PEPFAR Addendum to Fiscal Year 2024 Technical Considerations



Preface

This technical addendum highlights specific changes in global normative guidance released after December 2022, and is intended to help stakeholders understand how such changes may affect the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Country Operational Plan 2023 (COP23) Midpoint Review and 2024 Regional Operational Plan (ROP24) development.

Document Scope

The content in this document is limited to:

- 1. Technical areas where changes in global normative guidance issued since December 2022 up to the time of this document's posting (December 8, 2023) may impact PEPFAR program implementation (e.g., operations, investments, and/or activities that should be started or stopped).
- 2. Areas in which current PEPFAR guidance differs from global normative guidance issued since December 2022 up to the time of this document's posting (December 8, 2023), and for which we anticipate an effect on PEPFAR program implementation.
- 3. Substantial corrections to Fiscal Year 2024 (FY24) PEPFAR Technical Considerations that are likely to affect PEPFAR program implementation.

NOTE: Refer to the Monitoring, Evaluation, and Reporting (MER) Indicator Reference Guide 2.7 for information on MER updates.

Progress Update Regarding 95-95-95 Targets

In July 2023, the Joint United Nations Programme on HIV/AIDS (UNAIDS) published estimates that suggest Eswatini, Rwanda, and Zimbabwe have joined Botswana in reaching 95-95-95 targets. As of this document's posting, at least 9 additional PEPFAR-partner countries are also nearing the targets.¹

¹ Burundi, Kenya, Lesotho, Malawi, Namibia, Thailand, Togo, Uganda, and Zambia

Globally, approximately 29.8 million of the estimated 39 million (76%) people living with HIV are on life-saving antiretroviral therapy (ART), of which 20.47 million receive PEPFAR-supported services. Within PEPFAR programs, over 60% (12.5 million) of people living with HIV receive at least 3 months of ART at each refill, leading to improved clinical outcomes.² Among all people living with HIV worldwide, estimated viral suppression has risen from 40% in 2015 to 71% in 2022. Despite significant progress, gaps remain. According to UNAIDS data:²

- 43% of children living with HIV are not on treatment; of all children living with HIV, only
 46% are virally suppressed.
- In sub-Saharan Africa, adolescent girls and young women (AGYW) 15 to 24 years old account for 66% of new infections; HIV prevalence among adolescent girls and young women is more than 3 times higher than that of their male counterparts in the region.
- Globally, while 82% of women ≥15 years of age living with HIV are receiving ART, only
 72% of men ≥15 years of age are receiving ART.
- Treatment coverage and viral suppression in certain regions are far below global averages—in Eastern Europe and Central Asia, only 51% of people living with HIV are receiving ART; only 45% of all people living with HIV in the Middle East and North Africa are virally suppressed.
- Based on a subset of countries that reported available data as part of the Global AIDS
 Monitoring process, global ART coverage is lower among people from key populations
 than among the total population—with an estimated ART coverage of 65% among sex
 workers, 78% among men who have sex with men, 69% among people who inject drugs,
 and 44% among transgender people.
- Globally there were an estimated 1.3 million new HIV infections in 2022, underscoring the need to continue scale-up and improve access to effective, evidence-based HIV

² UNAIDS 2023 report. UNAIDS. July 12, 2023. Accessed November 30, 2023. https://thepath.unaids.org/.

prevention services such as pre-exposure prophylaxis (PrEP) for people at high risk of HIV infection, including key populations and adolescent girls and young women.

To accurately monitor progress toward 95-95-95 targets, countries need data systems that integrate individual patient data across all clinical sites and apply de-duplication algorithms to support effective clinical and program management, as well as serve public health surveillance and responses. Such systems can also help differentiate clients with true treatment interruptions from silent transfers.

Ending HIV as a public health threat by 2030 is within reach; however, success will require careful data analysis, innovative approaches to strengthen and expand HIV testing to identify those with undiagnosed HIV infection, and sustained viral load suppression for all people living with HIV. Ending HIV as a public health threat will also require continued focus on preventing new infections and equity in accessing HIV services, especially for key populations. Sustained impact also requires routine program monitoring with granular, accurate data (from partner-country systems when possible) that inform person-centered programs and policies.

