CAB PrEP Introduction in Zambia Value Chain Situation Analysis

FINAL REPORT
DECEMBER 2022

PEPFAR

USAID
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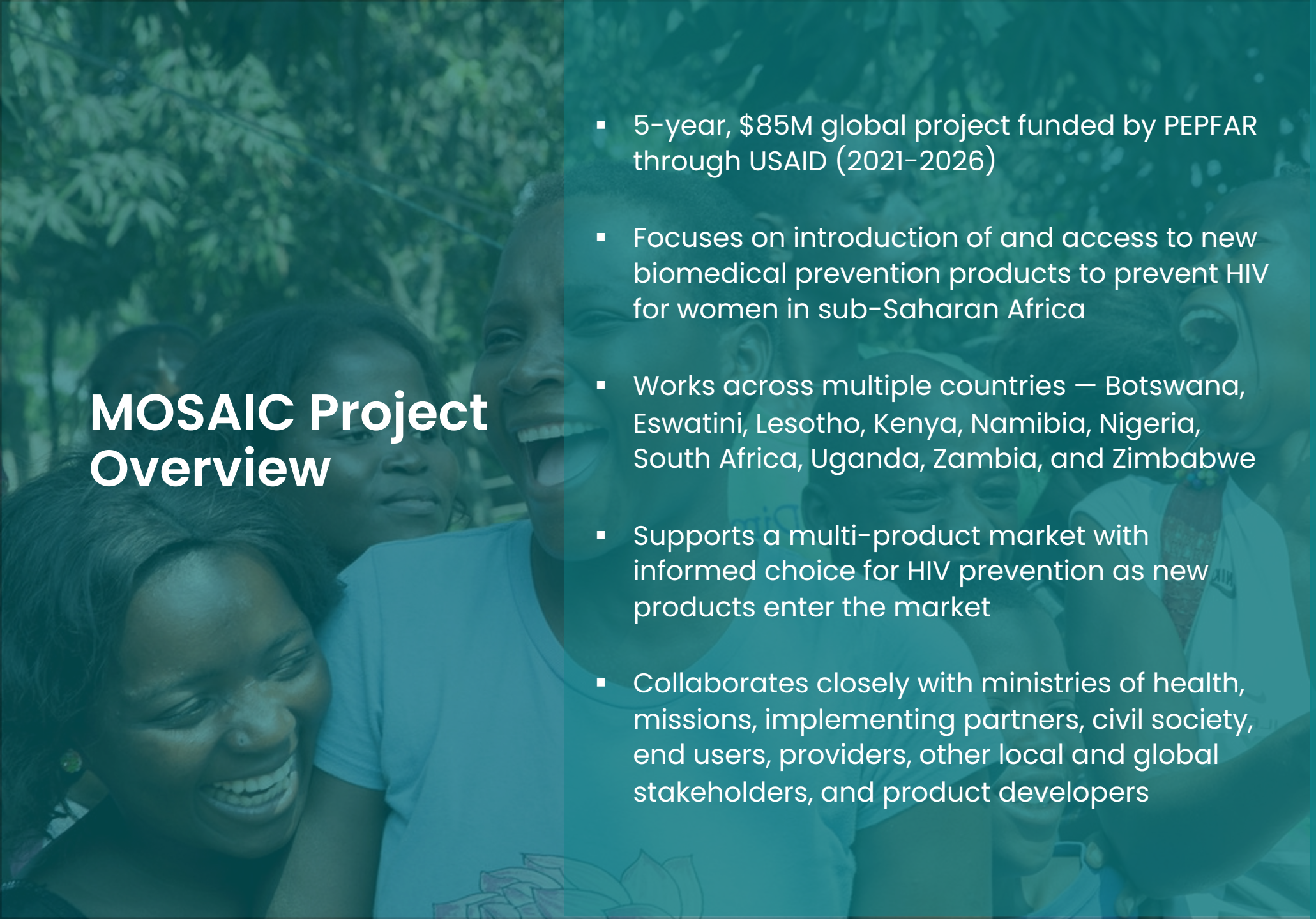
MOSAIC
Maximizing Options to Advance Informed Choice for HIV Prevention

Overview

Current situation of HIV prevention

Key findings for CAB PrEP introduction planning

Sources and notes



MOSAIC Project Overview

- 5-year, $85M global project funded by PEPFAR through USAID (2021-2026)
- Focuses on introduction of and access to new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Works across multiple countries — Botswana, Eswatini, Lesotho, Kenya, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe
- Supports a multi-product market with informed choice for HIV prevention as new products enter the market
- Collaborates closely with ministries of health, missions, implementing partners, civil society, end users, providers, other local and global stakeholders, and product developers

VALUES

Country-led

Women-focused with emphasis on AGYW

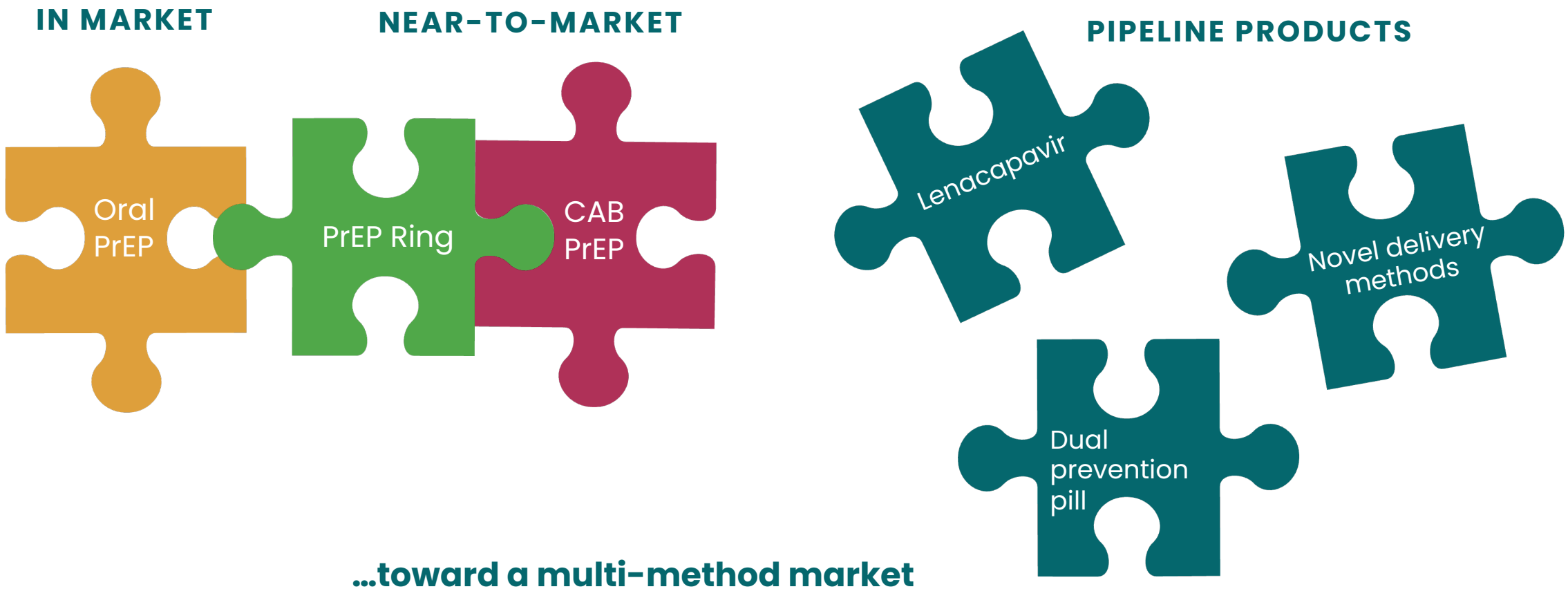
Informed choice

Equitable co-leadership

Intentionality

MOSAIC's goal is to accelerate access to new products

MOSAIC works to accelerate and expand introduction of new HIV prevention products, including those in and near to market, and to lay the groundwork for introduction of products in the research pipeline.



...toward a multi-method market

MOSAIC will accelerate access to a multi-method market through five strategic priorities

User-centered Approach

Promote a user-centered approach.

Research

Conduct research on how to enhance product availability, acceptability, uptake, and effective use.

Policy & Programs

Coordinate and provide technical assistance on regulatory review, policy, resource mobilization, supply chain, delivery, M&E, surveillance, and demand generation.

