# Making HIV Prevention Paramount in the Next Phase of the U.S. Global HIV/AIDS Response

A Report of the CSIS Task Force on HIV/AIDS Center for Strategic and International Studies

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## Making HIV Prevention Paramount in the Next Phase of the U.S. Global HIV/AIDS Response

Jennifer Kates, Phillip Nieburg, and J. Stephen Morrison

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.... 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.—The Institute of Medicine<sup>1</sup>

### Introduction

The creation of the President's Emergency Plan for AIDS Relief (PEPFAR) in 2003 marked a historic moment in the U.S. and global response to the HIV epidemic. PEPFAR, announced by the president and authorized by Congress in the *United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003*, P.L. 108-25 (The Leadership Act),² was critical to driving forward an emerging global consensus on the ethical imperative to scale up antiretroviral treatment (ART) and to bolstering confidence that mass treatment could be achieved in even the most resource-poor settings. By most accounts, treatment scale-up is seen as one of U.S. global HIV/AIDS efforts' signature achievements.

<sup>1.</sup> Institute of Medicine (IOM), *PEPFAR Implementation: Progress and Promise* (Washington, D.C.: National Academies Press, 2007), p. ix.

<sup>2.</sup> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, P.L. 108-25 (The Leadership Act), passed by 108th Congress (1st Session).

This same high-level priority has not been applied to HIV prevention, and the continued spread of HIV now threatens the longer-term sustainability of the global effort to combat HIV/AIDS by the United States and others. Indeed, this is a consistent warning contained within recent reports by the Institute of Medicine (IOM), the U.S. Government Accountability Office (GAO), the Global HIV Prevention Working Group (PWG), and the Joint United Nations Programme on HIV/AIDS (UNAIDS).<sup>3</sup> (See Box 1.)

As the U.S. Congress considers the reauthorization of the Leadership Act, important discussions about the role of prevention in the overall global HIV/AIDS response are already taking place. It appears that some of the earlier, more ideologically driven, debates about prevention could be giving way to a newer consensus on the urgent need greatly scale up and sustain prevention efforts. In this context, and as a global leader in the response to HIV/AIDS, the United States is well-positioned to help elevate HIV prevention to a new and higher level, both politically and operationally. Importantly, a new emphasis on prevention should not be at the expense of treatment but, rather, build on its success.

This paper: (1) describes the scope of HIV-prevention activities undertaken through PEPFAR; (2) outlines the main challenges to invigorating the HIV-prevention response in the U.S. global HIV/AIDS effort's next five-year phase (2009–2013); and (3) presents several options that could be considered by the Congress and the Office of the Global AIDS Coordinator (OGAC) in the context of reauthorization and implementation of the Leadership Act. These options are informed by recent reports on HIV prevention and the U.S. global HIV/AIDS response, by the experience of PEPFAR to date, and through discussions with congressional and administration staff convened by the CSIS Task Force on HIV/AIDS.

### **PEPFAR and HIV Prevention to Date**

Globally, an estimated 4.3 million people were newly infected with HIV in 2006; for every patient who began antiretroviral therapy in 2006, six other individuals were newly infected. Recent data from the World Health Organization (WHO) and UNAIDS indicate that most people at risk do not have access to effective HIV-prevention services. This situation is largely due to the fact that evidence-based HIV-prevention programs have not been brought to global scale, meaning they have not yet achieved sufficient coverage, intensity, and duration to turn the tide of the HIV epidemic. A new report from the Global HIV Prevention Working Group warns that without significantly scaled-up prevention, an ad-

<sup>3.</sup> General Accountability Office, "Spending Requirement Presents Challenges for Allocating Prevention Funding under the President's Emergency Plan for AIDS Relief," GAO Report #GAO-06-395, Washington D.C., April 2006, www.gao.gov/docdblite/summary.php?rptno=GAO-06-395&accno=A50798; UNAIDS, *Intensifying HIV Prevention: A UNAIDS Policy Position Paper* (Geneva: UNAIDS, August 2005), http://data. unaids.org/publications/irc-pub06/jc1165-intensif\_hiv-newstyle\_en.pdf; and PWG, "Bringing HIV Prevention to Scale: An Urgent Global Priority," June 2007, http://www.globalhivprevention.org/pdfs/PWG-HIV\_prevention\_report\_FINAL.pdf.

<sup>4.</sup> WHO, UNAIDS, and UNICEF, *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector: Progress Report, April 2007* (Geneva: WHO, April 2007), http://www.who.int/entity/hiv/mediacentre/universal\_access\_progress\_report\_en.pdf; and UNAIDS, *AIDS Epidemic Update: Special Report on HIV/AIDS* (Geneva: UNAIDS, December 2006), http://www.unaids.org/en/HIV\_data/epi2006/default.asp.

<sup>5.</sup> WHO, UNAIDS, and UNICEF, Towards Universal Access.

