainable gains against the HIV/AIDS pandemic.

At the core of the complex structure and approach of PEPFAR—which involves numerous U.S. government agencies and is centrally coordinated by the Office of the U.S. Global AIDS Coordinator (OGAC), but implemented by the U.S. teams in the focus countries (Country Teams)—is the U.S. commitment to the principles of harmonization (The Rome Declaration, 2003; UN, 2003; Tobias, 2003a, 2004; UNAIDS, 2004a; OGAC, 2005a; The Paris Declaration, 2005). The central tenet of harmonization is that sustainable gains against the HIV/AIDS pandemic will require that each country own and lead its response to its epidemic. The role of donors is to support and participate in the three country-determined elements critical for an effective response—one national AIDS plan, one national AIDS coordinating mechanism, and one national AIDS monitoring and evaluation framework (UNAIDS, 2004a). Therefore, the Committee evaluated the implementation of PEPFAR primarily through the lens of harmoniza-

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

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

tion and sought to determine how effectively the program is meeting its commitment to support the focus countries' responses to their HIV/AIDS epidemics (IOM, 2005b).

THE PROGRESS OF PEPFAR

PEPFAR Has Supported the Expansion of HIV/AIDS Services in the Focus Countries

In the 15 focus countries, the U.S. Global AIDS Initiative has, as intended, supported HIV/AIDS activities and programs on a national scale, and OGAC reports substantial early progress toward its targets. In roughly 2 years, OGAC reports that PEPFAR has supported ART for more than 800,000 adults and children; HIV testing and counseling for nearly 19 million people; services to prevent mother-to-child transmission of HIV to women during more than 6 million pregnancies, including preventive antiretroviral medications (ARVs) for more than half a million women found to be HIV-positive (estimated by OGAC to have resulted in the prevention of HIV infection in more than 100,000 infants); public education campaigns, school curricula, and other types of information and education community outreach that are estimated to have reached more than 140 million adults and children; care and support services for approximately 4.5 million adults, orphans, and other vulnerable children; training in HIV/AIDS care and support services for well over a million people, including physicians, nurses, clinical officers, pharmacists, laboratory workers, epidemiologists, community workers, teachers, midwives, birth attendants, and traditional healers; and expansion and strengthening of clinical laboratories, supply chain management systems, blood supply systems, safe medical practices, and monitoring and evaluation systems (OGAC, 2005b, 2006a,b, 2007). Although data are not yet available with which to determine the quality or impact of these services, the Committee believes this substantial expansion of services represents inroads into the HIV/AIDS epidemics in the focus countries. Thus the primary early accomplishment of the U.S. Global AIDS Initiative has been to demonstrate that HIV/AIDS services, particularly treatment, can be rapidly scaled up in resource-constrained and otherwise severely challenged environments such as those existing in the focus countries—something many had doubted could be done (UNAIDS, 2001; WHO, 2003a,b; IOM, 2005a).

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Transition from Emergency to Sustainability Is Essential to Achieve the Goals of the Leadership Act

Hallmarks of PEPFAR have been its continued sense of urgency and the rapidity with which it has supported the implementation of programs and delivery of services—not only ART, but across the spectrum of HIV/AIDS care and support (Nieburg et al., 2004). Although its emergency response has allowed PEPFAR to support rapid expansion of services in the focus countries, it has not necessarily facilitated coordination with global partners, harmonization with the strategies and plans of partner countries, services that are comprehensive and integrated at the community level, sustainable programs, or adequate monitoring and evaluation. Yet the Coordinator has described "building capacity for sustainable, effective, and widespread HIV/AIDS responses" as one of the cornerstones of the PEPFAR strategy (OGAC, 2004). According to the Leadership Act, as well as PEPFAR documents and official statements, the program has from the beginning been aimed at strengthening and expanding the capacity of the focus countries to develop HIV/AIDS programs and provide services (Tobias, 2003b; OGAC, 2004). PEPFAR has provided funding and technical assistance to help focus country governments develop national plans and monitoring and evaluation systems; improve existing and build new facilities; develop curricula for and train health workers; strengthen and expand laboratory, blood supply, and medical waste management systems; improve and expand supply chains; and strengthen existing and foster new community-based organizations.

> ***The continuing challenge for the U.S. Global AIDS Initiative is to simultaneously maintain the urgency and intensity that have allowed it to support a substantial expansion of HIV/AIDS services in a relatively short time while also placing greater emphasis on long-term strategic planning and increasing the attention and resources directed to capacity building for sustainability.*** **The U.S. Global AIDS Coordinator should continue to focus on planning for the next decade of the U.S. Global AIDS Initiative, taking full advantage of the knowledge gained from the early years of PEPFAR about the focus countries' epidemics and how best to address them. The next strategy should squarely address the needs and challenges involved in supporting sustainable country HIV/AIDS programs, thereby transitioning from a focus on emergency relief. (8.1)**[2]

The Committee's recommendations for improvement are premised on the assumption that Congress will reauthorize the U.S. Global AIDS Initiative and directed toward helping PEPFAR continue the transition from

[2]The first digit of each recommendation number refers to the chapter in which the recommendation is discussed in full.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

emergency response to sustainability, and thus to make further progress toward both its 5-year performance targets and the ultimate goal of the Leadership Act. None of the issues raised by the Committee or its recommendations for enabling PEPFAR to progress more effectively should be construed as a lack of support for the U.S. Global AIDS Initiative or its authorizing legislation.

THE PROMISE OF PEPFAR

Successful Prevention Is Key for Sustainability

If countries do not succeed in stemming the tide of new infections, the need for treatment will continue to increase and outpace their ability to develop the capacity to meet it (Mathers and Loncar, 2006). PEPFAR is currently supporting a wide range of programs directed at preventing the spread of HIV. Partly in response to legislative mandates, however, it has supported some preventive interventions that are not firmly evidence-based, addressed sources of HIV transmission in disproportion to their expected contribution to the ultimate goal of preventing new infections, and not fully capitalized on opportunities to integrate prevention activities optimally with each other and into treatment and care programs. To help countries sustain and expand their gains against their HIV/AIDS epidemics, the U.S. Global AIDS Initiative will need to emphasize effective, evidence-based prevention with the same urgency and intensity it has focused on treatment. Moreover, the initiative cannot afford to conceptualize prevention narrowly or as distinct from treatment and care, and needs to support countries in seizing the abundant opportunities for prevention throughout people's lives and regardless of their HIV status; across the full spectrum of health and social services; and in all settings, from the street to the school to the home to the clinic (Salomon et al., 2005; UNAIDS, 2005c).

