PEPFAR Scientific Advisory Board Recommendation for the Office of the U.S. Global AIDS Coordinator: Intensify Programmatic Activity and Implementation Science to Reduce HIV Burden, Increase Coverage and Improve PEPFAR's Impact for Key Populations

PEPFAR Scientific Advisory Board,

Including the Key Populations Subcommittee

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INTRODUCTION

Development of Recommendation

At the first meeting of the Scientific Advisory Board (SAB, January 2011, Washington, D.C.), the SAB agreed that identifying key questions regarding HIV prevention and treatment for key populations[1] was a priority that needed more attention. The SAB suggested that a smaller subcommittee be formed to consider the existing science involving key populations, identify critical remaining questions, and make recommendations specific for PEPFAR.

The Key Populations subcommittee presented this recommendation to the larger SAB on September 14-15, 2011, at the second full SAB meeting held in Washington, DC. The full SAB accepted the recommendation and planned next steps of the subgroup. This document, developed by the SAB, describes the recommendation, as well as the rationale and proposed way forward.

SAB Recommendation

The Key Populations sub-group, on behalf of the PEPFAR SAB, recommends that PEPFAR intensify programmatic activity and implementation science that addresses focused prevention, treatment and care programs for key populations. These key populations include people who inject drugs (PWID), men who have sex with men (MSM), and sex workers and their clients in PEPFAR partner countries.

Rationale and Description of Select Programmatic Approaches in Support of Recommendation

Addressing HIV prevention, care, and treatment needs among key populations is a critical priority for controlling the HIV pandemic. Even in generalized epidemics in which a significant share of the wider population is living with HIV/AIDS, people from these vulnerable communities generally have markedly higher rates of HIV infection. In concentrated epidemic contexts, key populations account for the majority of infections, as in the U.S., where MSM accounted for two-thirds of the HIV burden in 2011. In order to effectively respond to the global pandemic, the need to tailor and target recent advances in HIV prevention, care, and treatment to ensure that they are also effective for key populations remains paramount. The goals of a program targeted to key populations for PEPFAR are to: intensify targeted- and evidence-based prevention, increase linkages to treatment and care, and expand safe access to services in PEPFAR-supported country programs with significant concentrated epidemics among key populations. This is essential for the following reasons:

The policy environment in many countries is hostile towards key populations: Providing services to key populations may require that public health agencies work through community-based organizations in addition to supporting public agencies directly providing services. Building capacity for community groups is most critical in adverse policy contexts. Productive working relationships between public health agencies and community-based organizations are the most effective model in delivering services to key populations, but will require vigorous effort.

Coverage of existing evidence-based interventions for these populations is markedly low: In the 5 largest PWID-driven epidemics (Russia, China, Ukraine, Vietnam and Malaysia) PWID

[1] This paper addresses the needs for HIV prevention, care and treatment for "key populations." These populations are also referred to as "most at risk populations" (MARPs). We prefer the term key populations as it is less stigmatizing. Key populations refer to groups that are 1) at very high risk for acquiring and/or HIV, and 2) face structural barriers to obtaining services. The high level of risk is due to engaging in behaviors that are relatively efficient in transmitting HIV and/or having large numbers of risk partners. The structural barriers can be the result of stigmatization, laws and policies, and lack of economic resources. Key populations would thus include people who inject drugs, men who have sex with men, and persons who provide transactional sex (exchange sex for money, goods, or drugs, commercial sex workers). It is important to note that because of the stigmatization of key populations, some persons who are behaviorally members of key populations do not identify with the populations or the behaviors.

account for approximately 67% of all HIV infections, but for only 25% of persons with HIV receiving ART (Wolfe, et al, 2010). Coverage of PWID with core prevention services, including needle and syringe exchange (NSP) and medication assisted therapy/opioid substitution therapy (MAT/OST) was even lower, with none of these countries reaching 5% coverage of PWID with MAT/OST (range 0-3%) (Wolfe, et al, 2010). A recent estimate is that approximately 5% of MSM worldwide have access to the most basic set of prevention services, including receiving at least one condom per year and one message to seek HIV testing (Beyrer, 2011). Global coverage data on sex workers are not available, but reports suggest similar challenges exist for that population.