Research Utilization

Implement research utilization activities and establish mechanisms for rapid, effective knowledge exchange.

Local Partner Capacity

Strengthen and sustain local partner capacity to advocate for, design, and implement product introduction activities and research.

Overview of this analysis

- This document summarizes findings from the national situation analysis that can support the creation of a national biomedical HIV prevention platform.
- The situation analysis aims to clarify critical steps for the introduction of biomedical HIV prevention products.
- This analysis is based on several **inputs**, including a desk review, secondary research, and interviews with key stakeholders in Zambia.
- The analysis can be used by policymakers, implementers, and others **planning for introduction of CAB PrEP** (long-acting injectable cabotegravir for pre-exposure prophylaxis) in Zambia.
- This **analysis** was developed in early 2022 by members of the MOSAIC consortium.
- Summaries of similar analyses for other HIV prevention methods and other countries are available on **PrEPWatch.org**.

Overview

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Key findings for CAB PrEP introduction planning

Sources and notes

HIV in Zambia

Zambia is one of the highest-burdened HIV countries in the world. As of 2020, about 1.5M Zambians were living with HIV.[1] Despite progress over the past decade, the HIV burden remains high and disproportionately affects women.

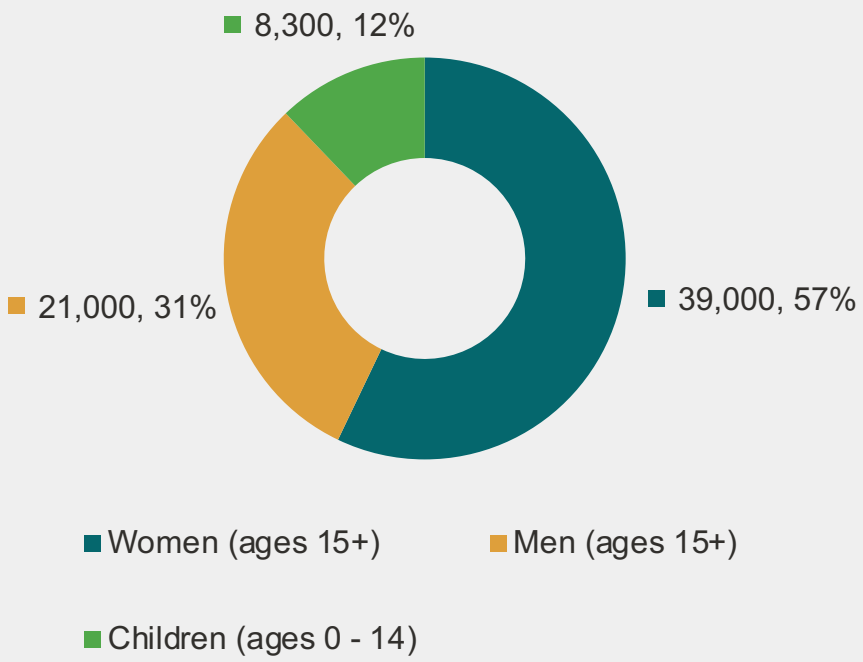
KEY STATISTICS (2021)

HIV prevalence

- National prevalence for people ages 15–49 is 9.9%[2]
- Prevalence for women (ages 15–49) is 13.2%[2] and for young women (ages 15–24) is 5.0%[1]
- Prevalence for men (ages 15–49) is 6.3%[2] and for young men (ages 15–24) is 2.0%[1]
- Prevalence among key populations (KPs) is significantly higher (e.g., 48.8% for brothel-based female sex workers); data on HIV prevalence for other KPs is unavailable.[1]

The rate of new HIV infections has declined by 6% since 2010, and AIDS-related deaths have decreased by 30% over the past decade.[3] The annual incidence of HIV infections also decreased, but women remain disproportionately affected by HIV.

New HIV infections (2020)[1]

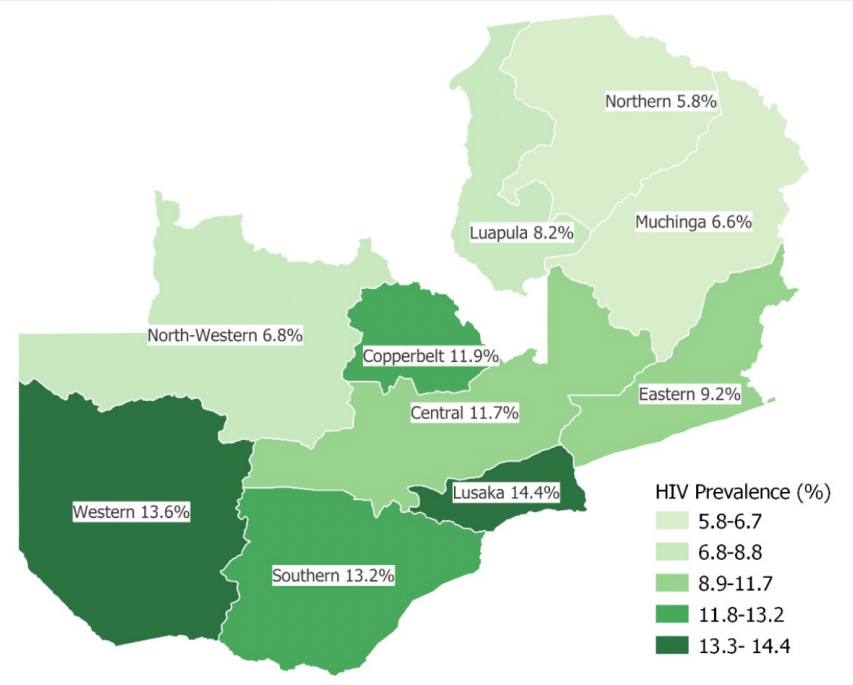


Sources: (1) UNAIDS. Zambia Country Fact Sheet, 2021. (2) ZAMPHIA Impact Assessment 2021. (3) UNAIDS. Country Progress Report – Zambia. Global AIDS Monitoring, 2020.

HIV in Zambia

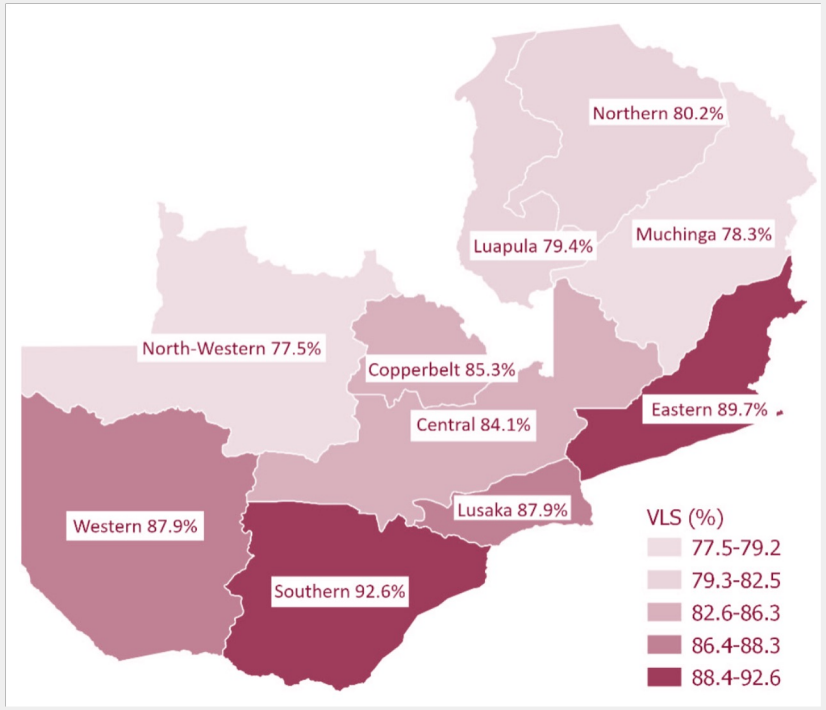
HIV PREVALENCE BY GEOGRAPHY (2021)[1]

Among adults ages 15+ years, HIV prevalence varies geographically across Zambia, ranging from about 5.8% in Northern Province to 14.4% in Lusaka.