The U.S. Global AIDS Initiative should enhance and intensify HIV prevention through a planning process that links timely national information on the epidemic to the selection of the most appropriate intervention packages and to the optimal targeting of interventions to populations in whom infections are most likely to occur. The U.S. Global AIDS Coordinator should enhance current data on HIV prevalence by supporting quality behavioral surveys to identify patterns of risk. The Coordinator should support country plans to identify where infections are to be averted to achieve prevention targets and should track progress toward achieving prevention goals by measuring risk behaviors, the prevalence and incidence of other sexually transmitted infections, and ultimately the prevalence and incidence of HIV. (4.1)

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Increasing Focus on the Status of Women and Girls Is Critical for Sustainability

The Leadership Act calls for a focus on women and girls, articulates the need to address their particular vulnerability if the fight against the HIV/AIDS pandemic is to succeed, and requires that the PEPFAR strategy address their unique needs. The strategy is largely responsive to this mandate, and PEPFAR is currently supporting numerous programs and services directed at reducing the risks faced by women and girls. These efforts are focused in five areas: increasing gender equity, addressing male norms, reducing violence and sexual coercion, increasing income generation for both women and girls, and ensuring legal protection and property rights (OGAC, 2005b, 2006b). However, no information is available with which to determine either the individual or collective impact of these activities on the status of and risks to women and girls. To the extent possible with data collection systems that do not always identify the sex of the person receiving services, PEPFAR has been able to demonstrate that women and girls are receiving PEPFAR-supported prevention, treatment, and care services in seemingly appropriate proportions to men and boys.

Most of the factors that contribute to the increased vulnerability of women and girls to HIV/AIDS cannot be readily addressed in the short term. The Leadership Act appropriately views these factors as priorities on the agenda for the fight against HIV/AIDS. In the transition from emergency response to sustainability, these factors will require increased emphasis and support, and the U.S. Global AIDS Initiative will need to keep gender issues at the core of its efforts. **The U.S. Global AIDS Initiative should continue to increase its focus on the factors that put women at greater risk of HIV/AIDS and to support improvements in the legal, economic, educational, and social status of women and girls. (8.2)**

Improved Harmonization and Coordination Are Needed to Strengthen the Foundation for Sustainability

Countries' ownership and leadership of their responses to their HIV/AIDS epidemics are recognized as essential for success and sustainability (The Rome Declaration, 2003; Tobias, 2003b; UN, 2003; The Paris Declaration, 2005). Because no single approach can work in the context of harmonization, the PEPFAR Country Teams need maximum flexibility to work closely with and within the framework and priorities of the partner countries. The PEPFAR Country Teams have been largely successful in aligning their plans with the partner countries' national HIV/AIDS strategies, coordinating with national AIDS coordinating agencies, and supporting national monitoring and evaluation frameworks (OGAC, 2005c, 2006g). However,

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

particularly as the partner countries improve their national programs and become more directive with donors, there is room for the U.S. Global AIDS Initiative to improve on all three aspects of harmonization, and greater flexibility would facilitate this improvement.

Closer coordination and cooperation with other international donors at both the global and country levels is also necessary for harmonization to succeed in empowering countries. As the number of donors and the amount of available resources increase, so, too, will the need for coordination. As highlighted by the Leadership Act, a key feature of U.S. leadership is commitment to coordination at all levels. At the global level, it is essential for the United States to continue to work closely with other multilateral and bilateral donors to ensure that the comparative strengths of each are maximized and have a positive, synergistic impact on countries, rather than a duplicative, inefficient, and disempowering one (OECD, 2003; UNAIDS, 2005a; GIST, 2006).

To support country leadership, the U.S. Global AIDS Coordinator should seek to identify and remove barriers to coordination with partner governments and other donors, with a particular focus on promoting transparency and participation throughout the annual planning process. (3.1)

During the Committee's visits to the focus countries, the most frequently cited example of an impediment to coordination and harmonization was PEPFAR's requirement for U.S. Food and Drug Administration (FDA) approval of ARVs. A previous IOM Committee strongly endorsed "a rigorous, standardized international mechanism to support national quality assurance programs for antiretroviral drugs" (IOM, 2005a, p. 8). The international mechanism on which most other donors and the majority of the PEPFAR focus countries rely is the World Health Organization (WHO) Prequalification of Medications Project (WHO, 2006b). When PEPFAR was initiated, however, the Coordinator determined that FDA approval would be the standard for ensuring the quality of PEPFAR-provided ARVs (OGAC, 2004). This standard posed a major challenge to implementation because most of the focus countries had selected generic versions of ARVs for their formularies, and no generic ARVs had FDA approval (GAO, 2005). Subsequently, the Coordinator has fostered and supported an expedited FDA review process for generic ARVs, and since December 2004, more than 30 generic versions of the first-line ARVs have been FDA-approved for purchase by PEPFAR (DHHS, 2004; FDA, 2006; OGAC, 2006c). However, many of these medications, including some of the fixed-dose combination ARVs that are most desirable in the focus countries, were approved only within the past year (FDA, 2006). According to OGAC, only 10 percent of total PEPFAR-supported ARV purchases were for FDA-approved generics

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

in fiscal year 2005, increasing to 27 percent in 2006 (OGAC, 2006c, 2007). In addition, because some focus countries rely on WHO prequalification, they require it in addition to FDA approval. Thus, PEPFAR's strategy for ensuring the quality of the ARVs it provides has impeded harmonization and the rapid availability of PEPFAR-supported first-line ARVs.

To support countries' ownership of their responses to their HIV/AIDS epidemics, the U.S. Global AIDS Initiative should maintain its commitment to harmonization and participate fully in the development of harmonized procedures. To this end, the U.S. Global AIDS Coordinator should work to support World Health Organization (WHO) prequalification as the accepted global standard for assuring the quality of generic medications. Specifically, the Coordinator should provide an analysis of WHO prequalification that determines whether it can adequately assure the quality of generic antiretroviral medications for purchase under PEPFAR. If the analysis shows that WHO prequalification needs strengthening to provide a sufficient guarantee of quality for PEPFAR, the U.S. Global AIDS Initiative should work with other donors to support strengthening of the process, and work to transition from U.S. Food and Drug Administration approval to WHO prequalification as rapidly as feasible. (5.2)

Budget Allocations Reduce Flexibility and Impede Harmonization and Program Implementation

One of the strengths of the U.S. Global AIDS Initiative is its orientation toward and accountability for specified results. The Coordinator's annual reports to Congress have shown progress toward the defined, measurable performance targets set forth in the legislation and the PEPFAR strategy (OGAC, 2005b, 2006b). Appropriately for a program this early in implementation, most of the results reported at this stage are for targets that can be measured in the short term, and thus they reveal more about the program's implementation than its impact.

