PEPFAR Scientific Advisory Board (SAB)
Fall 2013 Meeting, October 2-3, 2013
Executive Summary

The President's Emergency Plan for AIDS Relief (PEPFAR) Scientific Advisory Board (SAB) met for the fourth time on October 2-3, 2013 to discuss the following issues identified by the SAB and by the Office of the U.S. Global AIDS Coordinator (OGAC) as priorities:

I. PEPFAR Implementation Science (IS) Research Priorities
II. Strategic Information and Health Economics – Brief Updates
III. HIV Treatment, Care, and Support: Focus on Quality of Services
IV. Prevention and Treatment Cascade: Focus on Subpopulations
V. Transition to Greater Country Ownership

A summary of each topic area is below. Recommendations and action items are included where applicable.

I. PEPFAR Implementation Science Research Priorities: NIH administrative supplements

The PEPFAR program has supported implementation science (IS) through a variety of processes and funding mechanisms over the past ten years. Starting this year, the U.S. Global AIDS Coordinator, in combination with programmatic expertise from the entire PEPFAR program, will determine annual IS priorities that will then be further refined in discussions with the PEPFAR Scientific Advisory Board and tailored to short-term projects that can provide rapid results to programs (via NIH administrative supplements). This SAB meeting marked the initiation of this process. Existing grantees from participating NIH institutes and centers (i.e., NIAID, NCI, NIAAA, NICHD, NIDA, NIMH, and FIC) will be eligible to apply for supplements of up to $500,000 for one-year projects with the option of a no-cost extension for one additional year.

To frame the discussion of IS priorities for 2013 -2014, topics were proposed under the following broad categories: (I) General implementation science for treatment and prevention programs; (II) Integration of other health services into HIV services; (III) key affected populations; (IV) Prevention of Mother-to-child-transmission and maternal health; (V) pediatric and adolescent PLHIV populations. Input from the SAB directly informed the finalized list of priorities that will be published as funding opportunity announcements (FOA) for administrative supplemental awards in the National Institutes of Health (NIH) Guide.

II. Strategic Information (SI) and Health Economics: Brief Updates

As the newly named Deputy Coordinator for Strategic Information and Economics, Dr. Nalinee Sangrujee provided updates and general remarks about the future of PEPFAR's strategic information and expenditure analysis programming.

Recommendation: The SAB discussed numerous issues related to SI including better coordination of data collection across all stakeholders (implementers, implementing agencies, host governments and S/GAC), selection of indicators to further improve strategic programming, and making data public to increase accountability. These themes echoed those topics highlighted by the SAB data working group during previous SAB meetings.

Action Item: A more substantive discussion will occur at the next SAB conference call.

III. HIV Treatment, Care, and Support: Focus on Quality of Services

Dr. Lara Stabinski, Acting Director for Clinical Services at OGAC, confirmed that PEPFAR is well poised to reach the World AIDS Day 2013 target of supporting 6 million people on ARV treatment. Dr. Stabinski highlighted several clinical priorities including: increased treatment coverage so that countries approach a ratio where new infections are fewer than new initiates on ART; increased ART coverage for key affected populations and pediatric populations; expansion of PMTCT programs to eliminate MTCT to achieve the 90% coverage goal; and closing the gap to achieve universal ART coverage for TB/HIV patients.

Recognizing the need for a more streamlined, prioritized package of care and support services and monitoring to ensure the quality of services, Drs. Stabinski, Joseph Barker, and Carol Langley summarized upcoming PEPFAR strategies and guidance, including:

- Reassessment of Care Priorities: PEPFAR is conducting a review to examine how current care and support interventions affect morbidity, mortality, retention in care, quality of life, and prevention of further HIV transmission. The review will culminate in updated guidance for COP'14; See the updated guidance here.
- PEPFAR Quality Strategy: a harmonized framework with GFATM and WHO for institutionalizing improvement practices while programs are undergoing transition to greater country ownership. See PEPFAR's Quality Strategy here (when available).
- PEPFAR Linkage, Engagement, and Retention Strategy: this will provide a framework for support of country efforts to improve linkage, engagement, and retention (LER); set benchmarks of success; enable countries to identify barriers to LER and implement resulting country specific improvements; and enable countries to document demonstrated improvements. See PEPFAR LER strategy here (when available).

