**New PrEP Product Implementation Plan Template**

**INTRODUCTION TO THE TEMPLATE:**

The intent of this document is to provide an adaptable template that can be utilized by national governments, their ministries, and relevant stakeholders involved in rolling out new pre-exposure prophylaxis (PrEP) products as they come into market through a programmatic approach. This implementation plan template contains vital components of the value chain and outlines considerations for countries wishing to layer on these new PrEP products in existing PrEP programs. Please note that countries wishing to introduce new PrEP products through pilot or demonstration studies will require a different approach, including development of a research protocol. An example of an introduction study with associated materials, including the research protocol, can be found [here](https://www.prepwatch.org/catalyst/).

This template is designed to be adaptable, enabling the incorporation of pertinent content that aligns with country-specific requirements. The document incorporates prompts that guide national-level consideration during the adaptation of the template. Suggestions on what to include in specific sections are provided within brackets in each section, and blue boxes provide considerations or information that countries may choose to incorporate. Once relevant text has been included in the respective subcategories, the text within the brackets and blue boxes can be removed.

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# Acronyms

3TC lamivudine

AFAB assigned female at birth

AGYW adolescent girls and young women

ASPIRE A Study to Prevent Infection with a Ring for Extended Use

CAB PrEP cabotegravir long-acting injectable pre-exposure prophylaxis

CSO civil society organization

DREAM Dapivirine Ring Extended Access and Monitoring study

FTC emtricitabine

GBV gender-based violence

HOPE HIV Open-Label Prevention Extension

HPTN HIV Prevention Trials Network

IPM International Partnership for Microbicides

KP key population

LMIS logistics management information system

M&E monitoring and evaluation

MSM gay, bisexual and other men who have sex with men

MOSAIC Maximizing Options to Advance Informed Choice for HIV Prevention

MTN Microbicide Trials Network

PEPFAR U.S. President’s Emergency Plan for AIDS Relief

PrEP pre-exposure prophylaxis

PWID people who inject drugs

SHIPP Sub-national HIV estimates in priority populations

SOP standard operating procedure

STI sexually transmitted infection

SW sex worker

TDF tenofovir disoproxil fumarate

TWG technical working group

USAID U.S. Agency for International Development

VCSA value chain situation analysis

WHO World Health Organization

# BACKGROUND

### The HIV epidemic in [insert country]

*[Describe the current HIV epidemic in the country. Highlight the prevalence and incidence, both nationally and sub-nationally, as well as how these metrics vary when stratified by age, sex, key population (KP)—transgender people, sex workers (SWs), people who inject drugs (PWID),* *gay, bisexual and other men who have sex with men (MSM)—and other priority populations, including adolescent girls and young women (AGYW). Be sure to reference other national documents/plans, as relevant.]*

### HIV prevention in [insert country]

[*Describe the national HIV prevention strategy and current progress in HIV prevention. Provide an overview of currently approved HIV prevention products and a summary of national-level data for those products, mentioning other national documents/plans as relevant. It is important to include information about current uptake of pre-exposure prophylaxis (PrEP) and successes and/or challenges in PrEP rollout among all populations, including AGYW and key populations, as part of this section. Reference any relevant implementation plans or documents.*]

### Global prevention guidance

Randomized controlled trials and subsequent open-label extension studies and demonstration projects showed oral PrEP containing tenofovir, the dapivirine ring (PrEP ring), and cabotegravir long-acting injectable for PrEP (CAB PrEP) to be protective against HIV infection across populations. As a result, the World Health Organization (WHO) recommended each of these products as additional prevention choices for people at substantial risk of HIV infection in 2015, 2021, and 2022 respectively. In addition, new biomedical HIV prevention technologies are currently in development or undergoing safety and efficacy trials. These prevention methods include various administration modalities, such as injectables, implants, vaginal and rectal gels and inserts, and intrauterine devices—among others. Multipurpose prevention technologies, which provide both HIV prevention and contraceptive benefits, are also being developed.[[1]](#footnote-2)

**For consideration:** Since additional biomedical HIV prevention technologies are on the horizon, it is beneficial to include some flexibility in your plan to make it easier to edit, adapt, and implement as these new technologies become available. Including drivers of the epidemic within this section will help to identify structural realities, including stigma, unequal gender norms, and challenging policy contexts, that make it more difficult for specific populations to prevent HIV. Understanding and responding or being sensitive to these realities within implementation plans can produce better results in the short- and long-term.

### CAB PrEP overview

CAB PrEP is a long-acting PrEP method containing 600 mg of cabotegravir extended-release injectable suspension. It is an intramuscular injection administered into the gluteal muscle. CAB PrEP should be injected only into the gluteal muscle; the pharmacokinetics and efficacy of CAB PrEP when injected in other sites have not been studied. The first two injections are one month apart, followed by injections every two months. Cabotegravir belongs to a class of antiretroviral drugs called integrase strand transfer inhibitors that reduce the ability of HIV to replicate itself inside a healthy cell. CAB PrEP delivers cabotegravir systemically, so the drug is absorbed throughout the body.