However, one set of the Leadership Act's short-term targets—its budget allocations—has adversely affected implementation of the U.S. Global AIDS Initiative. In mandating the strategy that was eventually to become known as PEPFAR, Congress wisely required that the "strategy shall maintain sufficient flexibility and remain responsive to the ever-changing nature of the HIV/AIDS pandemic." However, Congress also required that the program adhere to a fairly large set of specific budget allocations.[3] At the

[3]The budget allocations include 55 percent 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"; 20 percent for "HIV/AIDS prevention, of which such amount at

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

time the Leadership Act was passed, little information existed with which to determine precisely how resources should be allocated to achieve the performance targets across the focus countries; thus the budget allocations could not be evidence-based. Furthermore, Congress established these allocations so that they become more, not less, restrictive over time as the pandemic evolves and the program gains experience and knowledge.[4] Contrary to basic principles of good management and accountability, the budget allocations have made spending money in a particular way an end in itself rather than a means to an end—in this instance, the vitally important end of saving lives today and in the future.

In the Committee's judgment, the Coordinator and the Country Teams have made reasonable attempts to both respect the congressional budget allocations and implement within these constraints an effective program that can achieve its ambitious targets. However, their task is to implement a comprehensive, integrated, evidence-based program to address the HIV/AIDS epidemics in 15 unique, resource-constrained countries within the framework of harmonization. Particularly because Congress demonstrated no relationship between the budget allocations and the performance targets—prevention of 7 million infections, provision of ART to 2 million people, and provision of care for 10 million people—the budget allocations have further complicated this already daunting task and thus have been counterproductive. It is readily apparent that PEPFAR's approach to and mechanisms for planning, implementing, and measuring the initiative are to a large extent structured to be able to adhere to and report on the budget allocations. PEPFAR staff, both in headquarters and on the Country Teams, have explained to the Committee and others their frustration with these allocations and have illustrated how they thwart rational and strategic planning to meet the performance targets (GAO, 2006). Thus the manner in which Congress has required resources to be allocated, rather than what is necessary to have an impact, is having an unwarranted influence on PEPFAR. The U.S. Global AIDS Initiative needs maximum flexibility and agility not only to adapt to a changing pandemic and be harmonized with the efforts of 15 different focus countries, but also to be able to incorporate what is learned through program implementation about how to have the greatest impact. Resource allocation that is the consequence of rather than

---

least 33 percent should be expended for abstinence-until-marriage programs"; 15 percent for "palliative care of individuals with HIV/AIDS"; and 10 percent for "assistance for orphans and vulnerable children affected by 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."

[4]Many of the budget allocations became mandatory beginning with fiscal year 2006.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

the precursor for adaptive, evidence-based programming, would better enable the initiative to have an optimal impact.

> ***Although they may have been helpful initially in ensuring a balance of attention to activities within the four categories of prevention, treatment, care, and orphans and vulnerable children, the Committee concludes that rigid congressional budget allocations among categories, and even more so within categories, have also limited PEPFAR's ability to tailor its activities in each country to the local epidemic and to coordinate with the level of activities in the countries' national plans.*** **Congress should remove the budget allocations and replace them with more appropriate mechanisms that ensure accountability for results from Country Teams to the U.S. Global AIDS Coordinator and to Congress. These mechanisms should also ensure that spending is directly linked to and commensurate with necessary efforts to achieve both country and overall performance targets for prevention, treatment, care, and orphans and vulnerable children.** (3.3)

Expansion, Improvement, and Better Integration of Services Are Needed for Sustainability

If the U.S. Global AIDS Initiative is to succeed, it is essential that PEPFAR support programs and services that are evidence-based; strategically planned using the best data available; and implemented equitably, efficiently, and effectively (UNAIDS, 1998, 2004b). Although PEPFAR does not necessarily categorize activities in accordance with global norms, it is supporting all of the major components of a comprehensive HIV/AIDS program recommended by global consensus (UNAIDS, 2001, 2005b; WHO, 2004). The Committee observed much promise in the programs PEPFAR supports, as well as room for improvement and a need for expansion. Of particular importance is for PEPFAR to support programs in a manner that fosters integration both within and among the program categories of prevention, treatment, care, and orphans and vulnerable children—or, more appropriately, regardless of categorization. Neither the congressional budget allocations discussed above nor the budgeting, planning, and reporting mechanisms the Coordinator established to ensure that PEPFAR complies with these allocations facilitate integration. Optimal integration is critical to achieve not only the success of individual interventions and services, but also to realize the additional benefits that derive from the synergy among them (Salomon et al., 2005). The Committee's recommendation for improving PEPFAR's approach to prevention was discussed earlier; recommendations for improving its approach to treatment, care, and services for

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

orphans and vulnerable children, as well as to ensuring equity, are presented below.

Treatment

The U.S. Global AIDS Coordinator should ensure that adequate medications are available to place 2 million people on sustained antiretroviral therapy to achieve PEPFAR's stated 5-year treatment target. To achieve this target, the Coordinator should also ensure that adequate linkages are established among prevention, treatment, and care programs and rapidly expand the availability of antiretroviral therapy to both children and adults. (5.1)

Care

The U.S. Global AIDS Coordinator should continue to promote and support a community-based, family-centered model of care in order to enhance and coordinate supportive care services for people living with HIV/AIDS, with special emphasis on orphans, vulnerable children, and people requiring end-of-life care. This model should include integration as appropriate with prevention and treatment programs and linkages with other public-sector and nongovernmental organization services within and outside of the health sector, such as primary health care, nutrition support, education, social work, and the work of agencies facilitating income generation. (6.1)

Orphans and Other Vulnerable Children

The needs of orphans and other children made vulnerable by AIDS cover a wide spectrum that cuts across all of PEPFAR's categories of prevention, treatment, and care and extends well beyond the health sector. It is essential for an HIV/AIDS response to address these needs adequately—not only to support these children in living healthy and productive lives, but also to protect them from becoming the next wave of the pandemic. **The U.S. Global AIDS Initiative should continue to support countries in the development of national plans that address the needs of orphans and other children made vulnerable by AIDS, as well as to support the priorities delineated in these plans. To ensure adequate focus on and accountability for addressing the needs of orphans and other vulnerable children, the U.S. Global AIDS Coordinator should work with Congress to set a distinct and meaningful performance target for this population. This target should be developed in a manner that both builds on the improvements PEPFAR has made in its indicator for children served and enhances its ability to support comprehensive and integrated HIV/AIDS programming. (7.1)**

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Equity

> ***The commitment of the U.S. Global AIDS Initiative to work toward reducing stigma and discrimination against people living with HIV/AIDS requires that marginalized and difficult-to-reach groups receive prevention, treatment, and care services. These groups include sex workers, prisoners, those who use injection drugs, and men who have sex with men—groups that not only are characterized by their high-risk behavior, but also tend to be stigmatized and subject to discrimination.*** **The U.S. Global AIDS Coordinator should document how these groups are included in the program planning, implementation, and evaluation of PEPFAR activities. (3.2)**

Expanded Capacity Is Necessary to Meet Current and Future Needs

Severe human resource shortages are a continuing challenge to PEPFAR implementation (OGAC, 2005b, 2006b; WHO, 2006c). Plans for ART scale-up that have been developed by some partner countries and are now being formulated in others include specific efforts to increase the health care workforce, with an emphasis on increasing the numbers of nurses, clinical officers, and pharmacists, among others. Training periods for these vital personnel are typically 2 to 3 years. Expansion of class sizes and repetition of existing programs are, in some partner countries, easily identified and cost-effective means for workforce expansion. In other countries, the lack of clinical faculty mirrors the lack of overall personnel, and increases in the numbers of teachers are badly needed (UNAIDS, 2006).