Public health officials and key population communities in many PEPFAR countries need to strengthen their technical expertise and knowledge of key populations issues: These technical issues include understanding the components of key populations programming. PEPFAR guidance promotes and supports a comprehensive package of prevention services including: condom and lubricant distribution, HIV counseling and testing, diagnosis and treatment of sexually transmitted infections, and intensified community and health worker support for entry into and retention in care, needle and syringe programs for PWID (though support for these is currently barred by law), MAT for opioid-dependent patients, best practices for reaching hidden populations of MSM, strategies for building social capital for sex workers, provision of couples-based counseling, testing, and treatment approaches for couples and "families" as defined within these key population risk groups. In many PEPFAR focus countries, technical capacity for addressing the needs of MSM is particularly limited. There are also clear needs to enhance technical knowledge, including the skills needed for conducting research with key populations, adapting evidence-based programs for key populations to local situations, and evaluating the effectiveness of programs for key populations. In the coming era of combination prevention, of "seek, test and treat" approaches, and of antiretroviral (ARV) treatment as prevention (TasP), it will be critical to strengthen the capacity of community and clinical partners so they can provide ARVs, but also identify individuals at risk, establish effective testing and case finding interventions, provide support services, and ensure retention of members of key populations in programs. This will help ensure access, protect dignity and non-discrimination, and maximize the prevention benefits of treatment for high incidence and prevalence populations who are too often excluded from treatment and care. In addition, the development and inclusion of community-based organizations and private sector service options are essential for stigmatized populations.

New research findings, including studies of pre-exposure prophylaxis (PrEP), ARV Treatment as Prevention, and microbicides, may provide new tools for reducing HIV transmission: Implementation of new interventions into public health practice may be of benefit for key populations. However, because key populations are often considered difficult-to-reach populations and because they are often heavily stigmatized and/or criminalized, public health officials may exclude many members of key populations from these programs. Because key populations are at high risk of HIV acquisition and transmission, their exclusion from new preventive interventions could undermine efforts to control HIV at population levels—those most at risk for transmission must be engaged if real gains are to be made in HIV control.

Many officials lack an understanding of the need for a human rights approach in HIV/AIDS work with key populations: The central need for a human rights approach to HIV/AIDS work with key populations is imperative. These populations are most at risk for HIV infection, but also most at risk for exclusion from HIV prevention, treatment and care. The legal, social, and political barriers to service faced by MSM, PWID, and sex workers are many and varied. But the fundamental human rights principle of non-discrimination based on status or being a member of a stigmatized group should continue to be a core principle for PEPFAR for the next phases of the HIV response. Public health, clinical, and human rights imperatives need to be understood and shared by officials. Denial of services to key populations will extend the HIV

epidemic overall. This is true both in generalized epidemics, where key populations are often hidden but are still key populations, and in concentrated epidemics, where key populations are not only the most at risk, but are the majority at risk, and yet remain underserved.

Implementation Science Research Considerations For Key Populations

Implementation science questions surround every aspect of the HIV care continuum for key populations including: identifying at-risk individuals, successful HIV counseling and testing, offering HIV prevention services, and providing care and treatment. The critical implementation science questions for key populations are centered on how best to roll-out effective HIV programs while protecting rights and reducing the many barriers of stigma and discrimination shared by these groups. MSM, PWID and sex workers share HIV prevention, treatment, and care needs with others at risk for, or living with, HIV. They also have distinct needs, risks, behaviors, practices, networks, and community contexts, which mandate that intervention and program adaptation include a significant focus on protecting human rights and dignity.

Several recent advances in HIV research may also be of relevance to these key populations. These include the new findings on ARV TasP (HPTN 052), and oral PrEP (oral Truvada for MSM and transgender individuals; oral Truvada and oral Tenofovir for high risk men, including those who sell sex). Research is also ongoing to determine the efficacy and best use of oral PrEP and the safety and effectiveness of vaginal and rectal ARV-based microbicides in MSM and other key populations.

