The United States President’s Emergency Plan for AIDS Relief (PEPFAR)

PEPFAR Scientific Advisory Board (SAB) Meeting

November 1, 2016

U.S. Department of State, Washington, DC

PEPFAR Scientific Advisory Board Members in Attendance

Quarraisha Abdool Karim—University of KwaZulu-Natal; Associate Scientific Director, Centre for the AIDS Programme of Research in South Africa (CAPRISA); Professor of Clinical Epidemiology, Mailman School of Public Health, Columbia University; Professor of Public Health, Nelson R. Mandela School of Medicine, University of KwaZulu (South Africa)

Judith Auerbach—Independent Science and Policy Consultant; Professor, Center for AIDS Prevention Studies, University of California San Francisco School of Medicine

Connie Celum—Director, International Clinical Research Center, Department of Global Health, University of Washington School of Medicine

Judith Currier—Division Chief, Infectious Diseases and Associate Director, University of California Los Angeles (UCLA) Center for Clinical AIDS Research and Education (CARE); Professor of Medicine, UCLA School of Medicine

Carlos del Rio—Chair, Department of Global Health, Rollins School of Public Health and Professor of Medicine, Division of Infectious Diseases, Emory University School of Medicine

Mark Harrington—Executive Director, Treatment Action Group (TAG)

Jennifer Kates—Vice President and Director, Global Health and HIV Policy, Kaiser Family Foundation

Lejeune Lockett—Operations and Program Manager, Global Health, Charles Drew University of Medicine and Science; Angola Military HIV Prevention Program, Drew Cares International

Ruth Macklin—Professor of Bioethics, Einstein School of Medicine

Celia Maxwell—Associate Professor of Medicine and Associate Dean for Research, Howard University College of Medicine; Infectious Disease Specialist, Howard University Hospital

Kenneth Mayer—Co-Chair and Medical Research Director, Fenway Health; Director, HIV Prevention Research and Attending Physician, Beth Israel Deaconess Medical Center; Professor, Harvard Medical School and Harvard School of Public Health

Jesse Milan—Interim President, AIDS United

Angela Mushavi—Coordinator, Mother-to-Child HIV Transmission Prevention and Pediatric HIV Care and Treatment, Ministry of Health and Child Welfare, Zimbabwe

Christine Nabiryo—Public Health Consultant, Uganda

Nyambura Njoroge—Project Coordinator, Ecumenical HIV and AIDS Initiatives and Advocacy, World Council of Churches

Jean William Pape—Professor, Weill Medical Cornell College; Director, GHESKIO (Haiti)

David Peters—Chair, International Health, Johns Hopkins University School of Public Health

Rev. Edwin Sanders—Senior Server, Metropolitan Interdenominational Church of Nashville; Chair, The Legacy Project, a collaboration with the HIV Vaccine Trials Network; Member, Presidential Advisory Council on HIV/AIDS (PACHA)

Fredrick Sawe—Director, HIV/AIDS Research, Walter Reed Project, Kenya Medical Research Institute

Carole Treston—Chief Nursing Officer, Association of Nurses in AIDS Care
Mitchell Warren—Executive Director, AVAC: Global Advocacy for HIV Prevention

PEPFAR Scientific Advisory Board Members Not in Attendance
Peter Berman—Professor, Global Health Systems and Economics, T.H. Chan School of Public Health, Harvard University
Sofia Gruskin—Director, Program on Global Health and Human Rights, Institute for Global Health, University of Southern California; Harvard School of Public Health
Mark Heywood—Executive Director, SECTION27, O’Neill Institute for National & Global Health Law; Chairperson, UNAIDS Reference Group on HIV/AIDS and Human Rights
Musimbi Kanyoro—President and CEO, Global Fund for Women
Etienne Karita—Site Leader, Project San Francisco, Rwanda Zambia HIV Research Group
Albert Siemens—Chair, FHI Foundation

PEPFAR Implementation Team
Ambassador Deborah L. Birx—United States Global AIDS Coordinator
Ebony Coleman—Foreign Affairs Officer/Research and Science Technical Advisor/AAAS Fellow, Office of Research and Science, Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC)
Andrew Forsyth—Director, Office of Research and Science, Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC)