Technical Addendum Information Aligned to Section Headings of FY24 PEPFAR Technical Considerations

6.2 Primary Prevention

• Condoms: Condoms remain an important prevention option for people able to successfully use them. Starting in COP25/FY26, the Condom Fund will be removed from discretionary budget controls to be absorbed into bilateral COP budgets. All PEPFAR operating units will be expected to incorporate procurement and distribution of no-cost and/or low-cost male and female condoms and personal lubricants into bilateral COP/ROP budgets, or work with country governments and other donors to address national need. To determine specific commodity needs, PEPFAR teams should conduct a

- detailed analysis of demand, availability, access, use, and funding source (including from partner countries and other donors) for condoms and personal lubricants.
- Post-exposure prophylaxis (PEP): World Health Organization (WHO) guidelines for PEP include occupational and non-occupational exposures to HIV (including through sex, shared needles/syringes, or sexual assault). PEP should be available to all adults, adolescents, children, key populations, and priority populations who have experienced a potential HIV exposure. Furthermore, PEP programming should include Information about how to access and use PEP and incorporate components that increase public awareness and streamline/fast-track PEP. Clients who have used or completed PEP in the 6 months prior should be offered PrEP. Updated WHO guidelines on PEP are expected in 2024.
- Long-acting injectable cabotegravir (CAB-LA): In collaboration with the Global Fund and other stakeholders, PEPFAR is currently working to roll out the limited allocation of CAB-LA in an initial 4 countries and expand to additional countries in 2024. Scale-up will continue to be coordinated centrally while commodities are constrained—likely through 2025, after which countries should be able to purchase and program CAB-LA through regular COP processes and budgets.
- DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe)
 NextGen: Elevated levels of new HIV infections among adolescent girls and young women in many geographic areas remain a concern. Thus, AGYW-combination prevention programming should remain a priority, with DREAMS programming evolving in response to specific country contexts.

DREAMS NextGen's more nuanced approach is intended to be responsive to each country's HIV epidemic context. Countries are divided into 3 epidemiological profile categories based on sub-national incidence levels, HIV burden, current DREAMS and Global Fund AGYW-programming coverage, and other factors. The category a country falls into drives DREAMS NextGen implementation as well as decisions on sustainability

and streamlining of program components. DREAMS NextGen includes complimentary intervention pathways—Core DREAMS and Enabling DREAMS. PEPFAR DREAMS countries should utilize the updated DREAMS guidance document in place of sections 6.2.2.2 and 6.2.2.3 in FY24 PEPFAR Technical Considerations.

6.3 HIV Testing Services Strategies: Reaching & Maintaining Global 95-95-95 Goals

- Social network testing: In July 2023, <u>WHO released a new recommendation</u>³ that "social network testing may be offered as an additional approach to HIV testing as part of a comprehensive package of care and prevention." PEPFAR supports this recommendation.
- Index testing: PEPFAR's Guidance on Safe and Ethical Index Testing is now available via PEPFAR's Virtual Academy.
- National HIV testing strategies: WHO has recently released an information note, "Preventing HIV misdiagnosis," reminding countries of the importance of implementing a national testing strategy that requires 3 consecutive reactive test results to increase the positive predictive value prior to establishing an HIV seropositive diagnosis. PEPFAR is available to provide technical assistance to ministries of health that choose to adopt a 3-test strategy, though this does not imply that PEPFAR is able to fund associated resources (e.g., commodities, trainings, etc.).

6.4 Optimizing HIV Care and Treatment

 Regimen optimization: For individuals weighing ≥ 30 kg, regimen optimization strategies should include use of tenofovir/lamivudine/dolutegravir (TLD) following failure of a

³ WHO recommends optimizing HIV testing services. World Health Organization. Accessed November 30, 2023. https://www.who.int/news/item/22-07-2023-who-recommends-optimizing-hiv-testing-services.