PEPFAR's initial emergency approach to meeting personnel needs has been to focus on HIV-specific training of existing clinicians and other health care workers (OGAC, 2006d). Support for expansion of the professional clinical workforce has been limited, even when such expansion is an explicit part of the country's HIV/AIDS plan, and the effort is endorsed and supported by other donors (OGAC, 2005c, 2006g). During its visits to the focus countries, the Committee saw many programs of all varieties—particularly ART programs—that were overflowing their capacity, had long waiting lists, and had insufficient numbers of staff who were highly stressed. PEPFAR Country Teams often expressed concern that they were not allowed to fund activities unless those activities were specifically part of the HIV/AIDS effort and so could not support, for example, the training of new clinical officers, who in some countries are the mainstay of the treatment effort.

PEPFAR reports that its response to the shortage of health workers to date has been to provide support, within national plans and priorities and the principles of harmonization, for policy reform to promote task shifting from physicians and nurses to community health workers; for

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

the development of information systems; for human resource assessments; for training for health workers, including community health workers; for retention strategies; and for twinning partnerships (OGAC, 2006d). One mainstay of this approach—task shifting—is not possible in countries with few health personnel because the nurses and clinical officers to whom tasks could be shifted are not available. A refocus on new personnel, with use of twinning to expand the numbers of faculty available, is needed to enable task shifting.

If focus countries' plans for expanding their health workforce are not supported, PEPFAR may also exacerbate national shortages by shifting a disproportionate share of the workforce to efforts against HIV/AIDS, with the result that other health priorities would be neglected. To ameliorate this potential negative consequence of PEPFAR's disease-specific focus, Country Teams need to work closely with governments and other donors to determine a reasonable proportion of PEPFAR funding to be allocated to the education of new health professionals. Also, to ensure that PEPFAR itself is not drawing workers out of the public system through disproportionate incentives and salaries, it is important that the Coordinator continue to study the impact of the program's hiring practices and compensation policies and act quickly and decisively to address any problems identified. Finally, evaluation of PEPFAR's impact needs to include indicators for areas of the public health system likely to be sensitive to the loss of personnel, such as maternal and child health and immunization programs.

To meet existing targets for prevention, treatment, and care, the U.S. Global AIDS Initiative should increase the support available to expand workforce capacity in heavily affected countries. These efforts should include education of new health care workers in addition to AIDS-related training for existing health care workers. Such support should be planned in conjunction with other donors to ensure that comparative advantages are maximized and be provided in the context of national human resource strategies that include relevant stakeholders, such as the ministries of health, labor, and education; other ministries; employers; regulatory bodies; professional associations; training institutions; and consumers. (8.3)

Knowledge About What Works Against the HIV/AIDS Pandemic Is Essential for Sustainability

Because of its magnitude and reach, the U.S. Global HIV/AIDS Initiative represents a golden opportunity to learn about what works best in addressing the pandemic, and such learning is in turn essential to the program's success. The Leadership Act emphasizes the importance of both basic and applied research, and requires that research be an integral part of the initiative. In addition, because of the many gaps in the knowledge base

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

for addressing HIV/AIDS, the initiative has an obligation to "learn by doing" (IOM, 2005a). In doing so, the initiative can help the global community learn not only about what approaches are cost-effective for preventing infection and caring for people affected by HIV/AIDS and its consequences, but also about how to scale up effective programs, how to implement programs in a manner that builds capacity and strengthens health systems overall, how best to manage such global initiatives, and how to work most effectively within the framework of harmonization to empower countries to own and lead their responses to their HIV/AIDS epidemics.

Functioning as a Learning Organization

Beginning with its strategy, PEPFAR has been committed to learning, and the program has displayed many of the characteristics of a successful learning organization. The PEPFAR strategy envisioned OGAC as a "small organization focused on leadership, coordination, learning, and oversight" that would "strive to remain flexible and innovative in its approaches" (OGAC, 2004, p. 67). The Committee has seen many examples of OGAC's success in realizing this vision and encourages OGAC to continue in this vein. However, OGAC currently does not formally evaluate or provide information about its performance on critical aspects of program management—such as coordination—and would benefit from doing so.

Research

The PEPFAR strategy also commits to building the evidence base on what works against HIV/AIDS and fostering innovation (OGAC, 2004), and the initiative is indeed helping to expand knowledge about the implemention of HIV/AIDS programs and services in resource-constrained countries. The U.S. Global AIDS Initiative supports the full spectrum of global AIDS research, from basic to operations research, through several entities in addition to OGAC, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the U.S. Agency for International Development. OGAC directly funds targeted evaluations to support the programs and policies of the initiative and is currently providing about $22 million for these evaluations, primarily in the focus countries. The evaluations cover a wide range of topics related to prevention, treatment, and care (OGAC, 2006e,f). However, many Country Teams and implementing partners believe that using PEPFAR funds for research of any kind is prohibited and thus have not rountinely incorporated operations research into their programs. Yet there are still more questions than answers about how best to respond to the HIV/AIDS epidemics in these countries, and the Committee highlights some of these in the ensuing chapters.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

The U.S. Global AIDS Initiative should increase its contribution to the global evidence base for HIV/AIDS interventions by better capitalizing on the opportunity PEPFAR represents to learn about and share what works. The U.S. Global AIDS Coordinator should further emphasize the importance of and provide additional support for operations research and program evaluation in particular—not as the primary aim but as an integral component of programs. All programs should include robust monitoring and evaluation that factors into decisions about whether and in what manner the programs are to continue. The initiative should maintain its appropriate openness to new and innovative approaches and programs, but unproven programs in particular should be required to have an evaluation component to determine their effectiveness. (8.4)

Key to understanding what works against the HIV/AIDS pandemic will be to learn whether PEPFAR has succeeded—that is, to understand its long-term impact. To measure what really matters—reductions in disability, disease, and death from HIV/AIDS; increases in the capacity of partner countries to sustain and expand HIV/AIDS programs without setbacks in other aspects of their public health systems; and improvements in the lives of the people living in these countries—the United States and other donors will be heavily dependent on the capabilities of the partner countries. To understand whether countries are achieving these ultimate goals and what contributions the U.S. Global AIDS Initiative is making to their achievement, the initiative will need to study national trends, such as rates of new HIV and other infections; rates of survival from HIV/AIDS and other diseases; child survival, development, and well-being; and the general health status of the population and key subpopulations. Particularly within the agreed framework of harmonization, the data and analyses necessary to study these trends will have to come primarily from the partner countries themselves (UNAIDS, 2004a). Thus it is essential that the United States, in conjunction with other donors, continue to place priority on helping to strengthen the monitoring and evaluation systems of the partner countries.