VLS BY GEOGRAPHY (2021)[1]

Prevalence of viral load suppression (VLS)[2] among people living with HIV also varies geographically across Zambia, ranging from about 77.5% in North-Western Province to 92.6% in Southern Province.



Sources: (1) ZAMPHIA Impact Assessment 2021. (2) **Note:** Viral load suppression is defined as HIV RNA <1,000 copies per ml of plasma among HIV-positive adults.

HIV Prevention in Zambia

NATIONAL HIV RESPONSE

- The Zambian national response to HIV has been guided by the National HIV and AIDS Strategic Framework (NASF, 2017–2021) and has been led with high-level political commitment.
- Several development partners also support the HIV response in Zambia: the US Government (PEPFAR, USAID, CDC, and DOD), the Global Fund, the Swedish International Development Cooperation Agency, the UK Government (Foreign Commonwealth & Development Organization), the European Union, the World Bank, and the United Nations agencies.
- Zambia's HIV policy framework prioritizes progress in HIV testing and treatment and includes oral PrEP, with a focus on KPs and serodifferent (SDCs) couples.[1]
- In August 2017, the President launched the Test and Treat initiative and called on all Zambians to know their HIV status so they can access early treatment to avert new infections and mortality, significantly increasing HIV testing.[2]

KEY STATISTICS

As of December 2022, Zambia is close to reaching the 95:95:95 targets set by the Joint United Nations Programme on HIV/AIDS to ensure people living with HIV have access to treatment by 2025:[3]

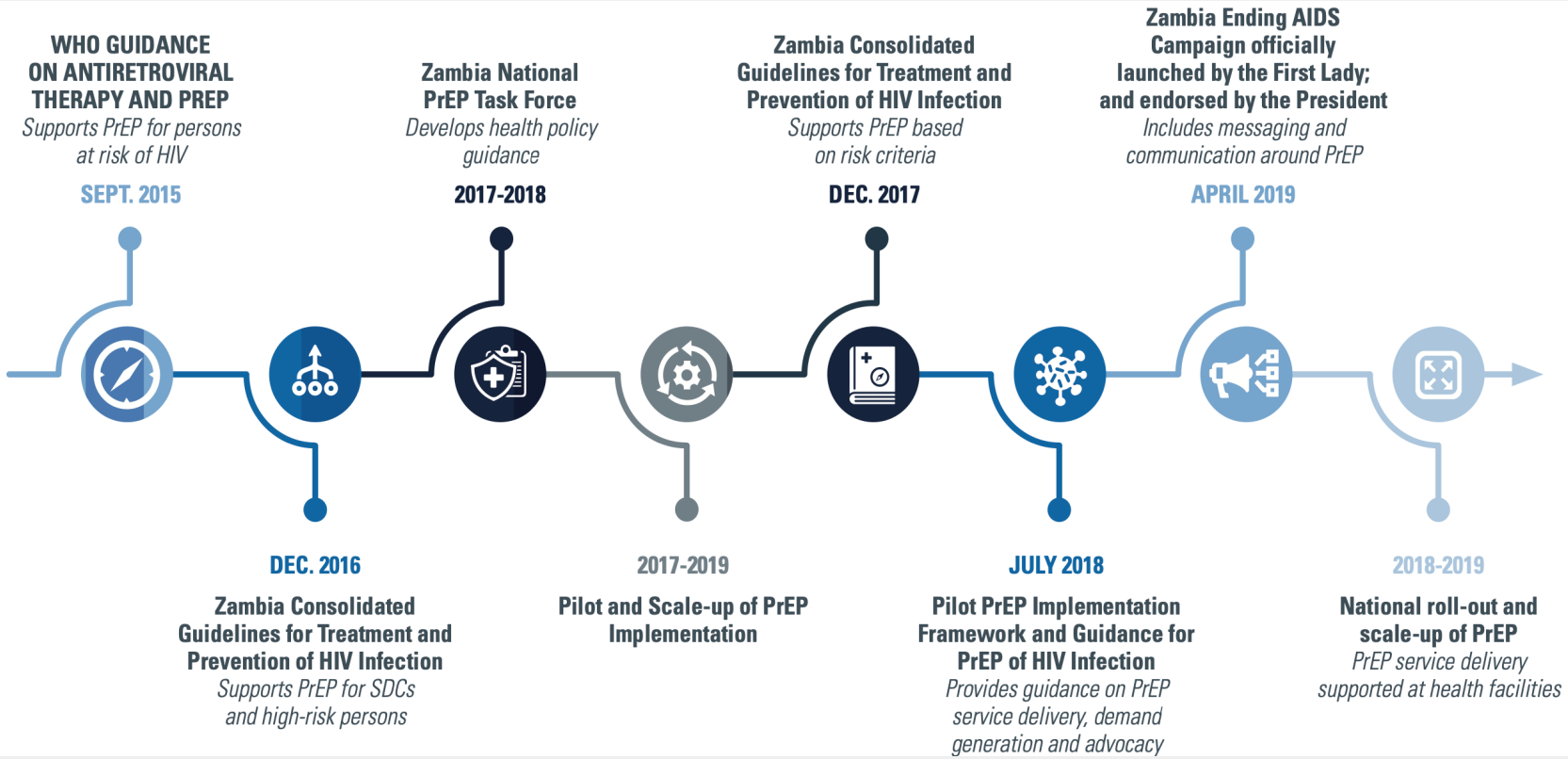
- **88.7%** of people living with HIV know their HIV status.
- **98.0%** of people who know their status and are living with HIV are on treatment.
- **96.3%** of people on treatment are virally suppressed.

Sources: (1) NASF, 2017–2021. (2) UNAIDS. Country Progress Report – Zambia, Global AIDS Monitoring, 2020. (3) ZAMPHIA 2021 Summary Sheet, December 2022.

Oral PrEP rollout in Zambia

Zambia has been implementing oral PrEP since 2017, starting in four sites in two districts (Lusaka and Livingstone). In 2018, oral PrEP was included in the HIV guidelines and a National PrEP Task Force was formed, including WHO, the National HIV/AIDS Council (NAC), the Ministry of Health (MOH), civil society, and PEPFAR implementing partners, to meet quarterly and work on policy and regulatory approval for TDF/FTC.[1]

Timeline for the introduction of oral PrEP in Zambia[2]



- As of 2020, access to oral PrEP had expanded to 906 public health facilities.[1]
- While oral PrEP is largely provided in antiretroviral therapy (ART) clinics, facilities have started to provide information and referrals for oral PrEP within family planning (FP) services and youth-friendly corners.
- The DREAMS initiative has been a major channel to reach adolescent girls and young women (AGYW) with oral PrEP services; church-related hospitals have also introduced oral PrEP.[3]
- A rapid assessment in 2020 found high acceptability and desire to access oral PrEP; however, the greatest challenge is continuation of oral PrEP.[1]
- Even during COVID, Zambia has seen growing PrEP uptake thanks to the expansion of mobile and community-based services and digital solutions.

Sources: (1) Interview with NAC 2021. (2) USAID DISCOVER-Health. Technical Update 2020. (3) USAID Zambia Community HIV Prevention Project (Z-CHPP). Best practices in programming for adolescent girls and young women (AGYW): a compendium of interventions and lessons learned from the Zambia Community HIV Prevention Project (Z-CHPP) project. PACT, October 2022.

PEPFAR-supported oral PrEP programs

All PEPFAR-supported partners provide oral PrEP services. At the national level, USAID DISCOVER-Health is still at the forefront, with the largest number of people accessing their services, and is supporting the introduction of oral PrEP by leveraging its social and behavior change activities to develop media campaigns promoting oral PrEP uptake and adherence.