Evidence from two randomized controlled trials shows CAB PrEP is highly effective at preventing sexual HIV acquisition and can be offered as an additional prevention choice as part of combination prevention approaches. Data are emerging on the use of CAB PrEP during pregnancy and breastfeeding, with research ongoing and no concerns identified; it is well tolerated in pregnant women, and maternal and pregnancy outcomes were consistent across study participants and in comparison to study background rates. It has not yet been studied for HIV prevention for parenteral exposure. CAB PrEP may be suitable for clients seeking less frequent dosing or increased privacy around PrEP use.

In clinical trials, CAB PrEP has been shown to be highly effective in cisgender and transgender women and cisgender men, including MSM. Although data on CAB PrEP use among transgender men and nonbinary people is limited, it is likely that CAB PrEP has a similar safety and effectiveness profile in these populations. In recent randomized controlled trials, CAB PrEP was shown to be more effective than oral PrEP, though that is likely due largely to better adherence to CAB PrEP. If a client is using CAB PrEP for HIV prevention, it is important they keep up with regular appointments for injections to make sure that there is enough cabotegravir in their body to continue to prevent HIV. When a client misses a scheduled injection or discontinues CAB PrEP, concentrations of the medication in the body slowly decline. During this pharmacokinetic “tail,” CAB PrEP becomes gradually less protective against HIV acquisition, and seroconversion may occur if the client continues to be exposed to HIV.

**For consideration:** WHO recommends long-acting injectable cabotegravir as a PrEP option for PWID, specifically for preventing HIV through sexual exposure. However, the efficacy of CAB PrEP in preventing HIV through parenteral (injection) routes has not yet been determined. Research indicates that long-acting PrEP options such as CAB are generally acceptable and preferred among PWID. Nonetheless, there is significant need among the PWID community to integrate CAB PrEP into a broader range of harm reduction services, including opioid agonist therapy, medication-assisted treatment, and needle and syringe programs, rather than limiting its use solely to HIV prevention.

### CAB PrEP summary of key evidence

**Efficacy:** CAB PrEP was shown to be statistically superior to daily oral tenofovir/emtricitabine (TDF/FTC) in preventing HIV acquisition when administered every two months among cisgender men, transgender women, and people assigned female at birth (AFAB) who were mostly cisgender women in two large clinical trials. HPTN 083, a Phase 2B/3 double-blind study among cisgender men, including MSM, and transgender women, found a 66% greater reduction in risk of HIV acquisition compared to oral PrEP.[[2]](#footnote-3) In HPTN 084, a Phase 3 double-blind study among people AFAB, participants in the CAB PrEP arm were found to have an 89% greater reduction in risk of HIV acquisition compared to the oral PrEP arm.[[3]](#footnote-4)

**Safety profile:** Two Phase 3 clinical trials (HPTN 083, 084) established that CAB PrEP administered every two months for HIV prevention was well-tolerated among cisgender men, transgender women, and people AFAB in eastern and southern Africa.[[4]](#footnote-5) Injection site reactions were usually mild, associated with pain, and typically occurred after the first injection. HPTN 077 evaluated injectable cabotegravir safety, tolerability, and pharmacokinetics among HIV-uninfected males and females in sequentially enrolled cohorts of two dosing strategies; preferences for injectable versus other PrEP methods were found to be higher among U.S. men than women, but higher among men than among women in non-U.S. settings.[[5]](#footnote-6)

Available data from a small number of women who became pregnant in clinical trials suggest CAB PrEP is safe during pregnancy. CAB PrEP was well tolerated, with no complications in pregnancy or delivery due to CAB PrEP and no congenital anomalies reported.[[6]](#footnote-7),[[7]](#footnote-8) Recent evidence from the HPTN 084 open-label extension included more than 300 individuals who became pregnant while using CAB PrEP and stayed on the regimen. In this group, CAB PrEP was well tolerated, with consistent maternal and pregnancy outcomes (infant growth, birth weight, median gestational age) across study participants and compared to real-world background rates.[[8]](#footnote-9) Available data on the pharmacokinetics of CAB PrEP during pregnancy suggest CAB PrEP concentrations decrease over time during pregnancy but remain above the minimum level needed for protection, so dose modifications are not likely needed; CAB PrEP concentrations were comparable among groups in pre-, during, and post-pregnancy.[[9]](#footnote-10) Additional analysis is required, and research is ongoing. No data are available on whether cabotegravir is present in human milk, affects human milk production, or affects the breastfeeding infants of clients using CAB PrEP.