The Need for U.S. Leadership Against the HIV/AIDS Pandemic Continues

The Committee found that the U.S. Global AIDS Initiative has made a strong start, is progressing toward its 5-year targets, and is increasingly well positioned to support countries in controlling their epidemics. At the same time, however, PEPFAR has not yet reached the half-way mark for any of its targets, each focus country still faces an enormous challenge in controlling its epidemic, and the HIV/AIDS pandemic continues to grow. The Joint United Nations Programme on HIV/AIDS has estimated that more than 4 million people worldwide became newly infected with HIV

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

in 2006, and, unless prevention efforts are highly successful, millions more will become infected every year (UNAIDS, 2006). Of the nearly 7 million people in low- and middle-income countries now estimated to need ART or to face an early death, fewer than one-quarter are receiving the therapy (WHO, 2006a), and millions more of those already infected with HIV will eventually need it. Fewer than 1 in 10 pregnant women infected with HIV in low- and middle-income countries are benefiting from ARVs to prevent transmission to their babies, and at most 12 percent of the children born to these women who require ART are receiving it (WHO, 2006a). With ART and appropriate care, AIDS is a chronic disease—it can be managed but not cured—and people receiving ART will need to be on it for the rest of their lives. Only a fraction of the legions of devastated families and orphaned children are currently receiving the support services they need, and the number of children orphaned by AIDS globally is projected to exceed 20 million by 2010 (UNICEF, 2006).

The Committee believes that continued commitment by the United States, along with all other donors, to supporting the fight against the HIV/AIDS pandemic will be required until countries have developed sustainable programs, and that continued U.S. leadership is necessary to prevent complacency and battle fatigue and to bring the virus under control.

REFERENCES

DHHS (Department of Health and Human Services). 2004. *HHS proposes rapid process for review of fixed dose combination and co-packaged products*. http://www.hhs.gov/news/press/2004pres/20040516.html (accessed September 6, 2006).

FDA (Food and Drug Administration). 2006. *President's Emergency Plan for AIDS Relief approved and tentatively approved antiretrovirals in association with the President's emergency plan*. http://www.fda.gov/oia/pepfar.htm (accessed January 11, 2007).

GAO (Government Accountability Office). 2005. *Global HIV/AIDS epidemic: Selection of antiretroviral medications provided under U.S. emergency plan is limited* (GAO-05-133). Washington, DC: GAO.

GAO. 2006. *Global health: Spending requirement presents challenges for allocating prevention funding under the President's Emergency Plan for AIDS Relief* (GAO-06-395). Washington, DC: GAO.

GIST (Global Implementation Support Team). 2006. *Fact sheet: The Global Implementation Support Team: Coordinating UN action and provision of technical support for accelerating HIV/AIDS responses in countries*. http://data.unaids.org/pub/BrochurePamphlet/2006/2006_gist_en.pdf (accessed January 12, 2007).

IOM (Institute of Medicine). 2005a. *Scaling up treatment for the global AIDS pandemic: Challenges and opportunities*. Washington, DC: The National Academies Press.

IOM. 2005b. *Plan for a short-term evaluation of PEPFAR implementation*. Washington, DC: The National Academies Press.

Mathers, C., and D. Loncar. 2006. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Medicine* 3(11):e442.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Nieburg, P., J. Kates, and J. S. Morrison. 2004. *Enhancing the rapid response capacity of the U.S. global AIDS coordinator: Lessons from other U.S. emergency responses. A report of the CSIS HIV/AIDS Task Force in collaboration with the Kaiser Family Foundation.* Washington, DC: Center for Strategic and International Studies.

OECD (Organisation for Economic Co-operation and Development). 2003. *Harmonising donor practices for effective aid delivery good practice papers: A DAC reference document*. Paris, France: OECD.

OGAC (Office of the Global AIDS Coordinator). 2004. *The President's Emergency Plan for AIDS Relief: U.S. five-year global HIV/AIDS strategy.* Washington, DC: OGAC.

OGAC. 2005a. *The President's Emergency Plan for AIDS Relief: Defining U.S. support for national strategies* (PowerPoint Presentation, July 2005). Washington, DC: OGAC.

OGAC. 2005b. *PEPFAR first annual report to Congress*. Washington, DC: OGAC.

OGAC. 2005c. *FY2005 Country Operational Plans*. Washington, DC: OGAC.

OGAC. 2006a. *PEPFAR semi-annual report, FY2006*. Washington, DC: OGAC.

OGAC. 2006b. *PEPFAR second annual report to Congress*. Washington, DC: OGAC.

OGAC. 2006c. *Bringing hope: Supplying antiretroviral drugs for HIV/AIDS treatment: The President's Emergency Plan for AIDS Relief report on antiretroviral drugs for HIV/AIDS treatment*. Washington, DC: OGAC.

OGAC. 2006d. *PEPFAR report on work force capacity and HIV/AIDS*. Washington, DC: OGAC.

OGAC. 2006e. *PEPFAR: Technical considerations for the FY2007 Country Operational Plans*. Washington, DC: OGAC.

OGAC. 2006f. *PEPFAR FY2007 COP resource guide*. Washington, DC: OGAC.

OGAC. 2006g. *FY2006 Country Operational Plans*. Washington, DC: OGAC.

OGAC. 2007. *PEPFAR third annual report to Congress*. Washington, DC: OGAC.

Salomon, J., D. Hogan, J. Stover, K. Stanecki, N. Walker, P. D. Ghys, and B. Schwartlander. 2005. Integrating HIV prevention and treatment: From slogans to impact. *PLoS Medicine* 2(1):e16.

The Paris Declaration on aid effectiveness: Ownership, harmonization, alignment, results and mutual accountability. 2005. High level forum on harmonization, February 28–March 2, 2005, Paris, France. http://www.aidharmonization.org (accessed November 10, 2006).

The Rome Declaration on Harmonization. 2003. High level forum on harmonization, February 24–25, 2003, Rome, Italy. http://www.aidharmonization.org (accessed November 10, 2006).

Tobias, R. 2003a. *Remarks at InterAction annual CEO retreat at the Washington Terrace Hotel, Washington, DC.* http://www.pepfar.gov (accessed December 9, 2003).

Tobias, R. 2003b. *Remarks at Woodrow Wilson Center of the U.S. Global AIDS Coordinator at the Ronald Reagan Building, Washington, DC.* http://www.pepfar.gov (accessed December 11, 2003).

Tobias, R. 2004. *Remarks on the five-year strategy for the President's Emergency Plan for AIDS Relief, Washington, DC.* http://www.pepfar.gov (accessed February 23, 2004).