Current PEPFAR-supported projects offering oral PrEP in Zambia[1]

U.S. Centers for Disease Control and Prevention (CDC) partners

- Eastern Provincial Health Office
- Western Provincial Health Office
- Southern Provincial Health Office
- Lusaka Provincial Health Office
- University of Maryland Circuits (for KPs) and Z-CHECK (for AGYW) in Lusaka and Southern provinces
- University Teaching Hospital, in Lusaka District only
- Centre for Infectious Disease Research in Zambia (CIDRZ), Lusaka Province
- Catholic Relief Services
- Development Aid from People to People (DAPP) in Zambia

U.S. Department of Defense (DOD) partner

- Jhpiego

USAID implementing mechanisms – *covering Central, Copperbelt, Luapula, Muchinga, Northern, and Northwestern provinces*

- DISCOVER-Health – currently in all USAID provinces in health posts + DREAMS centers in USAID provinces and differentiated service delivery (DSD) of oral PrEP to KPs in some districts in Central, Copperbelt, and Northwestern
- ActionHIV – Government of the Republic of Zambia (GRZ) facilities in Northern, Luapula, and Muchinga provinces
- SAFE – GRZ facilities in Central, Copperbelt, and Northwestern provinces (three districts only)
- ChekUp1 & ChekUp2 – GRZ and DREAMS facilities in Copperbelt, Central, Northwestern, and Southern provinces

Snapshot of oral PrEP in Zambia

- 356,784 cumulative initiations on oral PrEP[2]

DISCOVER-Health results as of 2020:

- 288 providers trained[3]
- 228 oral PrEP service sites, including all USAID DISCOVER-Health-supported facilities[3]
- 24 DREAMS centers and five correctional facilities providing oral PrEP[3]

Sources: (1) MOSAIC interviews. (2) USAID Zambia estimate, December 2022. (3) USAID DISCOVER-Health. Technical Update 2020.

Lessons learned from oral PrEP rollout

Successes and challenges of oral PrEP rollout, as informed by stakeholder interviews

What worked well

- **Oral PrEP rollout was well coordinated,** with strong government support through the PrEP Task Force. This support allowed for oral PrEP to be quickly integrated into HIV prevention plans, policy guidance, and national guideline frameworks in a coordinated manner.
- **Civil society organizations (CSOs) have been involved since the initiation of oral PrEP** and have helped inform planning processes. CSOs and advocates were well-positioned to build awareness of oral PrEP at the community level and develop high demand for the product once it was available.
- **DISCOVER-HEALTH tailored service delivery to meet the needs of end users** through programs such as the DREAMS centers, KP safe spaces, and home delivery of PrEP, as well as extending prescription periods of up to six months for PrEP during the COVID pandemic for increased convenience.

What was challenging

- **Drug supply** was a significant barrier in the initial rollout of oral PrEP due to low forecasting estimates, as well as cross-sharing of PrEP and post-exposure prophylaxis (PEP) drugs in HIV clinics. Furthermore, challenges emerged around the stocking of HIV test kits and systems for reporting lab HIV testing results. High PrEP discontinuation rates were linked to medication and test kit stock-outs.
- **Service provider misconceptions and misperceptions prevail for oral PrEP,** particularly for pregnant and breastfeeding people (PBFP) and groups not perceived to be at a high likelihood of exposure to HIV, such as AGYW, due to the focus on SDCs and KPs during the initial rollout. **Continuation remains a challenge for end users** due to discrimination at access locations, as well as stigma among community members and families.
- **Many clients are still not aware of oral PrEP — particularly in rural settings and for highly mobile KPs —** despite multiple efforts to implement demand generation and community sensitization strategies. Many potential end users are still not aware of PrEP due to lack of access to mass media or information that is not in local languages. Expanding engagement via CSOs at the grassroots level, community leaders, and other key influencers (e.g., religious leaders) will be critical for accurate information dissemination.
- **Monitoring & evaluation (M&E) data management has also been a challenge**, and the national M&E framework and monitoring tools need updating. Although a cascading system tracks national, facility-, and program-level data for PrEP, there are still gaps in reporting from community settings.

Source: VCSA stakeholder interviews, June 2022.

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Key findings for introducing CAB PrEP in Zambia

- **The demand for CAB PrEP is high, and people are already asking for the injectable as an alternative to the pill.** CAB PrEP may be highly desired across priority populations, especially KPs and AGYW, and is anticipated to significantly increase the overall demand for PrEP and associated uptake as a discreet, long-acting option. For AGYW and PBFP, the injectable form of contraception is noted as the most preferred option (over 75% of FP clients).

- **The success of CAB PrEP rollout will depend on a well-coordinated mechanism among stakeholders.** The PrEP Task Force provides an ideal platform for coordinating across the MOH, NAC, the World Health Organization (WHO), bilateral and multilateral donors, implementing partners, and CSOs. There is a need to further explore how to integrate PrEP within policies and guidelines for sexual and reproductive health (SRH) and FP channels, consistent with WHO recommendations for using these services as a starting point for CAB PrEP delivery. There is also an opportunity to invite private sector stakeholders into planning processes to identify opportunities to strengthen access to PrEP outside the public sector.

- **Leveraging existing oral PrEP service delivery channels will be key to reaching end users.** Stakeholders feel that existing programs have the capacity to easily integrate CAB PrEP. Ensuring that differentiated service delivery approaches (e.g., within maternal and child health [MCH] services, mobile sites) will reach clients who seek convenience and discretion is critical. Stakeholders feel that expanded community sensitization on biomedical HIV prevention methods within the existing channels will be essential before CAB PrEP introduction. Community-based volunteers also have the capacity to administer CAB PrEP and would be key stakeholders to support community sensitization.

- **Gender mainstreaming of PrEP is needed at a national level**. To prevent PrEP from becoming a “women's issue” only, there is also a need to leverage men’s health programs, such as voluntary medical male circumcision (VMMC) sites. The success of CAB PrEP and other HIV prevention products will depend on it being understood as not only for women and girls — but also for KPs, couples, and male partners.

- **The estimated high cost of CAB PrEP is a key obstacle.** Oral PrEP costs ~$1/day ($360/year) per person; CAB PrEP is expected to be much more expensive. Given the restrictive funding environment and need for support from donor agencies for HIV prevention, the private sector could be a pathway to lay the necessary groundwork for the scale-up of CAB PrEP and reach clients who can afford the drug until funding and affordability become more favorable over time.

CAB PrEP introduction framework

This value chain framework has been used across countries to support planning for the introduction of PrEP products. It identifies necessary steps for PrEP introduction and scale-up across five major categories and across priority delivery channels. It can also be used to track progress toward introduction of various PrEP products by different partners.

Value Chain for PrEP

PLANNING & BUDGETING

National and subnational plans are established to introduce and scale-up PrEP products.

SUPPLY CHAIN MANAGEMENT

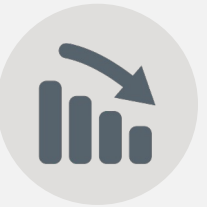
PrEP products are available and distributed in sufficient quantity to meet projected demand via priority delivery channels.

DELIVERY PLATFORMS

PrEP products are delivered by trained providers in priority delivery channels to effectively reach end users.

UPTAKE & EFFECTIVE USE

End users know about and understand PrEP products and know how to access and effectively use them.



MONITORING, EVALUATION, & LEARNING

PrEP products are effectively integrated into national, subnational, facility, community, and program monitoring systems.

CAB PrEP introduction situation analysis

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	UPTAKE & EFFECTIVE USE	MONITORING, EVALUATION, & LEARNING
Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning and private sector providers/pharmacies				
Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working groups (TWGs).**	**Register** CAB PrEP and include it on the national essential medicines list, if needed.	Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing CAB PrEP use.**	Develop and implement **demand generation strategies** that include CAB PrEP promotion.	Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.
Identify **focus populations and set targets** to inform CAB PrEP planning.	Update **supply chain guidelines and logistics systems** to include CAB PrEP.	Develop training and materials for **health care workers** (HCWs) on CAB PrEP.	Address social norms/stigma to build **community and partner acceptance** of CAB PrEP use.	Establish systems for **pharmacovigilance** and to monitor drug resistance.
Engage **community stakeholders** to inform planning for CAB PrEP rollout.	Conduct **forecasting and/or quantification** to inform procurement of CAB PrEP.	Establish **referral systems** to link clients from other channels to sites providing CAB PrEP.	Develop **information and tools for clients** to support product choice.	Conduct **implementation science** research to inform policy and scale-up.
Include CAB PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, FP).	Establish **procurement, commodity monitoring, and distribution** for CAB PrEP and associated materials.	Integrate support for **partner communication** and services for intimate partner violence response.	Support **effective use** of CAB PrEP.	
Issue standard **clinical guidelines** for delivery and use of CAB PrEP.	Establish **storage and distribution systems** that maintain temperature controls for CAB PrEP.			
Develop an **implementation plan and budget** to guide introduction and initial scale-up of CAB PrEP.				