OPENING SESSION
Welcome and Meeting Overview
Andrew Forsyth & Ebony Coleman
On behalf of Ambassador Birx and SAB Chair, Dr. Carlos del Rio, Dr. Forsyth welcomed all in attendance and reviewed meeting logistics. Dr. Coleman thanked SAB members, expert working groups (EWGs), and S/GAC staff for their preparation for the meeting. She noted that the SAB adheres to the requirements of the Federal Advisory Committee Act (FACA) and that it seeks relevant and objective advice that can shape PEPFAR programming. The meeting was open to the public for observation and comment, and minutes will be made available at www.pepfar.gov.

April 2016 Meeting Follow-Up
Brief Response to TB/HIV Expert Working Group Recommendations
Lisa Nelson, Acting Chief Medical Officer and Technical Assistance/Technical Collaboration Strategic Technical Alignment for Results (STAR) Initiative Lead, S/GAC
Dr. Nelson provided an update on behalf of Senior Tuberculosis Advisor J. Sean Cavanaugh, who has been leading the response to the recommendations of the SAB’s Tuberculosis and HIV (TB/HIV) Expert Working Group (EWG). She reviewed the EWG’s April 2016 recommendations as well as the key responses to date, noting a 2015 World Health Organization (WHO) report underscoring a high TB/HIV coinfection rate.
Discussion addressed low TB testing rates of persons with TB or HIV infection, benefits of integrated same-day TB diagnosis and treatment in people living with HIV (PLHIV), high co-morbidity of TB and HIV among those tested for either condition, and use of TB prophylaxis in persons living with HIV infection. Participants urged a more urgent response to TB as part of PEPFAR implementation.

Mark Harrington provided a brief update from the International Union Against Tuberculosis and Lung Disease (The Union) World Conference on Lung Health in Liverpool, UK in October, noting that recent South African studies on multi-drug resistant TB have achieved a 100% survival rate following six months of treatment. He suggested that PEPFAR or the SAB collaborate with the Global Fund to Fight AIDS, Tuberculosis, and Malaria to support scale-up of high-quality TB screening, diagnosis, and treatment programs.

New data have informed recent WHO guidance on the relative risk of infection by health care workers as compared to the general population, and PEPFAR is taking steps to reduce risk for supported health care workers as part of its infection control programs. Early TB diagnosis and treatment of health care workers is essential; Dr. Pape noted that, in the four years since Haiti implemented same-day diagnosis and treatment, no health care worker has become infected.

**PEPFAR 2016 and Beyond**

*Ambassador Birx, US Global AIDS Coordinator*

Ambassador Birx presented to the SAB information on the impact that PEPFAR programming has made through a data-driven strategy to optimize finite resources by targeting prevention and treatment services to the geographic areas and population groups that shoulder the greatest burden of HIV disease. Although a drastic decline has occurred in pediatric and adult HIV infections between 2000 and 2015 in most PEPFAR-supported countries, young people between the ages of 15 and 24 represent a priority population for two reasons: First, unlike pregnant women, those in this age group have limited contact with prevention and treatment services, largely because they are healthy and generally do not have health conditions that precipitate clinical care encounters. Second, due to the effective prevention of mother-to-child-transmission (PMTCT) programs, demographic trends now provide evidence of a youth bulge, as characterized by a doubling of the population group of 15-24 year olds. Taken together, these factors appear to account for an expanded epidemic in these youth that will require a greater focus on prevention and treatment strategies to interrupt new infections in this segment of the population. In addition to improving prevention and treatment services generally, AMB Birx emphasized the need to address the prevention and treatment needs of young women and adolescent girls and she highlighted near-endemic levels of sexual and gender-based violence that significantly increase risk of HIV-infection in this segment of the population.