### **Box 1. Recent Reports on HIV Prevention**

General Accountability Office, "Spending Requirement Presents Challenges for Allocating Prevention Funding under the President's Emergency Plan for AIDS Relief (GAO 2006).<sup>1</sup> This report on PEPFAR's HIV-prevention activities noted that prevention-program funding had remained within the legislated limits of 20 percent of overall PEPFAR funding, but that many PEPFAR country teams had found the A-B-C guidance to be difficult to interpret and implement. More specifically, GAO noted that the congressionally mandated abstinence-until-marriage spending requirement had presented programmatic challenges to at least some PEPFAR country teams, in terms of the integration and comprehensiveness of HIV-prevention programs. In more than one situation, funding intended for other PEPFAR-supported HIV-prevention programs actually had to be cut, even though sufficient funds were available, in order to meet the specific abstinence-until-marriage spending requirement. GAO called for additional flexibilities to be built into program guidance to allow OGAC and country programs to respond more appropriately to the need for program integration and to the specific circumstances within each country.<sup>2</sup>

Institute of Medicine, Preventing HIV Infection among Injecting Drug Users in High Risk Countries (IOM 2006).3 This well-documented and detailed report made a strong case for the need to greatly enhance efforts to prevent HIV infection among injecting drug users (IDUs) as fundamental to addressing the ongoing global spread of HIV. In addition to its strong support for the value of substitution therapy with opioid agonists (e.g., methadone) and antagonists (e.g., naltrexone), the IOM report documented consistent evidence of the effectiveness of needle and syringe exchange programs in reducing HIV risk associated with sharing of injection equipment among uninfected IDUs. The report called for implementation of such exchange programs "where feasible" as another important aspect of a comprehensive strategy to reduce HIV risk from sharing of equipment among injection drug users.

Institute of Medicine, PEPFAR Implementation: Progress and Promise (IOM 2007).4 In its 2007 interim evaluation of PEPFAR, mandated under the Leadership Act, the IOM found that, while PEPFAR had supported expansion of HIV/AIDS prevention, care, and treatment services in focus countries, a much greater emphasis on prevention activities is required, including the need for better linkages within individual focus countries between country program planning processes, acquisition and use of timely national data (including the respective prevalence of HIV infection and of risk behaviors), and the occurrence of other sexually transmitted infections. IOM further called on PEPFAR to provide attention to structural issues that are responsible in part for the greater vulnerability of women and girls to HIV infection; better linkage of PEPFAR's HIV-prevention planning process to national planning processes in focus countries; removal of explicit funding earmarks; more comprehensive integration of prevention, treatment, and care policies and programs; development of explicit prevention strategies and guidance for HIV-infected people under care in PEPFAR-supported care and treatment programs;<sup>5</sup> greater support

<sup>1.</sup> General Accountability Office (GAO), "Spending Requirement Presents Challenges for Allocating Prevention Funding under the President's Emergency Plan for AIDS Relief," GAO Report #GAO-06-395, Washington D.C., April 2006, www.gao.gov/docdblite/summary.php?rptno=GAO-06-395&accno=A50798.

<sup>2.</sup> This issue of local HIV/AIDS circumstances is of particular concern in countries such as Vietnam where the bulk of infections continues to occur through means other than heterosexual sex. See J. Stephen Morrison and Phillip Nieburg, HIV/AIDS in Vietnam (Washington, D.C.: CSIS, June 2006). http://www.csis.org/media/csis/ pubs/hiv\_in\_vietnam\_(5-8-06).pdf

<sup>3.</sup> Institute of Medicine (IOM), Preventing HIV Infection among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence (Washington, D.C.: National Academies Press, 2006).

<sup>4.</sup> IOM, PEPFAR Implementation: Progress and Promise (Washington, D.C.: National Academies Press, 2007).

<sup>5.</sup> The Prevention Rapporteurs' summary of prevention issues at the 2007 Implementer's meeting (cosponsored by OGAC and other organizations) highlighted a report that very few care and treatment programs even mentioned HIV prevention and that those that did only described prevention services associated with PMTCT

### **Box 1. Recent Reports on HIV Prevention** (continued)

for high quality behavioral surveys and surveillance among all risk groups in all focus countries; and greater attention to and use of prevention program outcome evaluations and operations research.

UNAIDS, *Intensifying HIV Prevention* (UNAIDS 2005). In 2005, UNAIDS released the first of a series of new policy documents on the urgent need to intensify HIV-prevention efforts globally; subsequent reports in 2006 and 2007 provided an action plan and technical guidance for the global community in moving forward on this front. As part of this series, UNAIDS developed "Principles of Effective Prevention," which include support for programs that are (1) differentiated and adapted to local epidemiologic, economic, and social contexts; (2) evidence based; (3) encouraging and enabling of true community participation; (4) comprehensive in scope, using as many interventions known to be effective as possible; (5) focused on long term sustainability; (6) attentive to gender and other rights issues; and (7) designed and implemented with intensity, scale, and high coverage in mind.

