

Prevention of New HIV Infections: Priorities for U.S. Action

A Report of the CSIS Global Health Policy Center
HIV Prevention Working Group

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Background

Building on its work of the last several years, the CSIS HIV Prevention Working Group organized in the summer of 2009 a consultation on “Revisiting U.S. Approaches to HIV Prevention”. The discussion brought together more than twenty HIV prevention experts to review the concrete priority steps the U.S. could take to enhance the effectiveness of HIV prevention programs during the next five years of the President’s Emergency Plan for AIDS Relief (PEPFAR). Participants were drawn from academia, research institutions, foundations, civil society, government and service delivery organizations. Each brought to the table significant professional expertise, operational experience and personal commitment. We are grateful to them for their valuable contributions. A list of participants is attached¹.

Executive Summary

Why a New Look at HIV Prevention Now?

In 2008, Congress reauthorized PEPFAR for Fiscal Years 2009-2013. In the first half of 2009, the Obama Administration entered office and Dr. Eric Goosby began work as the new U.S. Global AIDS Coordinator. A new openness regarding some of the more difficult HIV prevention related issues emerged within U.S. policy circles. Language within the reauthorization legislation as well as the repeal of the Mexico City provisions helped create greater latitude to introduce policies and programs that could increase the effectiveness of critical prevention interventions.

On December 1, 2009, World AIDS Day, Dr. Goosby unveiled a new five-year strategy for PEPFAR, aimed at shifting focus from an emergency response to building sustainable country programs worldwide. The strategy includes a FY2010 – FY2014 target of preventing more than 12 million new HIV infections. This report reinforces some of the key elements of PEPFAR’s five-year prevention strategy and also flags key challenges.

These developments provide an opportunity for re-energized U.S. leadership on HIV prevention, which is all the more critical as new HIV infections in developing countries continue to outpace the number of people beginning anti-retroviral therapy. A November 2008 report by the U.S. National Intelligence Council estimated that if prevention efforts remain at current levels of effectiveness, the HIV-infected population could climb to 50 million by 2025, with 25 - 30 million persons requiring anti-retroviral therapy. However, if currently available prevention interventions were to be more fully scaled-up by 2015, the number of persons who are HIV-infected might level off at 25 million by 2025 with 15 - 20 million people requiring anti-retroviral therapy². Unquestionably, prevention of HIV transmission remains fundamental to changing the arc of the HIV epidemic, and needs to be fully elevated to a strategic policy priority.

1 The opinions expressed herein solely reflect those of the authors, not necessarily those of the working group participants.

2 NIC, “Global Trends 2025: A Transformed World,” November 2008, p. 23

It was in this context that the CSIS HIV Prevention Working Group brought experts together to develop concrete, actionable proposals to help guide a reinvigorated U.S. approach to HIV prevention. The discussion was held under Chatham House rules: participation was on a not-for-attribution basis. This summary captures key issues from the day's discussion that are relevant to policymakers in both the Administration and the Congress as they chart PEPFAR's future course.

Among the most important recommendations to emerge from the group's deliberations:

- 1. Capitalize on PEPFAR's leadership opportunities:** PEPFAR has made a profound difference in the lives of many but it has not yet achieved its full potential as a vehicle for accelerating global action on HIV prevention. The White House, Department of State, and the Office of the Global AIDS Coordinator (OGAC) should step up to this leadership challenge, working to build a national and global consensus on the critical importance of preventing HIV transmission and cultivating greater political leadership in PEPFAR countries. Voices from the White House, State Department, and OGAC carry considerable weight in setting a more ambitious prevention agenda and putting more focused pressure upon political leadership in PEPFAR partner countries.
- 2. Leverage future U.S. commitments:** PEPFAR's Partnership Frameworks offer a significant opportunity for ensuring that PEPFAR and its partner governments have common prevention goals and a mutually agreed upon plan for achieving key targets and sustaining success. Frameworks should detail expectations for national leadership commitments on HIV prevention and highlight critical areas for action, including partner government reform of structural barriers which have often made HIV programs inaccessible to men who have sex with men, injecting drug users, and commercial sex workers. To be meaningful, the Frameworks need to have strong incentives for adherence and be actively backed by OGAC, the State Department, and the White House. Since aggressive, forward-looking leadership by national governments on prevention will likely be the single most important determinant in a successful long-term HIV response, future U.S. support should be clearly conditioned on such leadership.
- 3. Link resources to need and support programs that have been proven to work:** Prevention programs need to be better targeted to those countries, regions and population groups where the risk of HIV transmission is greatest. This effort to "know your epidemic" will require better understanding of local transmission patterns, setting local targets, developing surveillance tools to track transmission trends, and enhancing staff technical capacity to collect and interpret data both in partner countries and within PEPFAR. A reorientation of existing budgets around these priorities should be mandated for future programs.
- 4. Take on the tough research challenges and help build and share knowledge:** PEPFAR-supported programs should help build and share knowledge on key operational and scientific challenges. The group focused on the fact that HIV prevention programs still lack a strong evidence base. PEPFAR should support the research and development of models that are effective in different populations and countries, as well as capacity building and on-going technical assistance directly relevant to local challenges. A global system needs to be created for rapidly identifying, validating and sharing experience gained from program efforts and ensuring that emerging findings from research are disseminated, adapted and implemented as effectively and quickly as possible.

PEPFAR 2003 - 2008 – The Prevention Experience in Three Countries

The group focused its initial discussion on lessons learned from the PEPFAR experience in South Africa, Vietnam and Kenya. This focus highlighted the diversity of the epidemic, the real life challenges of HIV prevention programming, and key lessons learned over the last five years. Common themes, both positive and negative, emerged across these three experiences. Most significantly, it became clear that combinations of prevention programs - when carefully formulated, well-targeted and adequately monitored - can have a significant impact in changing behavior and reducing HIV transmission. Each of the three countries experienced some level of prevention “success,” even if those successes were limited in scope.

Several significant weaknesses also emerged. For many interventions, limited data on efficacy (i.e. effectiveness) and financial constraints have impeded measurement of cost-effectiveness. Prevention programs have sometimes been poorly designed and delivered, while approaches to measure the adequacy of scale, coverage and quality, as well as outcomes and impacts, have been inadequate.

The most fundamental constraint has been the lack of investment in research and evaluation aimed at accurately measuring whether prevention programs are having their desired effect in reducing HIV transmission. The difficulty of capturing changes in HIV incidence (i.e. new infections) in resource-poor settings has impeded both the ability to know what specific interventions are most effective and the overall population-level impact of HIV prevention programs. Without clear evidence of impact, it is difficult to make a credible case to policymakers and the broader public that HIV prevention programs are truly effective in containing the HIV pandemic. PEPFAR could make an enormous contribution in this area and should continue to develop the scientific expertise to evaluate prevention interventions.

Along with existing programmatic weaknesses that have impeded progress in HIV prevention, the group’s discussion revealed several formidable challenges to PEPFAR implementation that are likely to remain over the next five years.

- Extending current PEPFAR gains, particularly in the area of ARV therapy, will be difficult in most focus countries. The current budget crisis in the United States, accompanied by the inability of many host governments to step up their financial and human resources, could slow progress in areas where there have been rapid gains. Making decisions about future ART access will be especially challenging for PEPFAR host countries as need far surpasses currently available resources.
- Mobilizing communities in a strong and sustained way so they become cornerstones of the prevention response will continue to be difficult, but essential.
- Currently, more than 80% of HIV-infected persons in sub-Saharan Africa are unaware of their HIV infection and over 90% of discordant couples are unaware of their discordance. Without greatly expanded efforts to increase their knowledge of personal status and knowledge of partner status, HIV prevention efforts will never be successful. New approaches, including provider-initiated testing, community and home-based testing, and partner testing integration, are urgently needed and should be implemented broadly.
- Noncompliant partner governments pose a central problem to HIV prevention. Failures of political leadership, denial, stigma, criminalization of high-risk behaviors, and laws that run counter to human rights principles undermine HIV prevention regardless of how many resources are brought to bear.

Special efforts must be made to ensure that the most marginalized and high-risk populations – men who have sex with men, injecting drug users, and commercial sex workers – are able to safely access services.