COLOR KEY

- Opportunity to easily build on oral PrEP rollout
- Will require new effort, but no anticipated challenges
- Requires significant consideration specifically for CAB PrEP

Planning & budgeting key steps

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Convene new or existing subcommittee or task team within HIV prevention or PrEP **TWG.**	• The existing PrEP Task Force, part of the ART TWG, continues to lead the introduction of oral PrEP and is coordinated by the NAC. • During oral PrEP rollout, stakeholders felt there was a need for greater communication between different implementing partners and service providers, particularly for finding synergies across stakeholders.	• The PrEP Task Force will lead CAB PrEP introduction planning and will bring together the relevant stakeholders to guide further expansion of PrEP methods in sexual and reproductive health (SRH) and community-based models. • NAC stakeholders see the need to potentially establish a task force separate from the PrEP task force with field experts, regulators, and policy makers, as well as gatekeepers and community members who are key beneficiaries of CAB PrEP, to make rollout easier.
Identify **focus populations and set targets** for PrEP methods.	• Oral PrEP rollout initially targeted SDCs and KPs (e.g., men who have sex with men, female sex workers, transgender people, people who inject drugs, people in prisons). • Oral PrEP is now available for the general population, focusing on AGYW and PBFP. • Stakeholders feel there is a need for gender mainstreaming of PrEP. To prevent the program from becoming a "women's issue," but also for young men as well as male partners. PEPFAR sets the targets for focus populations for oral PrEP.	• Stakeholders feel CAB PrEP should be made available to all populations, with policy guidance then provided on specific focus populations (e.g., AGYW, KPs). • Stakeholders also feel there is a need for gender mainstreaming of PrEP to ensure it does not become a "women's issue" only, as well as ensuring that focus populations are inclusive of all people in terms of sexuality, sexual orientation, and gender identity. • The 2023 targets have not yet been set (as of June 2022), nor have discussions begun to include CAB PrEP within these targets. Stakeholders anticipate integration of CAB PrEP will focus on expanding PrEP access (to support product choice) rather than prioritizing subgroups for rollout.
Engage **community stakeholders** to inform planning for PrEP rollout.	• Stakeholders felt there was strong engagement of CSOs and community stakeholders during the initial planning phases of oral PrEP.	• Stakeholders expect further engagement with community stakeholders — end users, community leaders, parents and partners of younger PrEP users, grassroots CSOs, and community gatekeepers/influencers — will be needed to address stigma and consider cultural sensitivities for CAB PrEP in the Zambian context.
Include PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, FP).	• Oral PrEP has been included in the National HIV and AIDS Strategic Framework for 2017–2021. Updates to the strategic framework are under way. • Formal policies or guidelines to integrate oral PrEP in SRH, FP, and/or MCH services have not yet been developed.	• Stakeholders anticipate that the inclusion of CAB PrEP will be added as an addendum to existing policies and plans for oral PrEP (policy development usually takes about six months). • Stakeholders anticipate a phased rollout will occur after demonstration studies are completed. Facilities in Lusaka were noted as a good starting point for a phased rollout and reporting results to the PrEP TWG directors.
Issue standard **clinical guidelines** for delivery and use of PrEP methods.	• Oral PrEP was integrated into the Consolidated Guidelines for Treatment & Prevention of HIV Infection (last updated in 2020).	• Stakeholders expect CAB PrEP will need to be included as an addendum to the clinical guidelines.
Develop an **implementation plan and budget** to guide initial PrEP introduction and scale-up.	• PEPFAR is currently the leading funder for the procurement of oral PrEP in Zambia, and The Global Fund supports delivery in church-supported hospitals.	• Pending MOH leadership approval of CAB PrEP in Zambia, the PrEP Task Force will develop an introduction plan for CAB PrEP, building on the implementation plans for oral PrEP. • Stakeholders anticipate that funding for CAB PrEP will continue to be supported by donor agencies. • Given the estimated high cost of CAB PrEP, as well as the need for additional HCW training, there is an expectation that a cost analysis will need to be conducted within implementation research.

Supply chain management key steps

SUPPLY CHAIN MANAGEMENT

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Register PrEP methods and include them on the national essential medicines list, if needed.	• New products introduced in Zambia must be registered by the Zambia Medicines Regulatory Authority (ZAMRA) (reviewed once annually in December). Oral PrEP was approved in Zambia in 2017 following the creation of the PrEP Task Force.	• A product can be fast-tracked for approval depending on whether there is high interest from the MOH and development partners (e.g., WHO, PEPFAR/USAID). Stakeholders anticipate that CAB PrEP could be included in an interim circular between revisions of the PrEP guidelines. • Furthermore, a demonstration study can be conducted in a situation where the MOH and ZAMRA provide a waiver to use a product for study purposes only.
Update **supply chain guidelines and logistics systems** to include PrEP products.	• Zambia Medicine and Medical Supplies Agency (ZAMMSA) is responsible for integrating oral PrEP into supply chain guidelines and logistic systems.	• Policy guidelines and classifications will determine how CAB PrEP will be distributed and through which channels; challenges may arise in the integration of CAB PrEP into SRH or other care supply chains if it is classified as an antiretroviral (ARV) product.
Conduct **forecasting and/or quantification** to inform procurement of PrEP products.	• Quantification and forecasting are done by a small group comprised of the MOH and implementing partners based on targets set by PEPFAR. Quantification is reviewed and revised quarterly, typically with a six-month lead time for procured commodities to arrive in-country. • The challenges around oral PrEP supply and stock-outs that arose due to discrepancies in oral PrEP estimates and actual demand for the product were further exacerbated in ART clinics due to cross-sharing of the drug among PrEP, ART, and PEP programming. This affected end-user retention (e.g., due to inability to give clients a three-month supply, lack of HIV test kits, and laboratory equipment breakdown or lack of reagents). • Forecasting and quantification systems need to be improved; other products have also experienced stock-outs in both urban and rural settings (e.g., for FP commodities).	• Improvements to the forecasting and quantification systems will be important to avoid stock-outs as new PrEP methods are added to the HIV prevention plans. • Stakeholders anticipate that the MOH and implementing partners will be in charge of quantification and forecasting for CAB PrEP. However if CAB PrEP is introduced after quantification has been completed, the USAID Global Health Supply Chain–Procurement & Supply Management (GHSC-PSM) can offer technical assistance to the MOH to ensure that the procurement process begins and that the Zambia's electronic logistics management information system (eLMIS) ordering systems are updated to ensure that facilities have access to the commodity.
Establish **procurement, commodity monitoring, and distribution** for PrEP products and associated materials.	• ZAMMSA, with the support from USAID-funded GHSC-PSM, manages procurement, storage, and distribution of medicines and medical supplies for the public sector and implementing partners, including oral PrEP as well as other relevant laboratory commodities.	• Stakeholders do not anticipate any challenges around procuring CAB PrEP or additional materials required for CAB PrEP injection (e.g., gloves, alcohol wipes, syringes); the systems are already well integrated for these products in programs and facilities. However, some stock-outs of syringes may occur in rural settings.
Establish **storage and distribution systems** that maintain temperature controls for PrEP products, if needed.	• Storage and distribution systems have already been established for oral PrEP, building upon existing systems for ART.	• The maintenance of cold chain is already in place in most facilities for storage and distribution through insulated trucks, stock refrigerators, and facility air-conditioning units. However, there is still a need to figure out how syringes will be disposed of in rural settings.