Once the effectiveness of these tools becomes clear, failure to adapt such interventions in key populations could limit the overall impact of these interventions at a population-level, particularly in locations where HIV is most concentrated in key populations (Beyrer, et al, 2011). A key strategic priority for PEPFAR is to adapt and scale these interventions as implementation science where appropriate, when safety and effectiveness data are available. This will ensure that: (1) key populations are included, (2) more data are available on effectiveness of these interventions in key populations in an implementation setting and that (3) prevention benefits are maximized.

Ecological data on expanding ARV access among MSM in San Francisco and among PWID in Vancouver suggests that broader treatment can serve as prevention. However, in terms of access to prevention and treatment services for key populations, both contexts are the exception, rather than the rule (Das, et al, 2010; Montaner, et al, 2010). The way in which this and other interventions will perform in settings such as Vietnam, and Indonesia for PWID, or among MSM, or among women who sell sex in Sub-Saharan Africa, is unknown. Behavioral risks also play important roles in intervention effectiveness. Compared to heterosexual discordant couples, MSM have higher rates of partner exchange, more persons engaging in both receptive and insertive sex roles and have more undetected and untreated sexually transmitted infections [STI] (particularly oral and anal STI), all of which contribute to faster and more efficient transmission within couples, networks and communities. Biologically-based approaches to prevention, including earlier and broader treatment of HIV positive members of key populations, and perhaps PrEP for HIV uninfected individuals are necessary to address these dynamics of the epidemic building upon, and not replacing, high-coverage implementation of prevention, care and treatment services already included in UN and PEPFAR guidance documents.

In a like manner, sexually active HIV infected PWID are at risk for transmitting HIV to non-injecting sexual partners. The results of the HPTN 052 study provide an important new possibility for reducing sexual transmission of HIV from PWIDs to non-injecting sexual partners but the effectiveness of this intervention among drug users has not been investigated in a rigorous clinical trial. Adaptation of the HPTN 052 study results to couples where one or both partners are PWID, for same-sex male couples, and for couples with transgender partners is a key implementation science research agenda. Using ARV TasP for these populations may also need to go beyond the level of dyad, particularly for sex workers and key populations not in stable

relationships, and will require innovative research designs to investigate the effectiveness of these approaches in these populations.

Next Steps

The Key Populations sub-group and the broader PEPFAR SAB endorse a plan to develop and refine an implementation science agenda to test strategies to rapidly reduce the gaps in services and take advantage of new scientific developments and adapt them for key populations. In addition, we recommend the intensified scale-up of interventions already known to be effective.

Existing PEPFAR guidance documents, including the PEPFAR Prevention Guidance released in August 2011 (http://www.pepfar.gov/documents/organization/171303.pdf) and specific guidance on HIV prevention for PWID (http://www.pepfar.gov/documents/organization/144970.pdf) and for MSM (http://www.pepfar.gov/documents/organization/164010.pdf), need to be regularly updated as both randomized controlled trials (RCT) and effectiveness findings with relevance to key populations become available. PEPFAR has always successfully strived to be consistent and aligned to WHO guidance in these areas, and should continue to do so.

We propose joint meetings with the PEPFAR SAB HPTN 052 and the PEPFAR SAB Data Working Groups to work on further recommendations for inclusion of key populations in rolling out HPTN 052, implementation science, and data collection and management issues.

Finally, we propose development of regional key population networks. An example could be an East/Southern African syringe exchange network, modeled on the North American Syringe Exchange Network, as well as development and capacity building for regional networks of MSM. Another would be a West African Sex Worker network, since there is considerable transnational movement of women in West Africa, and high rates of sex worker mobility challenge single-country program efforts. Such networks would permit the exchange of experiences and expertise in operating programs on a regional basis, the coordination of evaluations, and the introduction of efficient technical assistance.

A dedicated PEPFAR implementation science program for key populations could help us better understand how to overcome gaps in services by testing strategies that will result in increased access, safety, cost-effectiveness, and better protection of human rights and dignity.

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