- tenofovir disoproxil fumarate (TDF)-containing, non-integrase inhibitor (non-INSTI) regimen⁴ and for routine transition from second-line protease inhibitor (PI) regimens.⁵
- Enhanced focus on tuberculosis (TB) in people living with HIV: At the 2023 High-Level Meeting on TB during the United Nations General Assembly, Member States affirmed their commitment to end TB by 2030 through the adoption of a new political declaration with ambitious targets—by 2027, 90% of people estimated to have TB will be diagnosed and treated. In support of this, PEPFAR announced a bold new effort that, over the next 5 years, aims to detect 2 million active TB cases and prevent at least 500,000 TB-related deaths among people living with HIV. Programs should review and align their HIV/TB programming to ensure they are finding the missing TB cases and contributing to the TB detection effort. Efforts should be intensified to diagnose TB in people living with HIV and avert TB-related mortality.
- Pediatric abacavir/lamivudine/dolutegravir 60/30/5 mg (pALD): A fixed-dose combination formulation is now available (and WHO endorsed⁶) for children who are at least 3 months old and weigh between 6 to 25 kg. PEPFAR-supported programs will be required to transition to pALD from separately formulated pediatric dolutegravir and abacavir/lamivudine for children in the relevant age and weight bands.⁷
- New resource with promising practices for improving pediatric and adolescent HIV
 service delivery: UNAIDS and PEPFAR produced a compendium of promising practices
 by African faith communities focused on closing gaps for children and adolescents.

⁴ Paton NI, Musaazi J, Kityo C, et al. Efficacy and safety of dolutegravir or darunavir in combination with lamivudine plus either zidovudine or tenofovir for second-line treatment of HIV infection (NADIA): week 96 results from a prospective, multicentre, open-label, factorial, randomised, non-inferiority trial. *The Lancet HIV*. Published online April 2022. doi: 10.1016/S2352-3018(22)00092-3

⁵ Ombajo LA, Penner J, Nkuranga J, et al. Second-Line Switch to Dolutegravir for Treatment of HIV Infection. *N Engl J Med*. 2023;388(25):2349-2359. doi: 10.1056/NEJMoa2210005

⁶ Hivtoolkit. GAP-F Pald introduction and rollout planning considerations for National Programmes. New HIV Drugs v2. July 22, 2023. Accessed November 30, 2023. https://www.newhivdrugs.org/post/gap-f-pald-introduction-and-rollout-planning-considerations.

⁷ Paediatric Abacavir/Lamivudine/Dolutegravir (pALD) Fixed-Dose Combination. Introduction and Rollout Planning Considerations for National Programmes - PAHO/WHO | Pan American Health Organization. www.paho.org. Accessed November 30, 2023. https://www.paho.org/en/documents/paediatric-abacavirlamivudinedolutegravir-pald-fixed-dose-combination-introduction-and

Models included in the "Compendium of Promising Practices on the Role of African Faith

Community Interventions to End Pediatric and Adolescent HIV" advance HIV testing

services for children and adolescents and may serve as a useful reference for PEPFAR

programs intending to implement similar approaches in a manner consistent with

applicable law and policy guidance regarding such programming.

- **CD4 testing:** PEPFAR has revised CD4 testing recommendations to include people living with HIV who have been out of care for 6 months or more at ART reinitiation.^{8,9,10}
- Human papillomavirus (HPV) vaccination: Recent studies suggest that HPV significantly increases (by 2 to 3 fold) the risk of HIV acquisition in women, indicating that early HPV vaccination, particularly in countries with high HPV and HIV burdens, could reduce the risk of both HIV and cervical cancer. Beginning in 2024, PEPFAR Go Further, DREAMS, and orphans and vulnerable children (OVC) teams will collaborate with stakeholders and host-county governments to accelerate HPV vaccine administration in girls 9 to 14 years old to fast-track primary prevention of cervical cancer and HIV acquisition in 15 countries. This shift represents an expansion in support of primary