IV. Prevention and Treatment Cascade: Focus on Subpopulations

Building on discussions from last year's linkage and retention sessions, the SAB examined various components of the prevention and treatment cascade, with a particular focus on measurement of essential region-specific indicators (presentations IV a-b) and special considerations for specific, key subpopulations (presentations IV c –f).

IV (a). Regional Considerations in the Care Cascade:

Dr. Thomas Odeny gave a talk that was a follow-up from last year's SAB presentation by Dr. Elvin Geng, which showed that rates of patient retention may be better than estimated because many patients categorized as lost to follow-up (LTFU) were often enrolled in treatment at a different facility. Dr. Odeny presented more granular data that showed dramatic regional- and facility-level variation in rates of retention in care and treatment programs. Early analysis showed that structural barriers (e.g. difficult or expensive transportation), clinic-specific barriers (e.g., scolding from clinic staff) and psychosocial barriers (e.g., feeling too well to need care) all played a role in disengagement from care.

Recommendation: The SAB noted that a sampling-based approach was an extremely cost-effective way to accurately measure LTFU at the facility-level to inform programs about factors that influence disengagement from care. Members also noted the questionable utility of retention indicators that lack a clear timeframe (e.g., retention in care at 3 months vs. 1 year, etc).

IV (b). Measuring Engagement in Prevention and Care at the Microepidemic Level:

Dr. Timothy Hallett presented data on the significance of microepidemics and emphasized their importance in informing and prioritizing prevention programing. There is a major opportunity for better geographic targeting, especially in seemingly "generalized" epidemics. More data are needed on existing epidemic patterns as well as patterns of service delivery in order to understand the "mismatch" between services offered and the nature of the micro-epidemic. Further testing of the feasibility and utility of geographic and "hotspot" targeting is needed.

Recommendation: The SAB agreed that microepidemic modeling and the identification of "hotspots" would make a valuable addition to PEPFAR methodology, although more data, particularly on service delivery uptake, is necessary if this approach is to be adopted widely.

IV (c). Prevention and Care for Key Affected Populations

Dr. Chris Beyrer discussed key affected populations (KP), defined during his presentation as populations that have high burdens of HIV and low access to services including MSMs, PWIDs, and SWs. He stressed the need for tailored prevention services—including treatment—for KPs. Although more study is needed to define the barriers to the prevention and treatment cascade for KPs (e.g., the stigma FSWs face in accessing PMTCT services), treatment is an urgent priority for KPs.

IV (d). Prevention and Care for Adolescents

Dr. Linda-Gail Bekker reviewed the challenges to retaining adolescents in HIV care and treatment—with a particular focus on young girls in the prevention and treatment cascade. She noted that adolescents are also KPs, and as such are challenging to reach, and have poor access to services. She highlighted the transition from pediatric and adolescent health services to adult health services is far from seamless. Programs must be streamlined to better address progression from pediatric/adolescent to adult care and ensure a continuation of services.

IV (e). Perspectives from the TB/HIV Working Group

Mr. Mark Harrington reviewed the care continuum for HIV/TB co-infected individuals (another vulnerable group), and the need for improved service integration stressing the importance of prompt ART initiation for patients receiving TB treatment. Another innovation and area for further research comes from the methods of molecular epidemiology, which now affords the ability to link infections to specific clinics so that appropriate preventive measures can then be undertaken.

Recommendation: Time-to-ART initiation for TB/HIV co-infected individuals should be a key strategic indicator in country monitoring plans.