- As noted above, the absence of reliable and cost-effective methods for capturing HIV incidence (i.e., new infections) in low-resource countries often results in an inability to measure the true impact of prevention programs. PEPFAR should actively draw on the expertise of the Centers for Disease Control and Prevention (CDC) and others to expand this aspect of USG operations research capacities. Consideration should be given to initiating a global consortium to better develop measures of HIV incidence.

A Way Forward – Priority Principles and Actions for PEPFAR’s Next Five Years

The group sought to develop core, actionable recommendations in part drawn from PEPFAR’s experience in Kenya, Vietnam and South Africa, but also informed by the participants’ broader collective knowledge. During the discussion, a number of key principles emerged that the group felt should guide prevention policies under PEPFAR II. Many of these principles have been a part of the standard prevention approach of recent years, but are not consistently applied. For that reason, they merit a special focus.

Key principles

Use data to drive programs – While the phrase “know your epidemic” has become a part of the HIV/AIDS lexicon, it has been practiced too rarely and without sufficient attention to the analytical and implementation requirements that determine success. In many individual countries, neither PEPFAR nor host country governments have yet invested sufficient energy and resources to truly understand the specific dynamics of HIV transmission. With expanded HIV testing and ART use, a country’s ability to “know its epidemic” will require new surveillance approaches that include self-reporting of HIV status, CD-4 testing, and additional resources for accurate surveillance. The group felt strongly that PEPFAR prevention resources need to be focused with sufficient intensity on the key drivers of the epidemic and where they can make the biggest difference.

Recognize that there is no single, effective approach – Since human behavior varies greatly, so too must prevention programs. In practical terms, this means that within a single PEPFAR-supported country program, it may be necessary to implement more than one effective program approach, which will pose multiple implementation challenges.

Measure outcomes – Urgent priority needs to be given to investing in prevention efficacy and cost-effectiveness research, together with the eventual development of accurate incidence measurements.

Design for synergy – There is widespread agreement about unrealized complementarities between - and service integration opportunities for -HIV/AIDS programs and other health interventions, particularly in the areas of tuberculosis and malaria control, reproductive health and family planning. A more focused effort to develop these linkages should become a hallmark of PEPFAR planning and implementation.

Learn from and share HIV prevention experiences – There is already a wealth of information to be derived from PEPFAR’s first five years about what works and what does not. More importantly, with the substantial funding allocated, PEPFAR has a real opportunity to incubate innovation and help drive an

operational research agenda that could contribute significantly to the HIV prevention field.

Plan long term. Act short term. Focus locally – HIV/AIDS remains a long-term global challenge, so the U.S. government must evolve a long-term global HIV/AIDS strategy, well beyond the current five year horizon. However, this longer-term perspective must be directly linked to short-term, concrete prevention goals – each of which must be made relevant to individual, local contexts.

Specific Recommendations

First and foremost, the U.S. has an unparalleled opportunity to forge a new global coalition that elevates prevention to a true priority status and is tied to new commitments and concrete goals. It should seize this moment. Accelerated action on the measures described below could have a catalytic effect in significantly advancing prevention as a global priority.

1. Capitalize on PEPFAR's leadership opportunity:

- Make a clear and early statement that prevention of HIV transmission is a core PEPFAR issue. Acknowledge the central complementarity of prevention and treatment programs and examine the potential that new approaches (i.e. male circumcision) may have for accelerating prevention progress. Continued research is also needed on the potential application of future interventions, such as pre-exposure prophylaxis.
- Engage the Global Fund to Fight AIDS, Tuberculosis, and Malaria; World Health Organization; UNAIDS and other major funders (e.g., DFID, European Commission) and technical agencies to build a greater global consensus on prevention as a priority.
- Support a global stock-taking on HIV prevention progress as part of the preparations for the 2010 UNGASS Universal Access Summit.