⁸ Namayanja G, Watera C, Pals S, Asio J, Ssemwanga D, Sanyu G, Zheng D, Zeh C, Hackett S, Ntale J, Mwangi C, Naluguza M, Nazziwa E, Kaleebu P, Nelson L, Dirlikov E, Raizes E, da Silva J. Cyclic Acquired HIV Drug Resistance to Dolutegravir among People living with HIV in Uganda. National Remnant Samples Surveillance 2022. International Workshop on HIV Drug Resistance and Treatment Strategies. In Cape Town, South Africa; 2023 [cited 2023 Nov 29]. Available from: https://www.hivresistance.co.za/programme/

⁹ Ismael N. HIV drug resistance profile in clients experiencing treatment failure after the transition to a dolutegravir-based, first-line antiretroviral treatment regimen in Mozambique. International Workshop on HIV Drug Resistance and Treatment Strategies. In Cape Town, South Africa; 2023 [cited 2023 Nov 29]. Available from: https://www.hivresistance.co.za/programme/

¹⁰ Kalata N. HIV Drug Resistance to Dolutegravir is Uncommon Among Adults Investigated for Treatment Failure in Malawi. International Workshop on HIV Drug Resistance and Treatment Strategies. In Cape Town, South Africa; 2023 [cited 2023 Nov 29]. Available from: https://www.hivresistance.co.za/programme/

¹² Houlihan CF, Larke NL, Watson-Jones D, et al. Human papillomavirus infection and increased risk of HIV acquisition. A systematic review and meta-analysis. *AIDS*. 2012;26(17):2211-2222. doi:10.1097/QAD.0b013e328358d908

Looker KJ, Rönn MM, Brock PM, et al. Evidence of synergistic relationships between HIV and Human Papillomavirus (HPV): systematic reviews and meta-analyses of longitudinal studies of HPV acquisition and clearance by HIV status, and of HIV acquisition by HPV status. J Int AIDS Soc. 2018;21(6):e25110.
doi:10.1002/jia2.25110

prevention since PEPFAR's cervical cancer prevention activities are currently limited to secondary prevention via Go Further. PEPFAR will start scaling this effort in a few countries through increased demand generation activities, vaccine education, and HPV vaccine administration. Since PEPFAR does not currently fund HPV vaccine procurement, PEPFAR operating units will need to rely on national procurement mechanisms or other donors for vaccine supply.

- Updated approach to measurable viral load among adults, children, and adolescents:

 WHO has identified 3 key categories for HIV viral load: (1) unsuppressed (> 1000

 copies/mL), (2) suppressed (detected but ≤ 1000 copies/mL), and (3) undetectable (viral load not detected by the test used). Individuals with undetectable viral load are not at risk for transmitting HIV to their sexual partners. People with suppressed but detectable viral load (detected but ≤ 1000 copies/mL) have a near-zero risk of transmitting HIV to sexual partners, but may be at risk for treatment failure, increased all-cause mortality, and serious non-AIDS events and should receive adherence counseling and support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and follow-up viral load testing. In the sexual partners is a support and sexual partners is a support and sexual partners. In the sexual partners is a support and sexual partners is a suppo
- **Drug resistance:** Available results from surveillance of persons with virologic failure do not support a prompt switch from dolutegravir (DTG) to a PI-based regimen because most patients will not have DTG resistance at the time of virologic failure.
- Integrated service provisions for people living with HIV: To address comorbidities and
 prevalent non-communicable diseases (NCDs) among people living with HIV, PEPFAR
 encourages programs to consider person-centered models of care that leverage
 PEPFAR-supported HIV services to provide integrated services to people living with HIV,
 with a prioritization of integrated services for hypertension. WHO released the following
 documents in 2023 that address integration and NCDs:

¹⁴ The role of HIV viral suppression in improving individual health and reducing transmission. www.who.int. https://www.who.int/publications/i/item/9789240055179

- "Integrating the prevention and control of NCDs in HIV/AIDS, TB, and sexual and reproductive health programmes"
- o "Global report on hypertension: the race against a silent killer" 16

Programs should work with partners to provide integrated NCD and HIV services that align with country priorities and sustainability plans.