PrEP delivery platforms key steps

DELIVERY PLATFORMS

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing PrEP use.**	• Oral PrEP is available at public health facilities (e.g., ART, antenatal care [ANC], and sexually transmitted infection [STI] programs), community-based programs (e.g., DREAMS centers), mobile sites (e.g., mobile KP clinics), and prison clinics. • Oral PrEP is also readily available through MCH clinics; however, further expansion to SRH and FP clinics is needed to reach AGYW and PBFP and to VMMC sites to reach men. • *See next slide for more details.*	• Stakeholders anticipate that existing oral PrEP programs should have the capacity to offer CAB PrEP, pending MOH approval and policy guidance. • There are opportunities for integration in existing community-based models (e.g., safe spaces with HCWs, DREAMS centers, and peer-to-peer referrals through CSOs).
Develop training and materials for **health care workers** on PrEP methods.	• Stakeholders noted that intensive service provider training is needed. Prior training on oral PrEP was not particularly comprehensive. • Efforts to develop training and job aids for oral PrEP faced difficulties during the initial rollout. For example, it took two years to develop a training guide. When oral PrEP became available, misconceptions about the use of drug prevailed among HCWs, given it had been available only in ARVs for ART. • Convincing the HCWs that PrEP is a useful intervention was difficult (e.g., HCWs initially saw it as additional paperwork).	• Integration of CAB PrEP will require additional training. Implementing partners anticipate two days of training will be needed to address issues such as storage, training for administration of the injection, and surveillance for adverse drug effects. • Further considerations may be needed regarding provider capacity to handle fourth generation rapid or viral load tests, if required for CAB PrEP. • Stakeholders also voiced concerns that service provider misconceptions continue to be a barrier to PrEP access. Training and information, education, and communication (IEC) materials will need be strengthened to address stigma and discrimination for PrEP, as well as ensure that providers can support clients' choices among PrEP methods.
Establish **referral systems** to link clients from other channels to sites providing PrEP.	• Under current pilot effort, facilities are establishing PrEP referral systems in SRH/FP/MCH services to have facilities for PrEP provision separate from HIV testing or escorted referrals (due to the stigma associated with these services among the general population). • Safe spaces are very limited in terms of the availability in districts and will need to work in collaboration with the facilities to establish referral systems.	• Further scale-up of referrals and integration of new products such as CAB PrEP would require additional personnel and training in HIV prevention because HCWs are primarily in ART departments (not FP). • Nevertheless, community health volunteers (CHVs) in FP and HIV clinics were also suggested as service providers who could administer CAB PrEP through the community-based distributor approach. CHVs will also play a crucial role in sensitizing communities on PrEP, especially for KPs in rural villages and hard-to-reach hot spot locations.
Integrate support for **partner communication** and services for intimate partner violence response.	• Health services (including HIV counseling and testing, ART, prevention of perinatal HIV transmission, and ANC sites) are trained to identify and respond to gender-based violence (GBV), and HIV services are integrated into GBV services. • Strategies to engage male partners via demand creation or couples counseling could also be considered.	• Stakeholders anticipate that CAB PrEP may reduce the risk of social harms or intimate partner violence given that it can be used discreetly. Reduce the risk of social harms or intimate partner

Potential delivery channels for CAB PrEP

Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning and private sector providers/pharmacies

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Integration in **public sector HIV services**	• Oral PrEP is widely available at public health facilities offering HIV services and ART. • Stakeholders noted the potential to reach clients of STI services while they are picking up condoms, lubricant, or other products.	• Stakeholders feel that there are opportunities to build on existing oral PrEP programming for the introduction of CAB PrEP. Some HCW training will be needed.
Integration in **public sector SRH/FP clinics**	• Oral PrEP has not been officially integrated in public sector facilities offering FP services; nevertheless, some women are engaged on PrEP use through FP clinics.	• The PrEP Task Force will need to engage FP stakeholders to explore further opportunities for integration of CAB PrEP as well as updates to the clinical guidelines and HCW training for administering CAB PrEP.
Integration in **public sector MCH/ANC/PNC health services**	• Currently only MCH services are providing oral PrEP for PBFP through screening of clients with antenatal care (ANC) appointments. • There are opportunities to further strengthen integration of oral PrEP within postnatal care (PNC), immunizations, and other services, including elimination of vertical transmission of HIV.	• Stakeholders feel that there are opportunities to build on existing oral PrEP programming for the introduction of CAB PrEP. Some HCW capacity training will be needed.
Integration in **NGO clinics/social franchises**	• Oral PrEP is widely available within PEPFAR/CDC-supported implementing partner organizations (see slide 10).	• Stakeholders feel that there are opportunities to build on existing oral PrEP programming for the introduction of CAB PrEP. Some HCW capacity training will be needed.
Integration in **community-based models** (e.g., faith-based organizations [FBOs], mobile, DREAMS, etc.)	• Among several implementing partner NGOs offering community-based models for oral PrEP, oral PrEP was integrated into PEPFAR-funded DREAMS centers implemented by Pact through the USAID-funded Zambia Community HIV Prevention Project (Z-CHPP), offering on-site HIV screening and initiation on oral PrEP for eligible AGYW as well as FP counseling. • CIDRZ and University of Maryland provide community support for service delivery, and DAPP/Circle of Hope are community partners for support for PrEP.	• PrEP methods (including CAB PrEP) could be integrated in faith and community initiatives through faith-based leaders. • Will require some training of community-based volunteers for CAB PrEP administration.
Integration in **private sector clinics and pharmacies**	• Consultations with KP groups have shown that they prefer to access PrEP services in the private sector as they found the quality of services to be better. • Nevertheless, policy guidelines ensure that oral PrEP is procured through the public sector; nevertheless, about 50 pharmacies (out of 600) source oral PrEP through the commercial market and sell it at a fee to end users, primarily for continuation, not initiation. • Users who access oral PrEP at pharmacies typically already have a prescription from the public health facilities and are seeking refills with reduced wait times, more discretion and convenience. • Most private clinics are still linked to the national supply chain for ARVs and could use the same mechanism to access other PrEP products. However, there is a need for greater advocacy to establish this system for HIV prevention products. • Funding for futher integration in the private sector could come from donor agencies.	• Expanded access to PrEP in the private sector – particularly for CAB PrEP, which likely will be much more expensive than oral PrEP – may be a good opportunity to offer PrEP for those who can afford to buy the drug, seek discretion, and appreciate reduced wait times in pharmacies. The PrEP Practitioners Association can be engaged to serve as an entry point and to support private sector PrEP implementation issues. • Access and provision of the injectable contraceptive DMPA-SC in private pharmacies will be a good model to study when considering expansion of CAB PrEP in the private sector.

DELIVERY PLATFORMS

Potential delivery channels for CAB PrEP

There is an opportunity to integrate CAB PrEP within existing oral PrEP services in public HIV clinics and expand on the variety of delivery channels available within community settings. There is also an opportunity to build on oral PrEP provision in ANC/PNC services and look for longer-term opportunities for further expansion within FP services.

	Access assessment			Capacity assessment		
Service delivery channels	**Reach to HIV-negative priority populations**	**Affordability of services for a range of income levels**	**Offers oral PrEP or other relevant products (e.g., condoms, FP, HIV testing)**	**Existing HIV counseling and testing services**	**HCW capacity to administer CAB PrEP injections and support follow-up**	**Link to national supply chain and temperature-controlled storage for CAB PrEP**
Public sector HIV services	High; although limited by stigma for non-KP groups	Very high; free services available through donor support	Very high; within ARV and HIV clinics	Very high	Medium; some difficulties with follow-up due to stigma	High; although potential risk of stock-outs due to shared use of Truvada or lamivudine and tenofovir in ART and PrEP services
Public sector SRH/FP clinics	Very high; particularly for SDCs, PBFP, and AGYW	Very high; free services available through donor support	Limited; need for oral PrEP integration	Medium; some HIV testing service (HTS) integration	Medium; can administer injections but need for training on PrEP methods	Medium; need to establish supply chains for PrEP and ensure limited supply maintained across types of clients
Public sector MCH/ANC/ PNC health services	Very high; particularly for SDCs, PBFP. and AGYW	Very high; free services available through donor support	High; oral PrEP available through ANC appointments	Very high	High	Medium: possible risk of stock-outs if supplies prioritized to HIV facilities
NGO clinics/social franchises	High; particularly for KPs and AGYW	High; free services available through donor support	High; wide number of PEPFAR-supported implementing partners	High	High	Medium: risk of stock-outs if supplies prioritized for HIV facilities and possible lack of cold chains or refrigerators in rural settings
Community-based models (e.g., FBOs, mobile, drop-in centers DREAMS)	Very high; particularly for AGYW and KPs	Medium; services offered for free with donor support but is high-cost programming	High; many differentiated models available for oral PrEP	High	Medium; requires training of community-based volunteers	Medium: risk of stock-outs if supplies prioritized for HIV facilities and possible lack of cold chains or refrigerators in rural settings
Private sector clinics and pharmacies	Medium; wide access to general population but limited access to KPs	Limited; need for organized support from donors for subsidized products	Medium; some pharmacies provide oral PrEP but high access to other relevant products	Medium; some clinics provide HTS	Medium; can administer injections but need for training on PrEP methods	Medium: risk of stock-outs if supplied prioritized for HIV facilities