Global HIV Prevention Working Group, "Bringing HIV Prevention to Scale: An Urgent Global Priority" (PWG 2007). This recent report of the PWG found HIV prevention globally to be largely a series of missed opportunities, raising concerns about the sustainability of AIDS treatment programs. The report discussed the numerous obstacles impeding scale-up of HIV prevention (e.g., insufficient and misallocated funding resources, inadequate human resource capacity, service fragmentation, and stigma and discrimination against the most vulnerable groups) and made specific recommendations for addressing each obstacle. The report also called for dramatic increases in access to *all* effective HIV-prevention interventions in order to allow millions more people to avoid HIV infection. Finally, specific recommendations to improve access to HIV prevention were provided for stakeholders at various levels (national government staff, technical agency staff, individual health care providers, civil society members, researchers, etc.).

2007 HIV/AIDS Implementers' Meeting (June 2007).8 An important opportunity to learn from field experience with HIV prevention occurred this past June at the 2007 HIV/AIDS Implementers Meeting in Rwanda. The meeting, cosponsored by PEPFAR; the Global Fund to Fight AIDS, Tuberculosis, and Malaria; UNAIDS; the World Bank; UNICEF; WHO; and the government of Rwanda, brought together 1,500 field implementers to discuss their program experience (it built on prior-year meetings convened by PEPFAR for its programs, expanding the involvement to other organizations). The Implementers' meeting provided a unique and innovative channel for sharing emerging and cutting-edge ground-level realities, including identification of prevention gaps and challenges, many of which echo those presented in recent reports. For example, implementers talked about the challenge and necessity of addressing the structural and human rights factors that increase HIV risk and vulnerability; the fragmentation of interventions that led to missed opportunities to interrupt transmission; the lack of sufficient resources in the HIV-prevention area; and the challenge of identifying recent infections.

 $interventions. See \ http://www.hivimplementers.com/pdf/rapporteur/2007-07-02\%20 Final\%20 Presentation\%20 for \ r\%20 Prevention\%20 Rapporteur\%20 FORM.pdf.$ 

<sup>6.</sup> UNAIDS, Intensifying HIV Prevention: A UNAIDS Policy Position Paper (Geneva: UNAIDS, 2005); UNAIDS, Prioritizing HIV Prevention: Guidelines for Intensifying HIV Prevention (Geneva: UNAIDS, 2006); UNAIDS, Practical Guidelines for Intensifying HIV Prevention: Towards Universal Access (Geneva: UNAIDS, 2007).

<sup>7.</sup> Global HIV Prevention Working Group (PWG), "Bringing HIV Prevention to Scale: An Urgent Global Priority," June 2007, http://www.globalhivprevention.org/pdfs/PWG-HIV\_prevention\_report\_FINAL.pdf.

<sup>8.</sup> HIV/AIDS Implementers' Meeting, Kigali, Rwanda, June 16–19, 2007, http://www.hivimplementers.com/.

ditional 60 million people could become infected with HIV by 2015, two-thirds more than would occur otherwise. Most new infections—almost 39 million or 63 percent—are predicted to occur in sub-Saharan Africa, the region of the world already hardest hit by the epidemic and where the United States has concentrated most of its PEPFAR response and resources (12 of PEPFAR's 15 "focus countries" are in sub-Saharan Africa). If prevention efforts in countries in sub-Saharan Africa were to reach a true national scale, half of the new HIV infections in that region could be averted.

Within PEPFAR, prevention has been officially defined through both legislative language and operational guidance and policy.

### **Legislative Language**

The Leadership Act, P.L. 108-25, enumerates the types of prevention activities that can be supported with U.S. government assistance in Section 301 (see Box 2). Most policy attention to prevention under PEPFAR has been concentrated in the authorizing legislation's explicit funding earmarks for HIV prevention, relative to AIDS care and treatment, and within prevention itself, as specified in Section 402 of P.L. 108-25. The authorizing legislation spells out that, of the amounts appropriated for PEPFAR, 55 percent should be allocated for treatment, 15 percent for care, 20 percent for prevention, and 10 percent for orphans and vulnerable children. Within the 20 percent earmark for prevention, "at least 33 percent should be expended for abstinence until marriage programs." These earmarks were provided as a Sense of Congress for FY 2004–2005. For FY 2006–2008, a subset of these earmarks is mandated under the law—the 55 percent treatment earmark, the 10 percent orphans and vulnerable children earmark, and, of whatever amounts are appropriated for prevention, the 33 percent "abstinence-until-marriage programs" earmark.