6.5 PEPFAR's Key Populations Approach and Strategy

• Event Driven-PrEP (ED-PrEP) in men: In 2022, WHO released a technical brief recommending that all cisgender men, trans and gender diverse people assigned male sex at birth not taking exogenous estradiol-based hormones can use ED-PrEP (also known as 2+1+1) to prevent sexual acquisition of HIV. This represents a revision to the FY 2024 PEPFAR Technical Considerations (Sections 6.2.5.2 PrEP for Men and section 6.5.1.1 Prevention for Key Populations) that describe ED-PrEP, as "an additional dosing regimen currently recommended for MSM only."

6.6 Cross Cutting

Laboratory strategies for a sustained HIV response: In 2023, global guidance was issued
on integrated diagnostics including: "Strengthening diagnostics capacity—World Health
Assembly Resolution (2023)," "WHO Essential Diagnostics List (2023)," and The

¹⁵ Integrating the prevention and control of noncommunicable diseases in HIV/AIDS, tuberculosis, and sexual and reproductive health programmes: implementation guidance. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

¹⁶ Global report on hypertension: the race against a silent killer. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

¹⁷ World Health Organization. Seventy-Sixth World Health Assembly, Agenda item 13.1 World Health Organization; 2023. Available at: https://iris.who.int/bitstream/handle/10665/371498/9789240077126-eng.pdf. Accessed November 30, 2023.

¹⁸ World Health Organization. The selection and use of essential in vitro diagnostics: report of the fourth meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2022 (including the fourth WHO model list of essential in vitro diagnostics). Geneva: World Health Organization; 2023. (WHO Technical Report Series, No. 1053). Licence: CC BY-NC-SA 3.0 IGO.

diagnostics landscape for sexually transmitted infections." PEPFAR programs should prioritize the following diagnostic integration enablers to support a sustained HIV response: (1) multi-disease testing policies; (2) collaboration across programs to support the transition from siloed to integrated laboratory services and systems; (3) all-inclusive pricing for essential testing commodities; (4) diagnostic system and service innovations (e.g., modular Laboratory Information Management Systems (LIMS), integrated sample transport, workflow optimization) that support integration across diseases at all levels of the tiered diagnostic network; and (5) laboratory continuous quality improvement (CQI) and accreditation processes for all integrated labs and testing procedures. To close current diagnostic equity gaps among priority populations, person-centered, decentralized, and community-based testing should incorporate community integrated specimen collection, referral systems, and a mix of high throughput (centralized) and low throughput (decentralized and point-of-care) testing platforms to ensure viral load, early infant diagnosis, TB, and other test results are returned within clinically relevant time frames for patient care.

• Securing information and protecting confidentiality: Information security limits access to data for authorized use and is required to protect client confidentiality—and even safety. In collaboration with host-country governments, and adhering to their relevant legislation, PEPFAR considers privacy and security protections essential components of health information system (HIS) investments and recommends allocating resources for these within data management investments. This approach has the following aspects: (1) privacy by design and practice; (2) cybersecurity; and (3) responsible data governance. (For more information, refer to WHO's "Framing the ethics of public health surveillance" resources.²⁰)

¹⁹ The diagnostics landscape for sexually transmitted infections. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

²⁰ World Health Organization. Framing the Ethics of Public Health Surveillance. Geneva: World Health Organization. Available at: https://www.who.int/activities/framing-the-ethics-of-public-health-surveillance. Accessed November 30, 2023.

• Evidence-based approaches and interventions for men: Data on progress towards 95-95-95 targets show persistent gaps among men, especially those aged 25 to 40 years old. PEPFAR programs should closely examine their clinical cascade data for gaps by age and sex and work to decrease those gaps. This focus will have the dual benefit of improving the health of men living with HIV and protecting their sex partners from HIV acquisition—including adolescent girls and young women. WHO recently released, "Men and HIV—evidence-based approaches and interventions. A framework for personcentred health services." This guidance includes evidence-based recommendations and interventions for men and provides a simplified and consolidated framework to increase men's engagement in health systems across HIV and related health services.