UN (United Nations). 2003. *Monterrey Consensus of the International Conference on Financing for Development: The final text of agreements and commitments adopted at the International Conference on Financing for Development, Monterrey, Mexico, 18–22 March 2002*. Geneva, Switzerland: UN.

UNAIDS (Joint United Nations Programme on HIV/AIDS). 1998. *UNAIDS best practice collection: Guide to the strategic planning process for a national response to HIV/AIDS, modules 1–4*. Geneva, Switzerland: UNAIDS.

UNAIDS. 2001. *The global strategy framework on HIV/AIDS*. Geneva, Switzerland: UNAIDS.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

UNAIDS. 2004a. *"Three ones" key principles*. Conference paper 1, Washington consultation of April 4, 2004. Geneva, Switzerland: UNAIDS. http://www.unaids.org/NetTools/Misc/DocInfo.aspx?LANG=en&href=http://gva-doc-owl/WEBcontent/Documents/pub/UNAdocs/Three-Ones_KeyPrinciples_en.pdf (accessed September 20, 2006).

UNAIDS. 2004b. *Clearing the common ground for the "three ones": A report of a consulation process*. Conference paper 2. Geneva, Switzerland: UNAIDS.

UNAIDS. 2005a. *Global task team on improving AIDS coordination among multilateral institutions and international donors*. Geneva, Switzerland: UNAIDS.

UNAIDS. 2005b. *Resource needs for an expanded response to AIDS in low- and middle-income countries*. Geneva, Switzerland: UNAIDS.

UNAIDS. 2005c. *Policy position paper: Intensifying HIV prevention*. Geneva, Switzerland: UNAIDS.

UNAIDS. 2006. *2006 report on the global AIDS epidemic*. Geneva, Switzerland: UNAIDS.

UNICEF (United Nations Children's Fund). 2006. *Africa's orphaned and vulnerable generations: Children affected by AIDS*. New York: UNICEF.

WHO (World Health Organization). 2003a. *A public health approach for scaling up antiretroviral (ARV) treatment*. http://www.who.int/hiv/toolkit/arv/en/index.jsp (accessed September 7, 2006).

WHO. 2003b. *Treating 3 million by 2005, making it happen: The WHO strategy*. http://www.who.int/hiv/toolkit/arv/en/index.jsp (accessed September 7, 2006).

WHO. 2004. *Guide to monitoring and evaluating HIV/AIDS care and support*. Geneva, Switzerland: WHO.

WHO. 2006a. *Fact sheet: Progress in scaling up access to HIV treatment in low- and middle-income countries*. Geneva, Switzerland: WHO.

WHO. 2006b. *Prequalification project: Ensuring the quality, safety and efficacy of HIV/AIDS medicines and diagnostics*. http://mednet3.who.int/prequal/ (accessed September 1, 2006).

WHO. 2006c. *Working together for health: The world health report 2006*. Geneva, Switzerland: WHO.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

PEPFAR IMPLEMENTATION

PROGRESS AND PROMISE

Committee for the Evaluation of the President's Emergency Plan for AIDS Relief (PEPFAR) Implementation

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

Jaime Sepúlveda, Charles Carpenter, James Curran, William Holzemer, Helen Smits, Kimberly Scott, and Michele Orza, *Editors*

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, N.W. Washington, DC 20001

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This project was supported by Contract No.SAQMPD05D1147 between the National Academy of Sciences and the U.S. Department of State. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the agency that provided support for this project.

Library of Congress Cataloging-in-Publication Data

Institute of Medicine (U.S.). Committee for the Evaluation of the President's Emergency Plan for AIDS Relief (PEPFAR) Implementation.

PEPFAR implementation : progress and promise / Committee for the Evaluation of the President's Emergency Plan for AIDS Relief (PEPFAR) Implementation, Board on Global Health, Board on Children, Youth, and Families ; Jaime Sepúlveda ... [et al.] editors.

p. ; cm.

Includes bibliographical references.

ISBN-13: 978-0-309-10982-6 (hardback : alk. paper)

ISBN-10: 0-309-10982-5 (hardback : alk. paper) 1. AIDS (Disease)—Prevention—Government policy—United States. 2. HIV infections—Prevention—Government policy—United States. 3. AIDS (Disease)—Prevention—International cooperation.

[DNLM: 1. Government Programs—organization & administration—United States. 2. HIV Infections—prevention & control—United States. 3. Disease Outbreaks—prevention & control—United States. 4. Emergencies—United States. 5. International Cooperation—United States. 6. World Health—United States. WC 503.6 I585p 2007] I. Sepúlveda Amor, Jaime. II. Title.

RA643.83.I57 2007

362.196´9792—dc22

2007023493

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

For more information about the Institute of Medicine, visit the IOM home page at: www.iom.edu.

Copyright 2007 by the National Academy of Sciences. All rights reserved.

Printed in the United States of America.

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

COVER: The flags of the 15 PEPFAR focus countries are overlaying the global symbol of the red ribbon for HIV/AIDS awareness arranged in alphabetical order by country.

Suggested citation: IOM (Institute of Medicine). 2007. *PEPFAR Implementation: Progress and Promise*. Washington, DC: The National Academies Press.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the Nation. Improving Health.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

The **National Academy of Sciences** is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Ralph J. Cicerone is president of the National Academy of Sciences.

The **National Academy of Engineering** was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Charles M. Vest is president of the National Academy of Engineering.

The **Institute of Medicine** was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The **National Research Council** was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Ralph J. Cicerone and Dr. Charles M. Vest are chair and vice chair, respectively, of the National Research Council.

www.national-academies.org

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

COMMITTEE FOR THE EVALUATION OF PEPFAR IMPLEMENTATION

Jaime Sepúlveda (*Chair*), 2007 University of California, San Francisco Presidential Chair and Visiting Professor
Helen Smits (*Vice Chair*), Former Faculty of Medicine, Eduardo Mondlane University, Mozambique
Charles Carpenter (*Treatment Subcommittee Chair*), Professor of Medicine, Director of the Brown University AIDS Center, Brown University, Providence, Rhode Island
James Curran (*Prevention Subcommittee Chair*), Dean, Professor of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, Georgia
William L. Holzemer (*Care Subcommittee Chair*), Professor of Nursing and Associate Dean, International Programs, School of Nursing, University of California, San Francisco
Stefano M. Bertozzi, Director of Health Economics, National Institutes of Health, Mexico
Geoff Garnett, Professor of Microparasite Epidemiology, Faculty of Medicine, Imperial College, London, United Kingdom
Ruth Macklin, Head, Division of Bioethics, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, New York
Affette McCaw-Binns, Professor, Reproductive Health Epidemiology, Section of Community Health, University of the West Indies, Jamaica
A. David Paltiel, Professor, Yale School of Medicine, Yale School of Management, New Haven, Connecticut
Priscilla Reddy, Director, Health Promotion Research and Development Unit, Medical Research Council of South Africa
David Ross, Director, Public Health Informatics Institute, Decatur, Georgia
Heather Weiss, Director, Harvard Family Research Project, Harvard University, Boston, Massachusetts