2. Leverage U.S. commitments:

- Since aggressive, forward-looking action by national governments on prevention will likely be the single most important determinant in a successful long-term HIV response, future U.S. support should be clearly conditioned on effective performance in preventing new HIV infections. In particular, partner governments must ensure that high-risk, marginalized populations – such as men who have sex with men, injecting drug users, and commercial sex workers – have full access to necessary, safe services. Starting now, PEPFAR should develop options for ensuring that its Partnership Frameworks include accountability provisions and enforcement mechanisms that can help ensure that all parties live up to their mutual responsibilities.
- Use PEPFAR's Partnership Frameworks as vehicles for building “sustainability strategies” with partner governments, securing the role of civil society in the national response and developing a longer-term plan for bringing prevention programs to scale. Sustainability will require robust political support in addition to long-term financial inputs. In some countries this has been aided by the creation of high-level prevention advisory boards that maintain momentum on prevention

activities. As an initial step, PEPFAR could pilot the development of a meaningful sustainability strategy in several countries by FY2011.

3. Link resources to need and support programs proven to work:

- Revisit U.S. HIV prevention priorities. Conduct an HIV prevention “audit” for all PEPFAR priority countries, matching prevention funding and known data about the efficacy of prevention programs to data about local transmission and risk factor patterns. Direct resources to where U.S. programs can have the biggest impact, both within national boundaries and regionally.
- Focus on selected populations and regions where transmission is the greatest and emphasize “prevention for positives”, i.e., prevention of HIV transmission from known infected people (e.g., within HIV-discordant couples), as well as prevention of HIV acquisition by those still uninfected. PEPFAR’s work in Kenya to reorient all prevention programs around a set of defined universal access prevention targets is an example of an effective process that could be replicated elsewhere.
- Recognize the epidemiologic and social complexity of the environment and pursue combination prevention composed of evidence-based strategies at the scale and depth required for success. Understand that this change will require a multitude of approaches and varied technical capacities both within PEPFAR and with partner governments and institutions, e.g., careful outcome evaluation of the effectiveness of various approaches.
- Focus on interventions with the proven potential to have major short-term impacts on mortality and morbidity (e.g., scaling up and improving quality of PMTCT programs, and increasing access to contraceptive commodities). Invest in supporting more effective programs for high-risk, deeply stigmatized groups such as men who have sex with men and injecting drug users. Pursue approaches that tackle structural barriers, such as legal and human rights-related issues.
- Actively build synergies across HIV prevention programs, between HIV prevention and AIDS care and treatment programs and between HIV and programs that address tuberculosis, family planning, malaria, and maternal and child health. Mandate that these “country integration strategies” be required as part of the FY 2011 country operational plan and funding cycles.
- Make programs work better for women. In sub-Saharan Africa, women account for nearly 60% of all HIV infections and their numbers continue to grow.³ Begin addressing these and other gender imbalances with a major push to use PEPFAR platforms to provide access to safe, accessible and voluntary family planning services for HIV positive women. Structural factors that increase women’s and girls’ risk of infection should also be addressed.
- Develop a culture of harmonized measurement. Set clear targets by geographic region/risk group. Move toward harmonization of PEPFAR’s data collection and monitoring methods with those of other donors and implementers, and ensure that this process occurs within the context of one national monitoring and evaluation system. Ensure that impact evaluations are conducted and capture both impacts and adequacy of implementation. Collect costing data so cost-effectiveness can be determined.

3 UNAIDS, “2008 Report on the Global AIDS Epidemic,” p.36.

- Given the complex environment in which prevention programs are often delivered, accept that it may not always be possible to attribute specific prevention outcomes to U.S.-funded interventions.

4. Take on the tough operational research challenges and help build and share knowledge:

- PEPFAR should leverage its influence to help incubate innovation across the HIV prevention field. In addition to providing services, PEPFAR should view testing and refining national-level prevention approaches as central to its mission. This will require a coordinated, PEPFAR-wide agenda on epidemiological surveillance, operations research, and metrics and evaluation. Acquired knowledge across PEPFAR countries should be used to advance prevention globally.
- PEPFAR should establish an external advisory group to bring in new perspectives from non-governmental experts on key challenging issues in HIV prevention, such as the expansion of male circumcision.