The SAB discussed a range of topics, including: post-rape kit program policy and implementation; DREAMS timeline; assessing DREAMS impact; LGBT anti-discrimination requirements; testing and treatment sex workers and men having sex with men (MSMs); sexual violence statistics; nurse and physician training in social determinants of health; scale-up of successful local programs; effective
messaging and social media; faith-based organizations serving the urban poor; integrating pregnancy prevention with HIV prevention; and the need for client-centered programming.

SAB SUBCOMMITTEE RECOMMENDATIONS

Finance and Economics EWG: Jennifer Kates and Peter Berman presented recommendations on behalf of the Finance and Economics EWG. The EWG is considering ways to maximize the impact of PEPFAR implementation in an era of flat or decreased funding. Specifically, the EWG sought to accomplish the following:

1. Project aggregate funding available for HIV in PEPFAR countries based on three scenarios: pessimistic, optimistic, and flat-line funding;
2. Provide direction for how PEPFAR could conduct case studies of 2-3 countries to illustrate how new program goals and policies will be affected by available resources; and
3. Starting with PEPFAR’s proposed level of achievement by 2020 (its contribution to 90-90-90), identify 2-3 scenarios based on different programming or efficiency assumptions that can be used to assess return on investment.

The Finance and Economics EWG offered the following recommendations:

- Consider how best to support future work to address financing issues, either by itself directly or with other partners;
- Work to integrate PEPFAR’s financial tracking (potentially through its Expenditure Analysis Data Collection Program) with other HIV financial tracking efforts to capture a fuller financing picture;
- Work to establish more robust domestic resource tracking for HIV in its top 20 countries; and
- Devote more effort to measuring the cost and financing implications of its “efficiency” strategies, which are critical to its plans to achieve its contribution to the 90-90-90 goals by 2020.

The SAB accepted the EWG’s recommendations.

PrEP and Pregnancy EWG: Connie Celum presented recommendations on behalf of the Pre-Exposure Prophylaxis (PrEP) and Pregnancy EWG pertaining to the safety and efficacy of tenofovir and emtricitabine in pregnant and lactating women. As part of its review, the EWG studied the relevant literature and evaluated the risks of HIV infection and mother-to-fetus transmission, effectiveness of daily oral PrEP, and the lack of evidence of adverse pregnancy and infant outcomes. The EWG offered the following recommendations:

- PrEP should be offered as part of combination HIV prevention to women at substantial risk of HIV infection during pregnancy and breastfeeding.
- PEPFAR should encourage national regulatory authorities to review information about the risks and benefits of PrEP during pregnancy whether such information is provided by the applicant (Gilead or generic FTC/TDF manufacturers) or by other sources (e.g., PEPFAR or WHO).
• PEPFAR should have country-specific discussions about the introduction of PrEP in pregnant women, including reference to local epidemiology, cost-effectiveness, affordability, and the local regulatory environment, including pharmacovigilance and whether a need exists for demonstration projects to fill remaining gaps.

• Against the background of the WHO review of data on tenofovir and tenofovir/emtricitabine use in pregnant and lactating women, PEPFAR should consider having discussions with pharmaceutical manufacturers about whether or not there is willingness to apply for their indication for PrEP use in HIV-negative pregnant and lactating women.

The SAB discussed the need for greater inclusion of pregnant women in PrEP research and related ethics guidelines; PrEP for HIV-negative women who are likely to acquire HIV infection during pregnancy or lactation; guidance for countries; off-label use of PrEP; and regulatory matters. The SAB conditionally accepted the EWG’s recommendations pending minor modifications to underscore the urgency to advance research in this area.

**Data-Driven Decision Making Task Force**: Co-chairs Donna Spiegelman and Paul Zeitz presented recommendations on behalf of the Data-Driven Decision Making Task Force (DDDM TF), which included representatives from WHO, AVAC, UNAIDS, IAPAC, Global Fund, and others to advise on promoting and enhancing secondary analysis of PEPFAR data; enhancing data for allocative efficiency and cost-effectiveness; harnessing the data revolution for an AIDS-free generation; and exploring PEPFAR data systems, governance, and management issues. The DDDM TF recommended that PEPFAR strive to:

• Ensure open access to PEPFAR data and strengthen research partnerships with academia, advocates, and others.