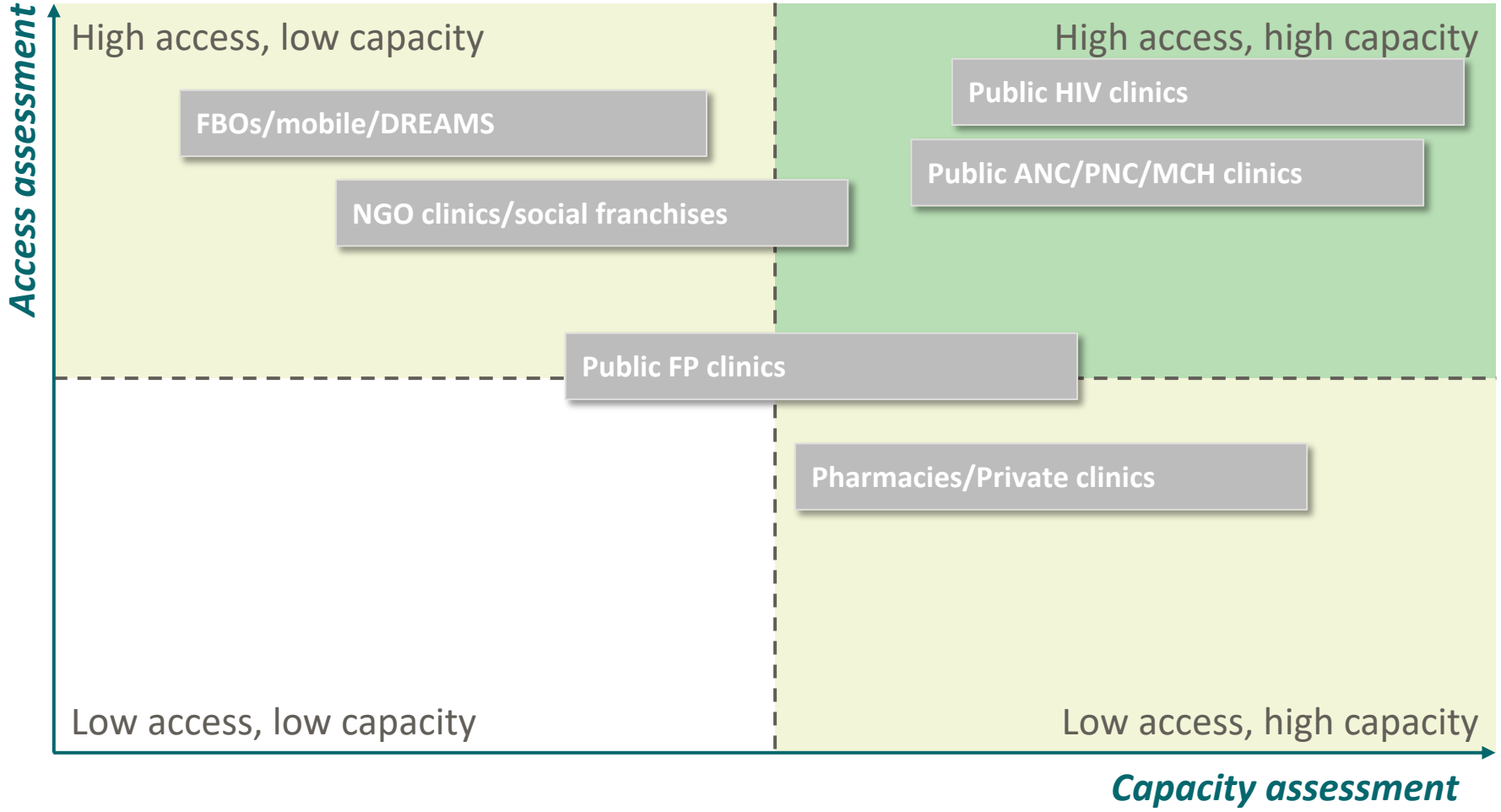
Rating key Very high / high access or capacity | Medium access or capacity | Limited access or capacity

Prioritizing delivery channels for CAB PrEP

DELIVERY PLATFORMS

- Bringing together the access and capacity dimensions allows us to assess delivery channels against **both criteria**
- Channels in the **upper right corner** have both high capacity to integrate CAB PrEP within HIV prevention services and high access to priority HIV-negative populations who would benefit from CAB PrEP.
- Channels in the **upper left** have less capacity to integrate CAB PrEP but have high access to priority HIV-negative populations.
- Channels in the **lower right** have less access to priority HIV-negative populations but have high capacity to integrate CAB PrEP.
- Channels in the **lower left** have neither the capacity nor reach to effectively integrate CAB PrEP.

Delivery channel prioritization



Uptake & effective use key steps

	Current situation of oral PrEP	What is needed to introduce CAB PrEP

Develop and implement **demand generation strategies** that include PrEP promotion.	• Several successful demand generation strategies have been deployed for oral PrEP through health talks, support groups, social media, couples counseling for SDCs, and end-user champions or peer-to-peer approaches, as well as sensitizing influencer populations (e.g., parents/partners).
	  • AGYW: Safe spaces, DREAMS centers, peer promoters, social media
	  • KPs: PrEP champions and peer promoters (for female sex workers [FSWs], people in prisons, men who have sex with men [MSM])
	  • General population: Faith-based leaders, faith and community initiatives, mass communication (e.g., radio, TV, social media platforms)
		• The many demand generation strategies for oral PrEP provide a strong opportunity for CAB PrEP.
		• Stakeholders do not anticipate challenges to integrating CAB PrEP within demand generation strategies; however, integration of CAB PrEP in these strategies will await clear MOH guidance on product availability in Zambia.

Address social norms/stigma to build **community and partner acceptance** of PrEP use.	• Stigma and myths/misconceptions continue to prevail for oral PrEP and will need to be addressed for the new HIV prevention products. • Key areas of misconceptions include low perceived need of HIV-negative clients (influencing client retention), stigma of being seen at PrEP initiation facilities, and/or fear of disclosure of sexual identity to families or risk of partner violence as a result of carrying oral PrEP pills, e.g., for FSWs, MSM, and AGYW. • The Zambia Activation Session for Youth-focused HIV Prevention Programming in 2022 revealed that youth wish their parents could be open to discussion HIV prevention and informed regarding different PrEP methods without judging their children. However, parents of adolescents and young people need support to obtain accurate, comprehensive SRH and HIV information and learn how to discuss sensitive issues with their children.[1]	• CAB PrEP is expected to be more widely accepted than oral PrEP because injections are more discreet than tablets (e.g., for FSWs, MSM). • There is a need adapt messages to promote PrEP for the general population and not perpetuate stigma and discrimination, highlighting the need for prevention beyond key population groups.
Develop **information and tools for clients** to support product choice.	• The Zambia Ending AIDS campaign communication platforms have been a key success, reaching clients with IEC materials and messages, primarily for urban populations. • However, the high cost of mass media and internet channels and limited access has limited their reach, particularly for rural populations.	• Community sensitization strategies for PrEP methods, especially CAB PrEP, could focus on more engagement with CHVs and community leaders (e.g., religious leaders) for information dissemination in local languages as well as motivating PrEP user champions to promote product use and provide accurate information.
Support **effective use** of PrEP products.	• The demand generation strategies have also served as successful models for supporting end users to effectively use oral PrEP after initiation of the method.	• Consideration of method switching from oral PrEP to CAB PrEP will be needed (e.g., ensuring end users have the option to switch products through a collaborative and open discussion with a provider). • Additional information and preparation will be needed for end users to understand the potential side effects (e.g., soreness or pain from the injection site may last two weeks after administration but diminishes over time).

Sources: (1) Zambia Activation Session for Youth-focused HIV Prevention Programming, Meeting Report & Recommendations, July 2022.