Subcommittee Members, Liaisons, and Study Consultants

Maureen Black, John A. Scholl Professor of Pediatrics, University of Maryland School of Medicine, Baltimore
Hoosen Coovadia, Victor Daitz Professor of HIV/AIDS Research, Centre for HIV/AIDS Networking, Doris Duke Medical Research Institute, University of Kwazulu/Natal, Durban, South Africa
Henry Fomundam, Regional Director, Howard University/PACE Centre, Washington DC/South Africa
Paul Gertler, Professor of Economics, Haas School of Business, Professor of Health Services Finance, School of Public Health, University of California, Berkley

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Carl A. Latkin, Professor, Department of Health, Behavior, and Society, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland
James Ntozi, Professor, Department of Population Studies, Makerere University, Uganda
James Sherry, Professor of Global Health, School of Public Health and Health Services, The George Washington University, Washington, D.C.
Olaitan Soyannwo, Professor of Anesthesia and Consultant Anesthetist, College of Medicine, University of Ibadan and University College Hospital, Ibadan, Nigeria
Burton Wilcke, Jr., Chair and Associate Professor, Department of Medical Laboratory and Radiation Sciences, University of Vermont, Burlington
Michael Merson (*Board on Global Health Liaison*), Founding Director, Global Health Institute, Duke University, North Carolina
Elena O. Nightingale (*Board on Children, Youth, and Families Liaison*), Scholar-in-Residence, Institute of Medicine, The National Academies, Washington, D.C.
Julia Coffman (*Consultant*), Independent Evaluation Consultant, Alexandria, Virginia
Thomas Denny (*Consultant*), Research Associate Professor, Chief Operating Officer, Duke Human Vaccine Institute and Center for HIV/AIDS Vaccine Immunology, Duke University Medical Center, Durham, North Carolina
Florencia Zulberti (*Consultant*), Assistant Director for Global Health, National Institutes of Health, Mexico

Study Staff

Patrick Kelley, Board Director, Global Health
Rosemary Chalk, Board Director, Children, Youth and Families
Michele Orza, Study Director
Kimberly Scott, Senior Program Officer
Lucía Fort, Program Officer (through November 2006)
J. Alice Nixon, Program Officer (through November 2006)
Angela Mensah, Senior Program Assistant
Kimberly Weingarten, Senior Program Assistant (through September 2006)
Sheyi Lawoyin, Senior Program Assistant (May 2006 through July 2006)
Jessica Manning, Mirzayan Science and Technology Policy Fellow (May 2006 through August 2006)
Keren Ladin, Mirzayan Science and Technology Policy Fellow (June 2006 through August 2006)

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Reviewers

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

Roberto Arduino, Division of Infectious Diseases, The University of Texas Health Science Center at Houston
Solomon R. Benatar, Department of Medicine, University of Cape Town, South Africa
Alan Berkman, Mailman School of Public Health, Columbia University, New York
Jo Ivey Boufford, Robert F. Wagner Graduate School of Public Service, New York University
Fred Carden, International Development Research Centre, Ottawa, Canada
Ambassador Johnnie Carson, National Intelligence Council of the Office of the National Director of Intelligence, Washington, District of Columbia
Thomas J. Coates, David Geffen School of Medicine, University of California, Los Angeles

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Susan A. Cohen, Guttmacher Institute, Washington, District of Columbia
Carlos del Rio, Emory AIDS International Training and Research, Rollins School of Public Health of Emory University and Grady Memorial Hospital, Atlanta, Georgia
Christopher J. Elias, PATH, Seattle, Washington
Helene Gayle, CARE, Atlanta, Georgia
Geeta Rao Gupta, International Center for Research on Women, Washington, District of Columbia
Grace John-Stewart, Department of Medicine, International AIDS Research and Training Program, University of Washington, Seattle, Washington
James W. Kazura, Center for Global Health and Diseases, Case Western Reserve University, Cleveland, Ohio
Mary Anne Koda-Kimble, School of Pharmacy, University of California, San Francisco
Adel A. F. Mahmoud, Merck Vaccines, Merck & Co., Inc., Whitehouse Station, New Jersey
Anne Mills, London School of Hygiene & Tropical Medicine, London
Roeland Monasch, United Nations Children's Fund, Harare, Zimbabwe
J. Stephen Morrison, HIV/AIDS Task Force, Center for Strategic & International Studies, Washington, District of Columbia
Anne Peterson, World Vision International, Washington, District of Columbia
Robert Redfield, Institute of Human Virology/Microbiology and Immunology, University of Maryland School of Medicine, Baltimore, Maryland
Catherine M. Wilfert, Duke University Medical Center, Duke University, Chapel Hill, North Carolina; The Elizabeth Glaser Pediatric AIDS Foundation

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Bernard Guyer,** Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, and **Charles E. Phelps,** University of Rochester, New York. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Preface

Only a quarter of a century after first reported, HIV/AIDS has become one of the largest global health scourges of all times. This preventable viral disease caused the death of almost 3 million people last year alone, while over 4 million others became infected. The majority of this disease burden occurs in the developing world, with sub-Saharan Africa carrying the largest burden. As a result, life expectancy in that region has decreased, causing enormous human suffering and long-lasting demographic, social, and economic consequences.

The very rapid scientific discoveries on the etiology and modes of transmission, and later the development of effective treatment against HIV/AIDS are a tribute to human ingenuity. Our collective social response, however, has taken longer to get organized. Although still far from adequate, the global response to the epidemic is finally growing and progress is evident on a number of fronts. Hope has been restored based on a broad awakening of international commitment and strong evidence that the technical challenges can be met on a large scale.

A major factor in the increasing global response is "The President's Emergency Plan for AIDS Relief," or PEPFAR. This plan derives from novel legislation, passed by the U.S. Congress in 2003, which also mandated an evaluation of progress on this initiative. It has been the challenge and privilege of our Institute of Medicine to be charged with the conduct of this independent evaluation.

The Emergency Plan set ambitious goals. It seeks to support the prevention of 7 million HIV infections, the treatment of 2 million people with

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

AIDS, and the care of 10 million orphans and others affected by this epidemic. PEPFAR has focused on 15 countries, which collectively represent around 50 percent of the HIV infections worldwide (12 countries of Africa plus Vietnam, Haiti, and Guyana). Our IOM committee has found its work to evaluate such a multidimensional plan to be a unique challenge. Not only are the programs focused on different activities of prevention, treatment, and care, but within the 15 countries they are also conducted by a variety of public- and private-sector organizations, with various degrees of expertise. Some programs were started shortly after the first funds started to flow in 2004 and others more recently. Few, if any, of the programs observed could be described as mature. Yet, the Committee found evidence to guide future planning and policy. The bulk of this report communicates that evidence and presents the Committee's conclusions and recommendations.