### **Policy and Implementation Guidance**

In addition to the legislative language that defines the overall framework for prevention, the White House issued an ambitious prevention goal: to prevent 7 million HIV infections by 2010. Thereafter, OGAC developed a five-year PEPFAR implementation strategy that included prevention activities. Based on technical support from its Interagency Technical Working Groups, OGAC has provided additional policy requirements and direction through guidance to U.S. country teams as they develop their operational plans. OGAC has also provided a number of topic-specific policy guidance documents for the field,<sup>7,8</sup> such as its guidance on the "ABC" approach (Abstinence, Be Faithful, and Correct and Consistent Condom Use.) As part of its strategy and guidance to the field, OGAC has interpreted the "abstinence-until-marriage" earmark to include both abstinence ("A") and faithfulness ("B") programs and hence specified to U.S. country teams that they should dedicate at least 50 percent of total prevention funds to sexual transmission, and within funds for sexual transmission, at least 66 percent to A and B activities (the 66 percent of 50 percent = 33 percent of all prevention funds, as required by law). U.S. country teams

<sup>6.</sup> PWG, "Bringing HIV Prevention to Scale."

<sup>7. &</sup>quot;The President's Emergency Plan for AIDS Relief: Guidance," http://www.pepfar.gov/guidance/.

<sup>8.</sup> Most OGAC guidance documents issued to date address issues of people already infected with HIV; fewer address HIV-prevention issues. For example, no current guidance document addresses preventionprogram planning issues for men who have sex with men (MSM).

### Box 2. P.L. 108-25 Section 301

### "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, reducing sexual violence and coercion, including child marriage, widow inheritance, and polygamy, and where appropriate, use of condoms;
- (B) assistance to establish and implement culturally appropriate HIV/AIDS education and prevention programs that focus on helping individuals avoid infection of HIV/AIDS, implemented through nongovernmental organizations, including faith-based and community-based organizations, particularly those 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);
- (E) assistance for the purpose of preventing mother-to-child transmission of HIV, including medications to prevent such transmission and access to infant formula and other alternatives for infant feeding;
- (F) assistance to ensure a safe blood supply and sterile medical equipment;
- (G) assistance to help avoid substance abuse and intravenous drug use that can lead to HIV infection; and
- (H) assistance for the purpose of increasing women's access to employment opportunities, income, productive resources, and microfinance programs, where appropriate."

### "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."

that are not able to meet these minimum criteria must show that the requirement is not epidemiologically appropriate in their country (e.g., because of a predominance of IDUdriven HIV transmission) or provide another acceptable justification to OGAC (e.g., that another organization is already committed to investing heavily in abstinence education in their country) to allow the requirement to be waived.

OGAC has also identified a set of HIV-prevention indicators that must be used by countries in reporting on their activities and that are intended to help monitor progress toward attaining PEPFAR's goals. These indicators form the basis of PEPFAR's monitoring and evaluation (M&E) system and determine, to a large extent, how PEPFAR-supported prevention programs are designed and resources allocated within individual countries. An earlier analysis of these indicators by the CSIS Task Force on HIV/AIDS found that the majority are designed to track program inputs, processes, and outputs and do not track national-level prevention outcomes and impacts. This pattern is consistent with some other HIV-focused international M&E efforts.

Overall progress on prevention, as well as other aspects of the U.S. global HIV/AIDS response, is detailed in annual reports to Congress. In its most recent annual report, 10 the main measures of progress toward the goal of preventing 7 million new infections were listed as follows:

- Supported community outreach activities to nearly 61.5 million people to prevent sexual transmission.
- Supported prevention of mother-to-child HIV transmission services for women during more than 6 million pregnancies (cumulative for fiscal years 2004 through 2006).
- Supported antiretroviral prophylaxis for HIV-positive women during 533,700 pregnancies, averting an estimated 101,500 infant HIV infections (cumulative for fiscal years 2004 through 2006).
- Supported training or retraining of nearly 520,000 people in provision of prevention services.
- Supported approximately 4,863 service outlets for prevention of mother-to-child HIV transmission.
- Supported approximately 3,848 service outlets for blood safety.

The report also provides additional data on other prevention activities. However, no outcome or impact data, in terms of lower HIV prevalence/incidence or in terms of numbers of HIV infections actually prevented, have yet been made available.

### Status of Reauthorization

As of early October 2007, the precise timeline for congressional reauthorization of the Leadership Act remains unclear, although both the Bush administration and Congress

<sup>9.</sup> Jennifer Kates and Phillip Nieburg, Prevention Indicators for the President's Emergency Plan for AIDS Relief (Washington, D.C.: CSIS, May 2005). Subsequently, OGAC has indicated that progress toward the 7 million infections prevented would be assessed through statistical modeling; see, OGAC, The Power of Partnerships: The President's Emergency Plan for AIDS Relief: Third Annual Report to Congress (Washington, D.C.: OGAC, 2007).