• Assess efficiency of program spending by implementing partners, and improve interoperability of expenditure data systems.

• Build S/GAC and country team capacity to utilize data to inform program planning, policies, and implementation.

• Invest in data systems, including existing global health data platforms, unique patient identifiers, and enhanced data-driven, QI/QA site performance systems.

• Establish an expert working group (EWG) to review progress and offer guidance on TF recommendations.

Ensuing discussion noted the large amounts of data that go unused for program monitoring or improvement; limited resource and capacity for data analysis; and the need to ensure that data are collected, analyzed, and interpreted in collaboration with key stakeholders.¹ A motion was made and seconded to establish an EWG, with a plan for the group to review and prioritize the task force’s recommendations.

¹ SAB members noted the recent The New York Times Bestseller *Weapons of Math Destruction: How Big Data Increases Inequality and Threatens Democracy* as a resource related to dealing with issues of trust and suspicion around data.
**Cervical Cancer Screening and Treatment Task Force:** Judith Currier presented recommendations on behalf of the Cervical Cancer Screening and Treatment Task Force (CCST TF), with input from Vikrant Sahasrabuddhe of the National Cancer Institute and Celina Schocken of Pink Ribbon, Red Ribbon. The TF noted current WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention and the range of available diagnostic tools and treatments, highlighting that PEPFAR has supported secondary prevention of cervical cancer in HIV-positive women since 2006. The CCST TF offered the following recommendations:

- HPV testing can improve efficiency and specificity of secondary prevention of cervical cancer without loss of sensitivity, and it should be incorporated into the screening algorithm as recommended by the current WHO guidelines where feasible and should be supported by PEPFAR.
- Utilize the HPV screening assay, which can reliably and accurately distinguish women at elevated risk of cervical cancer who need preventive, curative, or palliative treatment from those at lower risk.
- WHO guidelines and algorithm are appropriate for PEPFAR sites at this time (ref. WHO guidelines, annex 4: “Flowcharts for screen-and-treat strategies HIV-positive status or unknown HIV status in areas with high endemic HIV infection”). If there is infrastructure, implementation of these guidelines should occur initially. If HPV testing is unavailable, visual inspection with acetic acid (VIA) should continue with strong quality assurance programs until HPV testing becomes available. Expansion of HPV testing should be considered by PEPFAR as replacement to VIA as the initial screening test, followed by VIA for treatment triage.
- PEPFAR should consider support for obtaining more data on the outcomes of HIV-positive women treated with thermal coagulation, while alternatives are evaluated and data from comparative studies with cryotherapy are completed.

Subsequent SAB discussion including co-funding, implementation feasibility in rural areas, research support by multiple Centers for AIDS Research (CFARs), limited existing data (and thereby difficulty with analysis), low screening rates, and vaccine scale-up. Adding language to the recommendation about data collection was suggested. A motion was made and seconded to accept the task force’s recommendations pending verbiage to strengthen recommendation #2. The vote passed unanimously.

**Voluntary Medical Male Circumcision (VMMC) and Tetanus Task Force:** Mitchell Warren presented recommendations on behalf of the Voluntary Medical Male Circumcision and Tetanus Expert Task Force (VMMC TF), which was charged with evaluating the WHO’s 2016 recommendations on tetanus infection risk mitigation; these recommendations state that circumcisions using elastic collar compression devices should be undertaken only if clients are adequately protected against tetanus by full immunization with a tetanus toxoid-containing vaccine (TTCV). Following a careful consideration of the WHO analysis and a commentary from the manufacturer of the elastic collar compression device (PrePEX), the TF offered the following recommendations:
• Accept WHO’s risk analysis regarding significantly higher relative risk of tetanus infection associated with the use of elastic collar compression devices as compared to surgical circumcisions.
• Adapt each aspect of the WHO guidance in PEPFAR-supported VMMC programs.
• PEPFAR could offer elastic collar compression devices as an option for men seeking VMMC, but only when following the WHO-recommended tetanus mitigation strategies.
• Encourage operational research that may help PEPFAR better identify best practices for use of TTCV in its VMMC programming.
• Acknowledge that WHO recommendations will ultimately be up to each country, depending on its level of tetanus immunization coverage.