Appendix: Lessons Learned from Three National HIV Prevention Experiences

Kenya

Estimated national HIV prevalence⁴: 7.4%
Estimated number of PLWA: 1.4 million
PLWA on ART: 227,500
Estimated proportion of HIV-infected who know their status⁵: 16%
PEPFAR investment (FY2008): US \$534 million

New infections continue to be driven primarily by heterosexual transmission, although transmission among men who have sex with men and injecting drug users is playing an increasing role. Women face considerably higher risk of HIV infection than men, and also experience a shorter life expectancy due to HIV/AIDS. The prevention challenges are daunting: up to 84% of infected people are unaware of their status. In addition, in Kenya the vast majority of currently available HIV funding is from international donors. Little progress has been made in increasing the Kenyan government's financial commitments to prevention, although the government has initiated annual prevention summits, formed a national high-level advisory task force for prevention, and implemented key policies in support of prevention.

PEPFAR's investments in prevention, treatment, care and support have been considerable, contributing \$534 million in the last fiscal year. As of late 2008, 227,700 individuals are receiving antiretroviral therapy due to PEPFAR efforts and more than half a million individuals received care and support services in 2008 alone.

PEPFAR has also supported a broad range of HIV prevention interventions in Kenya including behavior change, prevention of mother-to-child HIV transmission, and improved blood collection and testing services. Antiretroviral prophylaxis services were provided to a total of 182,700 HIV-positive women during their pregnancies from FY2004-FY2008.

PEPFAR also supported a major epidemiological study, the Kenya AIDS Indicator Survey (KAIS), launched in 2007. The survey, in conjunction with a World Bank and UNAIDS funded HIV Modes of Transmission study, refocused Kenya's prevention priorities while building the needed political support and unity of effort required to realign policies and programs.

In 2007 and 2008 two national HIV Prevention Summits were convened and in 2008 a high-level National HIV Prevention Task Force developed Kenya's third National AIDS Strategic Plan (KNASP III) with a new, intensified prevention focus. Key features include: (1) a commitment to scaling up male circumcision programs; (2) expanding HIV testing at the community and provider levels; (3) focusing on 'prevention for positives'; (4) standardizing guidelines for prevention programs that target specific populations; (5) meeting unmet family planning needs for HIV-positive women; (6) exploring the possible expansion of administering early antiretroviral therapy as a prevention tool; and (7) developing better cost-effectiveness measures.

Reorientation of prevention programs in Kenya, including PEPFAR's programs, is only now beginning and there remain significant challenges to further progress. However, there is also strong sentiment that the new approach outlined in the National Strategic Plan offers a real opportunity to tackle directly some of Kenya's most pressing prevention challenges.

4 Data drawn from the Kenyan Ministry of Health, "Kenya AIDS Indicator Survey 2007", http://www.aidskenya.org/public_site/webroot/cache/article/file/KAIS__Preliminary_Report.pdf.

5 UNAIDS, "Kenya: Progress towards Universal Access and The Declaration of Commitment on HIV/AIDS," http://cfs.unaids.org/country_factsheet.aspx?ISO=KEN.

South Africa

Estimated national HIV prevalence⁶: 18%
Estimated number of PLWA: 5.7 million
PLWA on ART: 549,700
Estimated proportion of HIV-infected who know their status (2007)⁷: 90%
PEPFAR investment (FY2008): US \$590 million

In South Africa, new infections continue to be driven primarily by heterosexual transmission. HIV prevalence in young women is at least three times higher than in young men of similar age. In South Africa, nearly 30% of young women age 15 – 24 are HIV-infected and the numbers continue to grow.⁸ While official reports indicate that 90% of the general population ‘know their status,’ sentiment is that the actual figure is much lower. As the country with the fastest growing HIV-positive population in Africa and with the most rapidly expanding ART programs, mounting a more effective prevention response must remain a core PEPFAR goal. However, progress over PEPFAR’s first five years has been slow, frustrated not only by the recalcitrant South African government that recently left office, but also by a programmatic approach that has insufficiently targeted the key drivers of the epidemic.

The single largest country recipient of PEPFAR funds, South Africa received nearly \$590.9 million in FY2008. In FY2007, 5.2 million individuals were reached with abstinence and faithfulness programs, while less than half that number were reached with activities that promote condom usage and other prevention methods. In early 2009, PEPFAR embarked on an effort to rebalance its mix of prevention interventions. Specifically, a portion of funding for prevention programs focused on peer education in 15 to 24 year olds was expanded to focus on 15 to 29 year olds – the cohort responsible for 32% of all new infections in South Africa. Developing prevention programs that more effectively target women, including programs to prevent mother to child transmission, feature prominently in this revised strategy, as does the introduction of male circumcision. Taken together, these interventions represent a promising start to achieving a more effective balance of prevention programs.