<sup>10.</sup> OGAC, The Power of Partnerships.

have taken steps toward reauthorization, stating in part that it is important to signal to country recipients and international partners that the U.S. commitment to global HIV/AIDS efforts will continue into the future. In July of this year, the president called on Congress to reauthorize the Leadership Act at \$30 billion over five years (FY 2009–2013), double the legislation's current authorization level. That call included a 10-year prevention-program goal of preventing 12 million new infections. In Congress, public discussions and hearings on reauthorization have begun, and one bill has been introduced with others likely to follow. One of the issues being discussed is that of the prevention earmarks, including changing or relaxing them in some fashion to allow for more country flexibility; for example, some have proposed eliminating most of the earmarks except for the earmark for orphans and vulnerable children and, while not specifying a percentage that must be spent on prevention, specifying that of the amount spent on the sexual trans-

mission of HIV (versus nonsexual transmission such as prevention of mother-to-child

transmission or blood transfusion), 50 percent be spent on A and B activities.

## Challenges to Strengthening HIV Prevention under PEPFAR

Elevating HIV prevention to a strategic priority in the next phase of the U.S. global HIV/AIDS response necessarily involves numerous challenges. Some of these bedevil all global HIV-prevention efforts, while other challenges relate specifically to the U.S. response. Mapping these challenges is important for informing a future prevention response by the United States and others. Key challenges are identified below. In addition, a summary of the main prevention-related findings and concerns raised by several recent reports is given in Box 1.

- Political and policy gridlock. Given that HIV is primarily transmitted sexually, through injection drug use and from mothers to their children around delivery and lactation, efforts to prevent HIV necessarily are closely interlinked with socially, culturally, and politically sensitive issues. HIV-prevention activities for this reason are inherently vulnerable to becoming enmeshed in ideological debates that can impact implementation, imposing both real and perceived limits on what is and is not permitted under law and policy.
- Awareness of HIV infection status. Deciding what kinds of prevention messages should be provided to—or received by—specific individuals requires an awareness of HIV status on the part of both the individuals and the program implementers. Currently, although the numbers of people who have been recently tested for HIV and have received their results is slowly increasing in many countries, overall awareness levels globally remain extremely low, at approximately 11 percent, according to the most recent information. Increasing access to, and uptake of, HIV testing remains a persistent challenge. Recent WHO/UNAIDS recommendations for the implementation of provider-initiated testing and counseling (PITC) within health facilities<sup>11</sup> may help address this challenge, but it remains too early to know with any certainty.

<sup>11.</sup> WHO and UNAIDS, *Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities* (Geneva: WHO, May 2007), http://whqlibdoc.who.int/publications/2007/9789241595568\_eng.pdf.

- *Confronting the enduring power of HIV-related stigma.* Stigma and discrimination remain significant barriers to prevention efforts at the individual, community, national, and global levels. The presence of stigma has a multitude of effects, such as fear among those at risk and those living with HIV in seeking HIV testing and other needed prevention (and care) services; violence and exclusion of those who are or are thought to be HIV positive; unwillingness of policymakers to embrace HIV prevention; and reluctance to provide or expand access to HIV-prevention programs to marginalized and at-risk groups, including men who have sex with men (MSM), commercial sex workers (CSWs), and injection drug users (IDUs).
- *Addressing the structural dimensions of HIV risk.* Effective HIV-prevention efforts require addressing complex structural factors, such as gender inequality, economic class, literacy, cultural traditions, and weak legal protections (e.g., lack of protections for those who are HIV positive). In varying ways, each directly contributes to HIV risk and vulnerability.<sup>12</sup> Years of experience in addressing HIV have resulted in the identification of numerous structural interventions that could be used to modify social, economic, and political circumstances and thereby reduce HIV risk.<sup>13</sup> Yet such an embrace of "structural prevention" has not yet occurred, in part due to the fact that structural dimensions are by definition entrenched and longstanding. They predate the HIV epidemic, encompass much more than HIV, cannot be addressed solely through public health measures, and require a long-term, multifaceted and incremental approach. This will involve assessing to what extent existing HIV resources could be used for such efforts as well as reaching outside of the HIV area.

An important subset of these structural dimensions is linked to the particular vulnerabilities faced by women and girls and the inequity of program access faced by women and girls who might benefit from HIV-prevention programs. <sup>14</sup> While OGAC has recently taken a number of important steps on gender issues, including the adoption of specific gender-related strategies, the impact of these strategies or other gender-related HIV-prevention efforts has not yet been formally assessed. In addition, several reports have documented the need for better integration of HIV-prevention activities with—and into—reproductive health and family planning programs that represent the primary contact with the health system for many women and girls.