Monitoring key steps

MONITORING, EVALUATION & LEARINING

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.	• Monitoring systems and tools for oral PrEP have been integrated and cascaded through a national register at the national, facility, and program levels. As oral PrEP expanded in community settings, challenges arose in reporting through paper forms, leading to the rollout of an Electronic Health Record System using tablets. • Indicators for oral PrEP include: the number of individuals provided with PrEP, individuals who have initiated PrEP in a particular month, and individuals currently using PrEP (however, issues of data quality have been reported for this indicator). • Additional indicators are currently being integrated that track PrEP population data (e.g., measuring eligibility, adherence to PrEP for individuals who continue using PrEP, and discontinuation of PrEP).	• There are some concerns regarding whether the introduction of CAB PrEP will require additional indicators and how new indicators may crowd the already "bulky" monitoring tools. • Potential indicators for CAB PrEP include the kind of PrEP being administered, indicators to track different intervals between visits for each product, the duration of a client's use of a type of PrEP, and method switching between products during follow-up visits. Stakeholders anticipate M&E systems can rely on existing indicators at first and disaggregate the data by the type of PrEP being used.
Establish systems for **pharmacovigilance** and to monitor drug resistance.	• The pharmacovigilance form for oral PrEP is not widely circulated; general systems that cater to oral PrEP are paper-based tools that record adverse effects experienced by clients in hospitals. Forms are submitted and analyzed per province and inform decisions on the issue of side effects; however, there are no systems to elevate monitoring of adverse effects from the provincial level to the national government.	• Pharmacovigilance systems will need to be strengthened, especially for CAB PrEP, to elevate monitoring of adverse effects at a national level. This will be particularly important to monitor HIV drug resistance for CAB PrEP.
Conduct **implementation science** research to inform policy and scale-up.	• Implementation science or a demonstration study is typically required by the regulatory authorities and can be conducted pre-registration if the MOH and ZAMRA provide a waiver to use the product for study purposes. • Implementation science was conducted to inform the rollout and scale up of oral PrEP.	• Stakeholders feel that understanding CAB PrEP in the Zambian context will be important to highlight potential challenges with integration in-country (e.g., considerations on pricing, cost, and cultural acceptance). • Stakeholders also note there will be opportunities to learn from CAB PrEP implementation in other countries (e.g., South Africa and Zimbabwe).

MOSAIC project overview

Current situation of HIV prevention

Key findings for CAB PrEP introduction planning

Sources and notes

Key stakeholders interviewed

Stakeholder group	Organization	Department / Division	Name	Position
Government & Parastatal Stakeholders	Ministry of Health	HIV Prevention	Dr. Bupe Musonda	HIV Prevention Officer
	Ministry of Health	Reproductive, Maternal, Newborn & Child Health Department	Dynes Kaluba	Chief FP Officer, SRH Department
	Ministry of Health	Monitoring & Evaluation	Ovost Chooye	M&E Officer
	National HIV/AIDS/STI/TB Council	Civil Society	Daliso Mumba	Civil Society Coordinator
	National HIV/AIDS/STI/TB Council	Public & Private Department	Ellen Mubanga	Public & Private Coordinator
	Ministry of Health	Pharmaceuticals	Matthew Mwale	Assistant Director Pharmaceuticals
Donor & Multilateral Stakeholders	WHO	WHO	Dr. Lastone Chitembo	Country Representative
	USAID	Health	Musonda Chi Tembo	Community ART Advisor, Health Office
	CDC	Division of Global HIV & TB	Dr. Jackson Okuku	PrEP Coordinator
Civil Society Community-Based Stakeholders	Tubombelepamo	National CBO supporting key populations, particularly FSWs, in Central Province	Rodrick Nyendwa	Executive Director
	Treatment Advocacy & Literacy Campaign (TALC)	Advocates for equitable access to treatment, care, and support for people living with and affected by HIV	Chilufya Hampongo	Program Officer HIV Prevention/Research
	Lotus Identity	NGO promoting access to health care services for key population members and marginalized individuals	Sibusiso Malunga	Program Director
	Chreso	Provides ART services in prisons and to key populations	Nsangu Moono	Site Manager

Key stakeholders interviewed

Stakeholder group	Organization	Department / Division	Name	POC Position
NGO & Implementing Partners	USAID-Discover-Health/ZAM-HEALTH	Clinical Services; Prevention & Behavioral Interventions	Dr. Kalasa Mwanda; Dr. Mutinta Nyambu	Deputy Project Director; Deputy Project Director
	USAID-Discover Health	Monitoring and Evaluation	Dr. Luigi Ciccio	Deputy Director Strategic Information
	USAID GHSC-PSM	HIV Commodity Management	Lastone Phiri	Technical Advisor
	University of Maryland	CIRKUITS/DREAMS	Dr. Cassidy Classen	Chief of Party
	University of Maryland	M&E/PMP/Implementation of Community PrEP and ART for Adolescents (DREAMS)	Julian Chipukuma	DREAMS Coordinator
	University of Maryland	M&E/Strategic Information Lead	Pawel Olowski	SI Advisor
	University of Maryland	M&E/Strategic Information Lead	Adebayo Orlowski	M&E Advisor
	University of Maryland	Implementation and Administration	Beauty Ngandu Phiri	PMTCT Coordinator
	CIHEB (Center for International Health Education and Biosecurity) Zambia	Implementation and Administration	Linah Mwango	Deputy Chief of Party
	Center for Infectious Disease Research in Zambia	Key Population Investment Fund (KPIF)	Dr. Carolyn Bolton	Chief Medical Officer
	Center for Infectious Disease Research in Zambia	Implementation and Administration	Ranjit Warrier	Head of Lab Services
	Open Doors Project	USAID-funded bilateral focused on HIV prevention and treatment facilitation and community engagement for key populations	David Choombe, Lenny Sinkamba, Goma Nkula, Godfridah Nyambe, Sunni Wenson	Health Care Providers & Technical Advisor
Private Sector Stakeholders	Lusaka	Pharmaceutical Society of Zambia	Mr. Kennedy Saini	Pharmacists, Pharmacy Technologists, and Technicians
	Lusaka	Zambia Medical Association (ZMA)	Dr. Crispin Moyo	Medical Doctor

Selected desk review sources

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Note on terminology

In efforts to be more precise and not contribute to the stigmatization of people living with HIV or those who may benefit from HIV prevention products, we have made a few language shifts:

- **Serodifferent instead of serodiscordant**. This change reinforces that while the HIV status of people can be different, it does not put them in discord. It is completely okay for people to have different HIV serostatuses.
- **Minimizing use of the terms "risk" and "risky."** These terms can have so many different definitions and may stigmatize certain behaviors, impose labels on clients, or stigmatize living with HIV itself.
- Using **gender-neutral terms when text is not specifically about gender**. The terms are more inclusive of various gender identities.

Acronyms

AIDS	Acquired immunodeficiency syndrome
AGYW	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
CAB PrEP	Long-acting injectable cabotegravir (CAB-LA) as PrEP for HIV
CBO	Community-based organization
CDC	U.S. Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHV	Community health volunteer
CIDRZ	Centre for Infectious Disease Research Zambia
COVID	Coronavirus disease
CSO	Civil society organization
DAPP	Development Aid from People to People in Zambia
DOD	U.S. Department of Defense
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored and Safe
DSD	Differentiated service delivery
eLMIS	Electronic logistics management information system
FBO	Faith-based organization
FP	Family planning
FSW	Female sex worker
GBV	Gender-based violence
GHSC	USAID Global Health Supply Chain Program
GRZ	Government of the Republic of Zambia
HCW	Health care worker
HIV	Human Immunodeficiency Virus
HTS	HIV testing services
IEC	Information, education, and communication
JSI	John Snow, Inc.
KP	Key population
M&E	Monitoring and evaluation
MCH	Maternal and child health
MOH	Ministry of Health
MOSAIC	Maximizing Options to Advance Informed Choice for HIV Prevention
MSM	Men who have sex with men
NAC	National HIV/AIDS/STI/TB Council
NASF	National HIV and AIDS Strategic Framework
PBFP	Pregnant and breastfeeding people
PEP	Pre-exposure prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PrEP	Pre-exposure prophylaxis
PrEP ring	Dapivirine vaginal ring (DPV-VR) as PrEP for HIV
PSM	Procurement & Supply Management
SDC	Serodifferent couples
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
TDF/FTC	Tenofovir/emtricitabine (Truvada)
TWG	technical working group
USAID	U.S. Agency for International Development
VLS	Viral load suppression
VMMC	Voluntary medical male circumcision
WHO	World Health Organization
ZAMMSA	Zambia Medicine and Medical Supplies Agency
ZAMRA	Zambia Medicines Regulatory Authority
Z-CHPP	Zambia Community HIV Prevention Project

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