IV (f). Cascade Considerations for Asymptomatic High CD4 Count Individuals

The preventive benefits of ART have led to increased consideration for test and treat strategies globally. Successful test and treat strategies will increase the number of early-disease stage individuals who know their status and are enrolled in care and treatment. The following are a series of presentations focused on the cascade considerations for asymptomatic high CD4 count individuals.

i: Adherence Among Asymptomatic, High CD4 Count Individuals

Dr. David Bangsberg framed the primary challenge to good treatment adherence for individuals with early-stage disease, focusing on the fact that ART adherence relies on social support, social support requires disclosure, and disclosure of early stage disease is rare. He presented results from a series of studies that showed early treatment was associated with more frequent treatment interruptions and incomplete viral suppression. Longer-term studies are needed to further characterize treatment interruptions, understand their cause, and develop interventions to address them.

ii: EARLI: An HIV Treatment Study in High CD4 Count Individuals in Mbarara, Uganda

Dr. Vivek Jain presented preliminary findings from the Early Antiretroviral Therapy in Resource Limited Settings (EARLI) study. The study is testing a streamlined model of care which includes ART provision by non-M.D. health workers, viral load testing, extended return intervals for medications (3 months), and a focus on rapid clinic transit. Preliminary findings show high retention rates in patients with high CD4 counts.

iii. How to Effectively Treat Asymptomatic, High CD4 Count HIV+ Individuals

Drs. Myron Cohen and Wafaa El-Sadr "debated" how to best treat HIV-positive asymptomatic individuals with high CD4 counts. Dr. Cohen's presentation, "When Should We Start?" highlighted the benefits of early treatment for individuals and for public health benefit. He warned against conflating the logistical and financial challenges of providing ART, particularly in resource limited settings, with policy, which should be aspirational in order to send a clear, simple message about the benefits of early treatment.

Dr. El-Sadr's presentation focused on two main points: (1) HIV testing is the foundation for both prevention and care/treatment efforts, and the majority of people who are HIV-infected are unaware of their status; (2) A number of studies show that individuals with lower CD4 counts have better retention than those with higher CD4 counts. She stressed that policy and practice must follow from strong evidence, and only through additional studies about the harms and benefits of early treatment will we know how to best treat individuals at high CD4 counts.

V. Strengthening Greater Country Ownership

Sustaining PEPFAR programs in the long term requires a transition to greater country ownership. This is defined by the progressive transfer of decision-making, overall management, and funding of PEPFAR-supported programs from USG and international implementing partners to the partner country government and local implementing partners, including academic institutions and civil society. During this panel discussion on transitions, Ambassador Goosby and PEPFAR COO Julia Martin emphasized PEPFAR's ongoing commitment to strengthening the capacity of partner countries to assume greater ownership of their national AIDS responses, which will help ensure that these programs will be sustained over time.

The pace and scale of this progressive transfer of responsibility will vary according to national circumstances; PEPFAR could and would negotiate to sustain support in sectors that may be underserved by partner governments, such as key affected populations that remain marginalized in some countries. Further, the progressive transfer of greater ownership and management responsibility to partner countries should in no way be misunderstood as a withdrawal of PEPFAR's engagement, but rather as a natural evolution in support of strong, sustainable AIDS responses.

Accurately assessing when conditions are adequate for countries to assume progressively greater ownership of and responsibility for management, oversight, and financing of their AIDS response also requires reliable data on levels of HIV service coverage; these assessments are ongoing.

Vignettes highlighting key challenges to such progressive transfer of greater ownership and responsibility were shared with SAB members as a framework for further discussion.

The key challenges discussed included: (1) criminalization of key affected populations such as MSM, TG, PWID and SW; (2) questions around host government assuming support for cadres of health workers essential to the HIV/AIDS response, such as lay counselors for HIV testing and counseling and provision of ART by nurses; (3) questions around host government assuming support of ancillary services aimed at enhancing linkages to care and improving retention within care. Subsequent discussion focused on the development of ethical principles to guide transitions in the face of these and other challenges.

Recommendation: SAB members recommended that the staged transfer of responsibility for and ownership of HIV treatment and prevention programs to partner countries should be carefully managed to avoid any misinterpretation that this signals a hasty exit strategy. They also suggested active participation from in-country academic leaders and researchers as part of the transition process.

Action Item:
To ensure that science and evidence-based decision-making are part of the progressive transfer of ownership as well as critical elements of local solutions, an essential role for the SAB is to link local academics and researchers to the transition process. OGAC/ORS will work continuously to link SAB members and expertise to the appropriate stakeholders during the development and implementation of country-held partnerships (CHPs).