■ Answering the complex, long-term demands of behavior change. Unfortunately, HIV prevention does not lend itself to single "magic bullet" solutions. It rests instead on multiple behavioral and biomedical interventions that often must be implemented in concert with one another—"calibrated" to the specific needs and epidemic profiles of individuals and populations at risk. For example, even if a successful vaccine were to be developed, it would need to be delivered as part of a comprehensive HIV-

<sup>12.</sup> Esther Sumartojo et al., "Enriching the Mix: Incorporating Structural Factors into HIV Prevention," AIDS 14, supplement 1 (June 2000): Sl-S2.

<sup>13.</sup> Dan Wohlfeiler and Jonathan Ellen, "The Limits of Behavioral Interventions for HIV Prevention," in Prevention Is Primary: Strategies for Community Well-Being, ed. Larry Cohen et al. (San Francisco, Calif.: Jossey-Bass, 2007).

<sup>14.</sup> For a more detailed discussion of PEPFAR's gender-related HIV-prevention aspects, see Janet Fleischman, Priorities for Action: Gender and PEPFAR Reauthorization (Washington, D.C.: CSIS, September 2007).

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prevention program that also addresses risk behaviors.<sup>15</sup> Much like ART, effective HIV prevention needs to be seen as a life-long service, designed to reach individuals and key populations throughout their life cycles. HIV-prevention activities must be repeated, renewed, and updated systematically, as new knowledge emerges. For example, we now know far better than just a few years ago how having concurrent sexual partners can fuel the spread of HIV, particularly in sub-Saharan Africa. But shifting behavior away from concurrency is less well understood and is a complex and long-term enterprise.

- Building a cadre of skilled HIV-prevention experts. Successfully designing, implementing, and evaluating HIV-prevention programs requires the sustained input and involvement of a trained "prevention workforce," with diverse and comprehensive technical skills in multiple areas. To date, there has been a dearth of such skilled prevention experts among implementers and a lack of prevention-training curricula for use in official, nongovernmental, and public health educational settings, often constraining country-level efforts. Growing a new generation of seasoned prevention experts through greater investment in training and career advancement is greatly needed.
- Coordinating and integrating HIV prevention with other HIV services and more general health programs. Too often, HIV prevention is implemented as a stand-alone service, or one-off effort, losing the opportunity to coordinate and create synergies with AIDS care and treatment programs, other HIV-related services, and non-HIV services. Coordination and integration are fundamental, given the need to achieve economies of scale, to reach people at risk where they really are, to improve efforts to interrupt sexual networks that may be fueling HIV, and to better link those who are positive with the range of services they need. For example, concerted efforts to integrate HIV-prevention services efficiently into reproductive health and family planning programs, where many women receive their primary health care, have not yet been scaled up.
- Evaluating prevention methods and programs. Measuring and evaluating HIV-prevention efforts present unique challenges. These include the significant length of time required to demonstrate population-level impacts (in contrast, for example, to the much more immediate evidence of HIV treatment effects), the lack of easily available tools to identify and track the incidence of HIV infections, and the complexity of assessing behavior change.¹6 These challenges often lead to the reliance on proxy (e.g., process and output) measures, rather than outcomes and impacts to assess preven-

<sup>15.</sup> Margaret I. Johnston and Anthony S. Fauci, "An HIV Vaccine—Evolving Concepts," *New England Journal of Medicine* 356, no. 20 (May 2007): 2073–2081.

<sup>16.</sup> Judith D. Auerbach et al., "Overview of Effective and Promising Interventions to Prevent HIV Infection," in *Preventing HIV/AIDS in Young People: A Systematic Review of the Evidence from Developing Countries*, ed. David A. Ross et al. (Geneva: WHO, 2006); Seth M. Noar, "Behavioral Interventions to Reduce HIV-related Sexual Risk: Review and Synthesis of Meta-Analytic Evidence," *AIDS and Behavior* 11, no. 5 (September 2007); Audrey E. Pettifor et al., "Challenge of Evaluating a National HIV Prevention Programme: The Case of loveLife, South Africa," *Sexually Transmitted Infections* 83, supplement 1 (February 2007); Timothy B. Hallett et al., "Appropriate Evaluation of HIV Prevention Interventions: From Experiment to Full-scale Implementation," *Sexually Transmitted Infections* 83, supplement 1 (February 2007).

tion. More significantly, however, they have led to misplaced skepticism about the endeavor of HIV prevention itself.

### **Options for Congress and the Administration**

The reports summarized earlier in Box 1, combined with the experience of PEPFAR to date and discussions convened by the CSIS Task Force on HIV/AIDS with congressional and administration staff, suggest several options for elevating prevention during the next five-year phase of the U.S. global HIV/AIDS response. These include areas that could be addressed legislatively, through reauthorization itself, as well as administratively, through the use of policy, guidance, and other operational efforts. The following key options could be considered.

