

The United States President's Emergency Plan for AIDS Relief (PEPFAR)
PEPFAR Scientific Advisory Board (SAB) Meeting
October 14, 2015
US Department of State, Washington, DC
Executive Summary

Introduction

The United States President's Emergency Plan for AIDS Relief (PEPFAR), led by Ambassador Deborah Birx, held a meeting of their Scientific Advisory Board (SAB), a Federal Advisory Committee Act (FACA)-chartered advisory committee in Washington, DC on October 14, 2015. In addition to Board members, SAB-attendees included SAB-affiliated Expert Working Group members, representatives of US government agencies, and members of the public. PEPFAR SAB Chair Carlos del Rio, MD facilitated and led the meeting. The meeting held particular relevance and value in light of newly issued HIV/AIDS normative guidance by the World Health Organization (WHO) and additional guidance issued by the International Association of Providers of AIDS Care (IAPAC).

PEPFAR Briefing

AMB Birx thanked the Board for their commitment to ending HIV/AIDS as a public health threat. She pointed out that this group is comprised of leaders who were motivated to change the status quo of the AIDS epidemic and who contributed to the efforts in inspirational, transformative ways—by taking risks, standing up for others, and bringing compassion and passion to this work. Each member was selected based on her/his platform, vision, background, fortitude, and willingness to push government. AMB Birx expressed her appreciation and tremendous respect for SAB members' participation here as well as their efforts in the field. She provided the SAB with a briefing on the history and current state of the HIV/AIDS epidemic and PEPFAR programs. She noted that President Obama and leaders in his administration have made numerous statements in the recent past in support of an AIDS-free generation. At the Sustainable Development Goals (SDG) Summit, the President announced the US's two new goals of increasing the number of people who receive HIV/AIDS lifesaving treatment to nearly 13 million people, and investing \$300 million to help achieve a 40% reduction in new HIV infections among young women and girls in the hardest-hit areas of sub-Saharan Africa.

AMB Birx shared the details of the ongoing PEPFAR "pivot" focused on shifting resources to implementing high-impact HIV prevention, treatment and care programs in the highest-burden areas. She also shared PEPFAR's commitment to transparency and efficiency for all business practices, and success stories from the last year in PEPFAR, including de-duplication of programming and prompt approval for bilateral funds which together resulted in increased funding of direct services.

Impact of the WHO Guidelines

PEPFAR views the new WHO guidelines as the last fundamental, non-vaccine tool needed to ensure success in controlling the HIV/AIDS epidemic. Over the last 12 years, men with high CD4 counts have been sent away from care programs without treatment, while women were being treated because of their pregnancies through PMTCT programs. With new guidance, the message can now shift and needs to be reversed, to help men understand that they need treatment for their own health. The guidelines recommend the following:

- Treat ALL (at any CD4)—all people living with HIV

- The sickest remain a priority (symptomatic disease and CD4<350)
- New age band for adolescents (ages 10-19)
- Option B not taken forward; Option B+ as new standard for PMTCT
- Pre-exposure Prophylaxis (PrEP) as an additional prevention choice for all people at substantial risk of HIV infection (>3% incidence)

Priority Areas for SAB Consideration

AMB Birx shared the priority areas for SAB consideration, and she expressed her appreciation for the PrEP and Test and START documents produced for today's meeting as well as her anticipation of forthcoming discussion on those topics:

- Test and START
- PrEP
- HIV prevention in young women and adolescent girls
- Strategies to identify and link men with treatment
- Accelerate access to treatment for children
- Continue momentum towards virtual elimination of MTCT
- Strategic scale-up of VMMC
- Meaningful civil society engagement
- PEPFAR implementation science funding for the biggest impact

EWG Presentations on PrEP and Immediate Provision of Treatment for All (“Test & START”)

The SAB were provided with presentations from the [PrEP EWG](#) and the [Test and START EWG](#). For a brief overview of the EWG objectives and membership, please see the following [link](#).

Report and Recommendations to the PEPFAR SAB on the use of Pre-Exposure Prophylaxis (PrEP)

Connie Celum, MD presented the PEPFAR PrEP EWG's brief and recommendations on the use of PrEP.

The PrEP EWG made recommendations to the PEPFAR SAB in the following nine topic areas:

- Involvement of and Partnerships with Local Governments and Civil Society Structures including Non-Governmental Organizations (NGOs) and Community-Based Organizations (CBOs)
- PrEP Drug Selection
- Licensure Status of TDF-based PrEP in Countries Outside the US
- PrEP Delivery
- Safety Monitoring of PrEP in PEPFAR
- PrEP Adherence Monitoring
- PrEP Use in Pregnancy
- Sentinel Surveillance for Monitoring PrEP Use
- Implementation Science and Operations Research Priorities for PrEP Delivery

Recommendations and Vote

The SAB gave its unanimous approval of the following:

- Endorsement of the PrEP EWG document, noting opportunity for written amendments by Board members prior to finalization, especially in regards to greater specificity in training and adherence monitoring recommendations;

- Endorsement for PrEP as a priority within the DREAMS initiative;

Report and Recommendations to the PEPFAR SAB on the use of Test and START

Judith Currier, MD presented the PEPFAR Test and START EWG's report and recommendations, examining issues surrounding early treatment (key logistic and operational considerations, lessons learned from test and treat among pregnant women in B+ settings, establishment of priority populations and countries for Test and START initiatives, initiatives that address critical implementation issues along the clinical cascade (testing, linking to care, ART initiation, viral suppression, and retention) in key populations).