It is in our human nature to better respond to emergencies than to sustain efforts over time. HIV/AIDS, however, is a chronic infection that requires life-long treatment. The continuity of the support is a medical and moral imperative, and therefore PEPFAR will need to make the transition from an emergency plan to a sustained effort that invests in building the capacity within countries to eventually take full responsibility for responding to their epidemics. Constant learning should be at the center of such a transition considering the need to economically and effectively replicate these programs in so many places. The energy, empathy, perseverance, and technical competence of those implementing PEPFAR will be needed for many years into the future.

The number of newly infected people with HIV vastly outpaces the capacity to treat patients with AIDS. Treatment of patients is not only a humanitarian imperative; it is also an indivisible component of prevention. But let us make no mistakes here: the only way to eventually control this pandemic is by preventing new cases. The epidemiologic facts are clear. The past occurrence of still largely invisible HIV infections will generate a deluge of new AIDS cases needing treatment over the next decade. Even more sobering is the fact that the rate of new HIV infections continues to grow. Proud as we should be of PEPFAR's success in providing medication to many of those already ill, it needs to urgently put the accent on preventive measures of proven efficacy on a much larger scale.

Nothing is as persuasive as success. A proof of concept is required to make a case; to the usual skeptics, PEPFAR has successfully demonstrated that programs of quality can be implemented, even in resource-thin settings. The many heroic professionals working in suboptimal conditions in the field have proven that large-scale HIV/AIDS prevention services, care, and treatment are feasible. However, many more like them will need to be trained and supported if quality care is to be continued, as it needs to be, over the decades to come.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Indeed, one area of special concern for sustainability of efforts in affected countries is the local health workforce. Human resource capacity is projected to be a critical rate-limiting factor for all future HIV prevention and treatment initiatives. These capacities take time to build. Health infrastructures are being impaired as worker death and worker morbidity from AIDS, migration to more favorable and high-paying work environments (i.e., the brain drain), and retirements deplete the already thin workforce. The epidemic also has many negative collateral impacts on other health initiatives—such as maternal and reproductive health, vaccination, or malaria—as human, laboratory, and financial resources become overwhelmed by HIV/AIDS-specific needs and resources are diverted to AIDS from other health programs. Building human capacity will need to be an even more essential element of future global AIDS initiatives.

"Learning by doing" is a necessary corollary to this unprecedented scale-up of a complex global public health initiative. The Office of the Global AIDS Coordinator has increasingly been making investments into monitoring, evaluation, and various forms of operational research to this end. The IOM committee would like to see its work as part of this evaluative continuum and encourages transparency and wide dissemination of the findings from the ongoing program evaluations of the U.S. Global AIDS Initiative. Creative and accountable action needs to continue unabated, and quality must always be at the forefront. The citizens of the United States expect this, those in need deserve it, and our call to be humanitarians demands no less. The United States has taken a critical leadership role in responding to the HIV/AIDS pandemic but since it can not provide all the necessary resources, the lessons learned from PEPFAR will be critical leverage to motivate other donor nations to follow its lead with deeper investments.

The IOM evaluation of the implementation of PEPFAR reflects many months of work not only by 22 uncompensated committee and subcommittee members, but also dozens of consultants, staff members, editors, board liaisons, and reviewers. The committee members enjoyed and were honored by the professionalism of hundreds of individuals who gave candid testimony about how PEPFAR is working in the field and at the management level in Washington, DC. While opinions varied about specific scientific and management approaches and priorities, it became clear that PEPFAR represents a notable achievement not only in its conceptualization but also in its implementation.

Global security is profoundly influenced by our increasing health interdependence. No one is safe from the international transfer of risks, and no one should be left out of the international transfer of opportunities, in the form of knowledge, resources and technology. The PEPFAR initiative should be seen not only as an important investment in the lives of many individuals and their families, but also as an investment in global security.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

This is a good example of the kind of health diplomacy needed on a global scale.

PEPFAR is a vertical program. Much debate has existed in the past around the relative merits of vertical versus horizontal approaches to health care. To me, this is a false dilemma and an unnecessary dichotomy, for we should aim to have the best of both. A diagonal approach is one in which explicit intervention priorities—such as HIV/AIDS—is used to drive the desired improvements into the health system. AIDS is certainly not the only health problem in sub-Saharan Africa, nor can we tackle all problems at once. PEPFAR is laying the grounds for a unique opportunity—by contributing to the necessary capacity building—to incrementally incorporate other selected health priorities in the different countries' agendas.

While the Committee approached its task to conduct the evaluation in a dispassionate manner, it feels passionate about the problem and the potential solutions. It could not be otherwise; after all, the progress of PEPFAR is measured in real people—men, women, and children supported with vital HIV/AIDS services; health care workers trained to provide HIV/AIDS care; people enabled to change themselves, their communities, and their nations to better respond to the epidemic. Though the programs evaluated are still young, it was clear that millions of people are being served and life-saving medical care is being delivered on a large scale in some of the world's most challenging settings. As a Foreign Associate member of the Institute of Medicine who had the distinct privilege of leading this evaluation, I strongly believe that the American people, acting through PEPFAR, are to be complimented for supporting this remarkable humanitarian undertaking.

I would like to express my deep appreciation to the Institute of Medicine's authorities for the trust deposited in us, and to the heroic staff for all their hard work; and my perennial gratitude to all our Committee members, from whom I learned so much. The Committee hopes that the recommendations presented herein will be a constructive contribution to the current and future U.S. Global AIDS Initiatives.

Jaime Sepúlveda, M.D., Dr.Sc.
Chair

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Acknowledgments

The Committee is deeply appreciative of the valuable contributions to this project of many knowledgeable and experienced people. Appendix A lists the many people and organizations who generously assisted the Committee with its study.

The Committee would like to thank the Office of the U.S. Global AIDS Coordinator—in particular Ambassador Mark Dybul, Dr. Kathy Marconi, and Dr. Nadine Rogers for their assistance throughout the project.

The Committee expresses its admiration for and gratitude to its dedicated, hard-working staff, ably led by Dr. Michele Orza—particulary Kimberly Scott and Angela Mensah who saw this book through to completion. Thanks also to the many IOM staff not listed in the following pages including Bronwyn Schrecker, Janice Mehler, Lara Andersen, Allison Brantley, Elizabeth Sharp, Bethany Hardy, and Tyjen Tsai. Special thanks to Hellen Gelband for assistance in drafting background chapters of the report and to Rona Briere and Alisa Decatur for editorial assistance.

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Contents

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Tables, Figures, and Boxes

TABLES

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

FIGURES

BOXES

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

PEPFAR Implementation: Progress and Promise
http://books.nap.edu/catalog/11905.html

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at http://www.nap.edu