- Designating specific "focus" countries or "hot spots" for intensive HIV prevention. Part of the success of the U.S. effort thus far is attributable to its use of focus countries—countries where significant financial, human, technical, and other resources have been concentrated and in which country-level mobilization and improved coordination have been explicit goals, largely in the antiretroviral treatment arena. Indeed, this approach has helped to create models for the successful creation and scale-up of ART programs. But while the general concept of prevention has been explicitly included within the focus country mandate, it has yet to receive the intensity, focus, and coverage needed. One option that could be considered is the designation of certain countries (including existing focus countries), regions, or areas for an "HIV-prevention focus." This could be done by OGAC or via legislative language. Focusing on a high-prevalence region, such as southern Africa, for example, would offer certain strong advantages including targeting areas with very high HIV-transmission rates, putting a premium on coordinated action and high-level leadership among neighbors; tackling the issue of intra-regional migration; and leveraging support of subregional bodies such as the Southern Africa Development Community (SADC). Areas considered "emerging epidemics" could also become focus prevention hot spots. If such a focused approach were to be pursued, however, it would be important to address prevention needs in all countries, not just those designated for focus.
- *Investing in high-level "global HIV-prevention diplomacy.*" Providing visible leadership on HIV prevention could help to send a message to other leaders and to the field about the importance of HIV prevention, and it could provide a mechanism to encourage governments hosting U.S. programs to increase their attention to prevention. This could be achieved through the creation of an HIV prevention deputy or assistant director of prevention in the Office of Global AIDS Coordinator or the identification of a well-known current or recent member of the administration or Congress. While this could lead to an elevated presence and focus on HIV prevention globally, it would be important not to segment prevention from treatment or other HIV-related areas.
- Balancing accountability and flexibility at the country level. While all programs must balance the need for accountability with the need for flexibility, this balance has proven particularly delicate in the area of HIV prevention. The IOM, the GAO, and others have recommended providing greater flexibility at the country and program

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level (e.g., removal or relaxation of earmarks; clarifications on which interventions can and cannot be utilized) to allow country teams and implementing partners to tailor and quickly respond to their unique epidemiologic profiles and health system realities. Empowering country teams to devise integrated prevention strategies that are driven by ground-level realities, reliable local data, and proven, effective interventions, is critical in the next phase; such efforts will need to be tracked through systematic evaluation.

- Embracing "structural HIV prevention." In order to better address the structural aspects of HIV risk and vulnerability, there has been a greater move toward addressing "structural HIV prevention" interventions, both through U.S.-funded programs and through coordination with other U.S. government-funded efforts that are not HIV-specific (such as nutrition, reproductive health, and broader microfinance efforts), as well as with the programs of other international and national partners. Three of the many possible examples of structural interventions that could be explored include: (1) working with national and local governments to alleviate any legal and other barriers existing in the public sphere; (2) creating legal protections (or better enforcing existing protections) that can help reduce HIV risks; and (3) finding opportunities to bolster educational attainment more broadly. While limited HIV resources cannot address, let alone solve, many of the difficult structural issues facing those at risk, it is increasingly clear that without more attention to structural issues involved in the spread of HIV, the long-term success of HIV prevention (and also, the sustainability of HIV/AIDS care and treatment) is at risk.
- Defining a "minimum HIV-prevention service package." UNAIDS, OGAC, and others have identified the need to define a "minimum prevention package" or packages, and UNAIDS is currently in the process of developing recommendations for package content. U.S. country teams would benefit from technical guidance in this area, including guidance on how to reach specific populations at risk (e.g., women and girls and "most at-risk populations" [MARPs]), the level and duration of services needed, and the content of prevention packages in different epidemic settings. As part of a minimum prevention package, the critical importance of integrating HIV prevention and treatment, which has been identified in numerous reports but has yet to be firmly translated into practice, could be underscored. Defining a minimum prevention package in this way could help programs to augment more practically the intensity and coverage of their HIV-prevention services and to move beyond the tendency to view HIV prevention as a single, one-time intervention. It also would give practical and specific tools to implementers.
- Developing a robust HIV-prevention "workforce." A clear need has been identified for additional technical expertise in HIV prevention at the field level. Options for addressing this issue include: (1) providing additional, and ongoing, in-service prevention training for current U.S. government staff, implementing partners, and host country collaborators; (2) providing additional staff to OGAC with technical experience in designing, implementing, or evaluating various types or aspects of

<sup>17.</sup> Joshua A. Salomon et al., "Integrating HIV Prevention and Treatment: From Slogans to Impact," *PLoS Medicine* 2, issue 1 (January 2005).

<sup>18.</sup> PWG, "HIV Prevention in the Era of Expanded Treatment Access," June 2004, http://www.global-hivprevention.org/pdfs/Prevention%20in%20Era%20of%20Treatment.pdf.

HIV-prevention programs in the field; (3) providing additional staff with the requisite prevention expertise assigned to embassy teams.