Summary of Recommendations

Test and START is a paradigm shift from stopping death from AIDS to stopping AIDS itself. The required investment in training, communication, staff, facilities, drugs and infrastructure will be worthwhile as it will dramatically decrease HIV transmission. Innovation, wherever possible, is necessary to make treatment effective. The information that informs best practices will come from current studies and successful programs in the field, and that knowledge will be critically important to the success of our future efforts.

Recommendations and Vote

Dr. del Rio recommended that the SAB approve the following:

- We are in consensus agreement with the Test and START EWG document and its initial recommendations.
- We are in consensus agreement that PEPFAR expedite the implementation of Test and START.
- The Test and START EWG will bring back to the group specific recommendations on prioritizing treatment, thereby finalizing a document for presentation to AMB Birx.

There was unanimous agreement on all points.

PEPFAR Updates

Facilitated PEPFAR Program Discussion

Dr. del Rio raised two issues for discussion around implementation:

1. Integration of HIV care, PrEP, and more into healthcare systems
2. Integration of HIV treatment with treatment of TB specifically, as well as with other diseases

Discussion followed, in which numerous issues and key points were raised, including:

- The importance of quantifying and mapping service delivery to ensure provision of services for the populations most in need.
- PEPFAR Country Operational Plans (COPs) need to reflect a focus on who is being missed by existing services (e.g. men, adolescents, stigmatized populations such as MSM and PWID, pediatric patients); how to ensure they are engaged rapidly; and ensuring cost-effective and sustainable programming.
- The need for a critical review of what has been funded under the rubric of treatment in order to fully understand the new prevention targets.
- TB/HIV: the critical role of early combined ART/IPT and the urgent need to document successes where they exist and share best practices in the many places that are still failing the HIV/TB co-infected population.
- Integration of HIV care using existing infrastructures.

- The need for messaging to quell fear that PrEP and treatment are being coercively forced on individuals.
- Invest in the ascertainment of how to maximize the benefit of the treatments that exist over the longest possible duration.
- We must ensure that utilization of suboptimal therapy decreases, despite the push to get more people on ART rapidly.
- Embedding systematic social science assessments in PEPFAR's programmatic activities to collect real data on topics such as the role of stigma and discrimination during HIV service delivery and the best methods to eliminate them.
- Questions were raised about the current funding duration for the PEPFAR DREAMS partnership.
- Understanding what real cost-drivers are (service delivery, not commodities such as ARVs).
- Stimulating more countries to develop programs themselves based on their particular populations, needs, and outcome goals.

Facilitated Discussion of PEPFAR-Funded Combination Prevention Trials

OGAC Chief Medical Officer, Douglas Shaffer, MD, offered a synopsis of PEPFAR-supported Combination Prevention Trials (CPTs), in order to create a context for the discussion:

- Many national treatment guidelines shifted before study implementation occurred, or shortly thereafter; the relevant studies were modified.
- The massive investment of programmatic funds in these research trials (overall CPT study budget is roughly \$240 million).
- All studies are overseen by Data and Safety Monitoring Boards (DSMBs).
- Two of the studies are roughly one year into implementation and cohort follow-up, and the third is more than 1.5 years into implementation and cohort follow-up. All studies are projected to report out in late 2017 or early 2018. The new guidelines have shifted the standard of care.

Discussion Questions:

What is the impact of the new WHO guidelines recommending treatment for all regardless of CD4 count and PEPFAR's aggressive Test and START strategy from a programmatic perspective upon clinical equipoise as it relates to the CPTs and their continued funding?

The discussion that followed included the following elements:

- An update on the ANRS-funded large HIV CPT study set in South Africa, which will end within the next year.
- The elements of the CPT interventions beyond early provision of ART, including various methods of providing counseling and testing; scaling up VMMC; and integrating HIV care with care for other health conditions.
- PEPFAR encouragement to nations hosting the studies to consider their timelines for implementing new WHO normative guidance and considering the role of these studies in informing the rollout of new national standards of care; biostatisticians and bioethicists are going to play a key role as appropriate due diligence is performed for people who need treatment and could have access to it.
- A proposal that a larger group be convened to engage in these very important discussions; SAB members agreed that trial leaders should meet in light of new WHO guidance.

- Importantly, none of the three PEPFAR-funded trials include provision of PrEP in the study intervention arms. The recent WHO guidance advocating PrEP for all individuals at high risk of HIV infection warrants a swift reconsideration about including PrEP.