The SAB discussed vaccination programs and coverage rates in PEPFAR-supported countries; availability and use of VMMC data; surgery risk and its adverse effect on uptake; the challenge of reaching and enrolling men for VMMC services; and the integration of VMMC into STD and HIV prevention and treatment services. The group recommended developing an executive summary or guidance for use by PEPFAR country teams and others for effectively communicating the implications and nuances of the WHO guidelines and implications of tetanus mitigation strategies by VMMC method. Comments were welcomed from representatives from WHO and CircMedTech, the manufacturer of the PrePex device. The SAB accepted all recommendations.

PROGRAMMATIC UPDATES

Key Populations Investment Fund: Tom La Salvia, Deputy Coordinator, Affected Populations, Human Rights, and Community Engagement, Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC). Tom La Salvia presented the background and current activity of the PEPFAR Key Populations Investment Fund (KPIF) - a $100 million fund launched at the UN High Level Meeting in June 2016 to expand access to proven HIV prevention and treatment services for key populations. KPIF will support innovative, key population-led approaches. It has developed five focus areas based on community input, and it received more than 150 applications before the October 31 deadline in response to its notice of funding opportunity.

Discussion covered the timeliness and effectiveness of the KPIF announcement, types of organizations that have applied, addressing of structural barriers, technical assistance, grassroots strategy for capacity building, directing of non-awardee organizations to seek to work with prime awardees, and a potential public-private funding partnership.

Stigma and Discrimination Expert Consultation: A. Cornelius Baker, Chief Policy Advisor, Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC). Cornelius Baker provided an update on activities of the PEPFAR Stigma and Discrimination Task Force, which surveyed agencies about their mitigation strategies for HIV stigma and discrimination. Most of these provide training and technical assistance, as well as capacity building. The task force also explored the curricula used for in-country
trainings. The EWG seeks to better define stigma and discrimination and to measure the impact of related activities. Additionally, Mr. Baker provided a preview of the upcoming (November 2-4, 2016) AmFAR-cosponsored Stigma and Discrimination Expert Consultation. The purpose for convening an expert consultation is to help PEPFAR better understand the complexity and dimensions of stigma and discrimination, identify what is working and how we know it is working, and develop a strategic framework for future initiatives. Recordings from the meeting will be used to produce videos for training and messaging.

SAB discussion highlighted the need to: a) accelerate efforts to reduce stigma and discrimination for PLHIV; b) ensure full access to preventive and treatment services; c) develop cultural competence and awareness in the Foreign Service Corps and others beyond ambassadors; d) sensitize the PEPFAR workforce in a timely and economical manner; and f) empower key and priority populations by supporting democracy strengthening.

PUBLIC QUESTION AND ANSWER SESSION

A TB advocate asked if TB-related stigma and discrimination would be included in implementation activities. It was noted that TB-related stigma and discrimination had been extensively discussed during planning and would likely emerge in the expert consultation.

A university professor advocated the acceleration of HPV screening and vaccination coverage in PEPFAR supported countries. Others raised concerns about VIA limitations.

A UNAIDS representative advocated for scale-up of early detection and treatment for cervical cancer in high-burden countries, noting that UNAIDS could help to support community engagement.

SUMMARY AND ADJOURNMENT

Dr. del Rio thanked all groups for their excellent presentations. In the interim between PEPFAR SAB meetings, S/GAC staff will consider more frequent communication- perhaps monthly updates and in noteworthy cases, such as the formation of a new EWG. Learning about new and ongoing activities will allow SAB members to become involved at will.

AMB Birx expressed appreciation for the SAB and the high quality of the recommendations. She asserted that it is time to consider alternative service delivery for TB such as the WHO recommended directed observed therapy.

Dr. del Rio noted that December 1 will be the last World AIDS Day message by President Obama, and he suggested it needs to convey the opportunities and challenges that lie ahead. This is a critical juncture in the epidemic.

Dr. del Rio adjourned the meeting at 5:15 pm ET.