■ *Defining success and measuring impact.* Key to defining success in HIV prevention generally, and for the U.S. global HIV/AIDS effort specifically, is the measurement of outcomes and impacts. This was an overall recommendation of the IOM in its assessment of PEPFAR and a need faced more broadly by global HIV-prevention efforts. Reauthorizing legislation could include the early planning and rapid implementation of one or more well-designed impact and outcome evaluations of U.S. HIV-prevention programs, by the IOM or another independent body. Having access to objective data on the effectiveness of specific aspects of U.S. government-supported prevention programs early in the next five-year cycle would allow informed decisions to be made about any need for further adjustments to prevention programs. In addition to an independent assessment, the U.S. effort would benefit from greater use of and support for operations research (applying public health science in the field, such as research to determine the acceptability of new interventions in local settings or to determine the most efficient and effective way to implement prevention programs using new technologies). This would not only provide more "real time" knowledge and direction for day to day activities, it would greatly enhance the entire global community's knowledge of what works in the field. As recently noted by researchers in this area, despite the repeated demonstration of the efficacy of behavioral interventions in research trials, much less work has been done to examine how best to translate them into real world situations and diverse settings (e.g., effectiveness).<sup>19</sup> Finally, one common challenge facing all prospective and evaluative assessments of HIV-prevention efforts is the lack of affordable and accessible tools for identifying recent (incident) HIV infections. Without such a tool, directly measuring changes in HIV rates, or understanding and intervening in sexual networks where HIV is present, is not possible. Promising efforts are underway by the United States and others to adapt the "BED capture enzyme immunoassay" technology for this purpose,<sup>20</sup> and the next phase of the U.S. global HIV/AIDS response could enhance its use and/or the use of any other methodologies that may emerge for the purpose of more directly measuring prevention-program impact.

### Conclusion

U.S. leadership on global HIV/AIDS since the creation of PEPFAR has demonstrated that life-sustaining antiretroviral treatment is possible on a mass scale, which has helped to mobilize others behind that historic conviction. In addition, it has had a tremendous impact on those living with HIV in many parts of the world. As the U.S. government considers the reauthorization of the Leadership Act, there is a unique opportunity to elevate

<sup>19.</sup> Noar, "Behavioral Interventions to Reduce HIV-related Sexual Risk."

<sup>20.</sup> Two recent examples of the use of this technique are: J. Steven McDougal et al., "Surveillance for HIV-1 Incidence Using Tests for Recent Infection in Resource-Constrained Countries," AIDS 19, supplement 2 (May 2005): S25-S30; and T. Rehle et al., "National HIV Incidence Measures—New Insights into the South African Epidemic," South African Medical Journal 97, no. 3 (March 2007): 194-199. The latter report documented a 5.2 percent HIV incidence (infection rate/year) among pregnant women.

a focus on HIV prevention, building on lessons learned by the United States and others, particularly during the last five-year period, when resources have been greatly increased overall. An invigorated prevention approach, involving a new focus on what prevention efforts will truly require to reverse the tide of the HIV/AIDS pandemic, is essential to making prevention paramount as all look forward.

### The CSIS Task Force on HIV/AIDS

The CSIS HIV/AIDS Task Force seeks to build bipartisan consensus on critical U.S. policy initiatives and to emphasize to senior U.S. policymakers, opinion leaders, and the corporate sector the centrality of U.S. leadership in strengthening country-level capacities to enhance prevention, care, and treatment of HIV/AIDS. J. Stephen Morrison, director of the CSIS Africa Program, manages the overall project, in cooperation with the CSIS Freeman Chair in China Studies, the CSIS Russia/Eurasia Program, and the CSIS South Asia Program.

The honorary cochairs of the task force are Senator Russell Feingold and Senator John E. Sununu. William H. Frist, former majority leader of the U.S. Senate, remains an active partner of the task force. The CSIS Task Force on HIV/AIDS is funded principally by the Bill and Melinda Gates Foundation, with project support and input from the Henry J. Kaiser Family Foundation, the David and Lucile Packard Foundation, and Merck & Co. The task force outlines strategic choices that lie ahead for the United States in fighting the global HIV/AIDS pandemic and comprises a core network of experts drawn from Congress, the administration, the public health arena, the corporate sector, activists, and other concerned groups. This panel helps to shape the direction and scope of the task force and disseminate findings to a broader U.S. audience.

Now in its seventh year, the task force's principal focus is on two critical issues: first, raising the profile and improving the effectiveness of U.S. support to global prevention efforts and facilitating a bipartisan discussion of global HIV prevention policy; and, second, examining how U.S. leadership can facilitate the sustainability of HIV/AIDS programs, both in terms of resource flows and in terms of situating HIV/AIDS responses within a broader strategy to address gaps in gender equity, health infrastructure, human capacity, and international collaboration on global health. The task force continues to engage on the emerging dynamics of the epidemic in Russia, China, and India with recent delegation visits in mid-2007.