How does PEPFAR ensure that insights from these rigorous research trials remain relevant in the current HIV treatment era (given WHO guidance issued September 30, 2015) and are promptly translated at the program level?

The discussion that followed included the following elements:

- The importance of the adaptive design of the trials; value would be added if trials could include PrEP in the next 3-6 months.
- These trials are poised to provide additional insights to national governments and international donors as they need to prioritize programs and balance investments in PrEP, Test and START, and other impactful interventions.
- At a minimum, these trials must respond quickly to the new WHO guidelines and ensure they gather information to inform adoption of WHO guidelines.
- The need for investigators to have the opportunity to articulate the studies' value and the way in which the research will inform program.
- The need to allow stakeholders in these complex trials to be a part of the conversation about how to move forward.

Should an EWG under the SAB be convened promptly to further consider relevant implementation science questions and funding priorities?

- The SAB endorses that the study DSMBs should meet promptly to address particular questions.
- PEPFAR will aim to quickly convene a stakeholders' meeting to include study Principal Investigators (to include the ANRS-funded trial), implementers, host nation governments, local stakeholders, and civil society.

Presentation: Affected Populations and Civil Society

A. Cornelius Baker, Acting Deputy Coordinator, Office of Affected Populations and Civil Society Leadership (OAPCSL), OGAC

Mr. Baker provided a background on the OAPCSL, noting the new office was created as a focal point for the human rights agenda; includes gender, key populations, and civil society leadership. All staff members work on engaging civil society in specific projects as well as around the COP/ROP planning process, other central initiatives, and the work of teams on the ground. OAPCSL recently concluded gender and sexual identity and orientation diversity trainings for all PEPFAR staff and implementing countries, teams, and partners. Mr. Baker noted a number of new initiatives, including Health4Men, a partnership between PEPFAR and the Elton John AIDS Foundation that began as a pilot program in South Africa.

Mr. Baker explained that AMB Birx is co-chairing one of the lead initiatives aimed at increasing engagement with civil society: the Robert Carr civil societies Networks Fund (RCNF). This program was created to provide a strong core funding source for the global civil society network. A replenishment meeting was recently held as the program is coming to the end of its first three years; the following results were reported:

- The US has increased its contribution from \$6 million to \$10 million over three years.
- All original donors have committed to renewed funding:
- The Ministry of the Netherlands has recently joined as a funder with a \$3 million commitment.
- The fund will increase from \$18 million to \$30 million by the end of 2015.

PEPFAR is already involved in activities that address human rights and discrimination, such as contributing to the State Department’s Global Equality Fund. It is also assessing in four African countries how stigma and discrimination impede efforts to address HIV among LGBT people and undermine human rights. The next step is to establish ways to affect an impact on the legal environment and on stigma.

Mr. Baker requested the SAB’s help to identify ways in which the environment can be changed regarding stigma and discrimination so that people feel safer in seeking HIV services. The goal is to make this an essential component of the OAPCSL’s work.

Affected Populations and Civil Society Q&A

SAB members posed questions around countries’ legal frameworks, benchmarks for addressing stigma, measuring impact, training, defining targets, key populations, FBOs, building on past efforts, self-stigma, the importance of policy, codes of conduct, and the military. Details can be found in the SAB meeting minutes.

Public Comments and Questions

Comments and questions were presented by members of the public around PrEP’s specific recommendations relating to types of projects, counseling messages, funding and delivery access, and the ways in which PrEP reduces stigma. Details can be found in the SAB meeting minutes.

Wrap-up & Next Steps

EWGs focusing on HIV/TB, data, finance and sustainability, combination prevention, and implementation science will be developed. Also, a DREAMS/ACT group, to convene before the January meeting, has been suggested. OGAC will reach out to members to ask for participation, with feedback sought in approximately six months, as the upcoming July IAS meeting in Durban as a major landmark point; the SAB will convene for a one- or two-day meeting prior to that event in order to develop a framework as well as clear recommendations.

Closing Comments

AMB Birx remarked that she learned a lot in this meeting around data use and about issues around Test and START and PrEP. She expressed appreciation that the SAB is changing PEPFAR’s thinking about combination prevention, in particular.

AMB Birx acknowledged OGAC staff for their efforts in coordinating and supporting the SAB and this meeting. Dr. Shaffer expressed his appreciation for AMB Birx’s passion and for the leadership, efforts, and what AMB Birx calls “infectious impatience” of Drs. Celum, Karim, Currier, and del Rio and of their EWGs. He thanked Drs. del Rio and Currier for governing the meeting and noted that, by holding today’s meeting at the State Department, PEPFAR will be able to fund treatment of approximately 500 children on first-line ART for an entire year.

Dr. del Rio shared his gratitude to SAB members for traveling to Washington, DC for the one-day meeting and for focusing so clearly on the issues and topics discussed. He shared his belief that AIDS can be ended with the available tools as well as with the opportunity existing through PEPFAR. All of this group's input will be highly valuable in creating achieving the goal of an AIDS-free generation.