Mental health and psychosocial support (PSS):

- o In 2022, UNAIDS released the following guidance document: "Integration of mental health and HIV interventions—Key considerations." The guidance brings together and refers to existing HIV and mental health, PSS and other service provision guidelines, recommendations, and tools. PEPFAR operating units should utilize this UNAIDS guidance document in place of the lengthier mental health and PSS sections (sections 6.6.5.1 and 6.6.5.2 respectively) in the FY24 PEPFAR Technical Considerations.
- In 2023, WHO released, "<u>Integrating psychosocial interventions and support into</u>
 <u>HIV services for adolescents and young adults</u>."²³ PEPFAR operating unit team
 members are encouraged to review this resource.
- Behavioral and social sciences (BSS): The 2023 World Health Assembly²⁴ urged the use
 of behavioral science to develop and strengthen effective, tailored, equitable, and

²¹ Men and HIV: evidence-based approaches and interventions. A framework for person-centred health services. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

²² Integration of mental health and HIV interventions. Key considerations. Geneva: Joint United Nations Programme on HIV/AIDS and the World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

²³ Integrating psychosocial interventions and support into HIV services for adolescents and young adults: technical brief. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

²⁴ World Health Organization. Seventy-Sixth World Health Assembly, Agenda item 16.6 World Health Organization; 2023. Available at: https://apps.who.int/gb/ebwha/pdf files/WHA76/A76 R7-en.pdf. Accessed November 30, 2023.

human-centered health-related policies and functions. PEPFAR operating units are urged to deploy evidence-based approaches based on BSS that are cost-efficient, scalable, and tailored to local needs to address critical barriers such as service uptake, medication adherence, and stigma reduction. PEPFAR is developing BSS resources and identifying subject matter experts to assist PEPFAR operating units in applying a behavioral lens to close persistent gaps in prevention and treatment cascades.

• Implementation science (IS): As part of PEPFAR's commitment to following science as a core pillar, PEPFAR programs are encouraged to consider how IS can strengthen HIV programming. IS can inform the impact and sustainability of PEPFAR's programs by integrating diverse stakeholder engagement, interrogating health systems, evaluating innovative implementation strategies with an emphasis on contextual sensitivity and harmonized outcomes, utilizing interdisciplinary methods to optimize equitable care, and fostering cross-strategy learning opportunities.^{25,26}

Illustrative opportunities where PEPFAR programs can utilize IS to advance goals include defining and addressing priorities relevant to reaching priority populations, evaluating strategies to deploy new biomedical tools, determining how and where to integrate NCD care with HIV programs,²⁷ and advancing strategies to ensure lifelong care on ART. In addition, IS can inform the broader sustainability roadmap process, including determining how and where to optimize efficiencies and implementing system-level audits to identify and address inefficiencies and inequities within service delivery frameworks. PEPFAR's alignment with IS principles reflects a dynamic and strategic

²⁵ Kerkhoff AD, Muiruri C, Geng EH, Hickey MD. A world of choices: preference elicitation methods for improving the delivery and uptake of HIV prevention and treatment. Current Opinion in HIV and AIDS. 2022;18(1):32-45. doi:https://doi.org/10.1097/coh.00000000000000776

²⁶ Geng EH, Nash D, Phanuphak N, et al. The question of the question: impactful implementation science to address the HIV epidemic. *J Int AIDS Soc.* 2022;25(4):e25898. doi:10.1002/jia2.25898

²⁷ Goldstein D, Salvatore M, Ferris R, Phelps BR, Minior T. Integrating global HIV services with primary health care: a key step in sustainable HIV epidemic control. *Lancet Glob Health*. 2023;11(7):e1120-e1124. doi:10.1016/S2214-109X(23)00156-0

orientation towards achieving 95-95-95 targets with maximized impact and sustainability.

Sustainability Roadmap process: With UNAIDS and PEPFAR support, all PEPFAR-partner countries will co-develop sustainability roadmaps by World AIDS Day 2024. For the second year of COP23, PEPFAR operating units may include resources to support the development, finalization, and implementation of Country-led Sustainability Roadmaps.