Echoing the experience in Kenya, this shift in approach resulted from a realization that PEPFAR’s prior strategy in South Africa was not adequately addressing the most important sources of new infections and that existing programs were fragmented with too little opportunity for integration. Previously inadequate South African government support also impeded progress. However, with the recent change in government, Jacob Zuma’s powerful declaration on World AIDS Day 2009 that the country is entering a new era with “no more shame, no more blame, no more discrimination and no more stigma,”⁹ and a commitment to halving new infections by 2011, there is hope that more effective prevention efforts could significantly change the course of South Africa’s epidemic.

6 Data drawn from PEPFAR, “FY2008 Country Profile: South Africa,” <http://www.pepfar.gov/documents/organization/81668.pdf>.

7 UNAIDS, “South Africa: Progress towards Universal Access and The Declaration of Commitment on HIV/AIDS,” http://cfs.unaids.org/country_factsheet.aspx?ISO=SOA.

8 UNAIDS, “2008 Report on the Global AIDS Epidemic,” p.41.

9 Kaiser Family Foundation, “Leaders Respond to World AIDS Day; South Africa to Expand HIV Treatment Program,” <http://globalhealth.kff.org/Daily-Reports/2009/December/02/GH-120209-World-AIDS-Day.aspx>.

Vietnam

Estimated national HIV prevalence¹⁰: <0.5%
Estimated number of PLWA: 290,000
PLWA on ART: 24,500
Estimated proportion of HIV-infected who know their status¹¹: < 5%
PEPFAR investment (FY2008): US \$89 million

Vietnam's epidemic remains highly concentrated, with new infections driven primarily by injecting drug users with heterosexual transmission in specific populations (e.g. sex partners of drug users and commercial sex workers and their clients). Vietnam's injecting drug user population is estimated at more than 200,000, 20% - 30% of whom may be HIV-infected and who can spread or acquire HIV from both reusing HIV contaminated syringes and high risk sex. Transmission among men who have sex with men is also playing an increasing role, although only limited data is available. There is concern that these numbers could increase considerably without an additional focus on prevention.

Not originally one of PEPFAR's 14 focus countries, Vietnam received an estimated \$89 million from PEPFAR in FY2008. As of September 30, 2008, 24,500 HIV-positive individuals have been put on antiretroviral treatment. In FY2008 according to PEPFAR data, abstinence and faithfulness programs reached 375,000 individuals, and 400,000 individuals were reached by condom promotion and other related prevention services. The PEPFAR prevention effort in Vietnam has been largely focused on assisting the Ministry of Health and provincial health services, supporting nascent non-governmental organizations, scaling up HIV counseling and testing, developing peer outreach programs for at-risk populations, and helping establish a national surveillance and monitoring and evaluation system.

The evolving policies of the Government of Vietnam have played an important role in both advancing, but in some cases also limiting, prevention effectiveness. Government policies are articulated in the National Strategic Plan on HIV/AIDS Prevention for 2004-2010 that calls for a comprehensive response. Needle distribution is available in some provinces, with methadone maintenance therapy offered on a more limited basis, but plans have been made for scale up. An aggressive antidiscrimination policy has also started to have some effect. However, the government's "Three Reductions Policy" (i.e. reduce and control crime, drug use and commercial sex work), which has resulted in the incarceration in government-run rehabilitation centers of those arrested for drug use or prostitution, has inhibited the effectiveness of HIV prevention programs. It is believed that up to 40% of center detainees may be HIV-infected, with additional significant numbers infected with tuberculosis.

10 Data drawn from PEPFAR, "FY2008 Country Profile: Vietnam," <http://www.pepfar.gov/press/countries/profiles/116324.htm>.

11 UNAIDS, "Viet Nam: Progress towards Universal Access and The Declaration of Commitment on HIV/AIDS," http://cfs.unaids.org/country_factsheet.aspx?ISO=VTN.

Consultation on Revisiting the U.S. Approach to HIV Prevention
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