**Acceptability:** Ongoing research regarding the acceptability of CAB PrEP across Africa includes three studies: HPTN 083, HPTN 084, and HPTN 084-01, a sub-study of HPTN 084 that has enrolled participants younger than 18.

CAB PrEP research to date has included more than 7,920 participants, including cisgender and transgender women and men.2,3,4,5

### PrEP ring overview

The PrEP ring is a long-acting HIV prevention method that has been studied for HIV prevention among people AFAB and is recommended by WHO for use by cisgender women. Currently, the ring is recommended for prevention of HIV acquisition only through receptive vaginal sex. It is inserted into the vagina and should remain in place for 28 days. The ring is made of a flexible silicone material containing 25 mg of dapivirine, an antiretroviral drug. Dapivirine belongs to a class of antiretrovirals called non-nucleoside reverse transcriptase inhibitors that reduce the ability of HIV to replicate itself inside a healthy cell. The ring delivers the drug directly to the site of potential infection over the course of one month, with low absorption elsewhere in the body, lowering the likelihood of systemic side effects. Each month, clients can insert, remove, and replace the ring themselves or with the assistance of a health care provider if desired.

### PrEP ring summary of key evidence

**Efficacy:** The ring was clinically shown to reduce the likelihood of HIV-1 acquisition through vaginal sex in two randomized controlled trials: by 35% in IPM-027/The Ring Study and 27% in MTN-020/ASPIRE.[[10]](#footnote-11),[[11]](#footnote-12) Two subsequent open-label extension studies—DREAM and HOPE—found increased ring adherence compared to adherence in the clinical trials. In DREAM, 95% of returned rings showed some use compared to 83% in The Ring Study; in HOPE, 90% of returned rings showed use compared to 77% in ASPIRE.[[12]](#footnote-13) Multiple efficacy analyses among participants who used the ring consistently suggest that the PrEP ring can reduce the likelihood of HIV acquisition during receptive vaginal intercourse by 50% or more with consistent use throughout the month.[[13]](#footnote-14),[[14]](#footnote-15)

**Safety profile:** The number of pregnancies among participants actively using the ring during the clinical trials was small; however, the data collected to date show the ring is safe during pregnancy and breastfeeding, with adverse pregnancy outcomes and complications proving uncommon and dapivirine concentrations detected at extremely low levels in infant plasma samples.[[15]](#footnote-16),[[16]](#footnote-17),[[17]](#footnote-18),[[18]](#footnote-19) In a small study among lactating people, ring use was associated with low concentrations of detectable dapivirine in breastmilk and plasma and was shown to have a favorable safety profile.[[19]](#footnote-20) Results from a clinical trial of ring use while breastfeeding demonstrated a favorable safety profile for the ring in both breastfeeding people and infants.[[20]](#footnote-21)

**Acceptability:** Studies exploring the safety and acceptability of the ring among adolescents and young people AFAB ages 15–21 have demonstrated that the ring is acceptable to younger individuals, has a similar favorable safety profile among younger and older individuals, and can be used effectively by younger individuals with proper adherence support.[[21]](#footnote-22),[[22]](#footnote-23)

Research to date on the ring has included over 8,700 participants in Eastern and Southern Africa, including women of reproductive age, pregnant and breastfeeding women, adolescent girls and young women, male partners, and other key stakeholders.11,12,13,14,15,16,17,[[23]](#footnote-24),[[24]](#footnote-25)

# SITUATION ANALYSIS

*[Insert the methodology for the PrEP value chain situation analysis here (if conducted), and what the strengths and barriers were across the value chain.]*

Example text: The situational analysis highlighted the following strengths and barriers across the value chain (Table 1).

**Table 1. Strengths and barriers across the value chain**

|  |  |  |
| --- | --- | --- |
| **Category** | **Strengths** | **Barriers and Gaps** |
| Planning and budgeting |  |  |
| Supply chain management |  |  |
| Delivery platforms |  |  |
| Uptake and effective use |  |  |
| Monitoring, evaluation, and learning |  |  |

**For consideration:** A value chain situation analysis (VCSA) may be conducted by policymakers and other stakeholders supporting policy development for PrEP products. VCSAs help to assess current PrEP programming in the country and establish a common understanding of what is needed to effectively introduce a new product(s). They help identify opportunities and gaps that should inform planning for introduction and scale-up of these products. For countries wishing to conduct a VCSA, the [PrEP ring interview guides, templates, and question bank](https://www.prepwatch.org/plan4ring-toolkit/), as well as the [CAB PrEP overview guide](https://www.prepwatch.org/resources/value-chain-situation-analysis-for-cab-prep-overview-guide/) and [interview bank](https://www.prepwatch.org/resources/value-chain-situation-analysis-for-cab-prep-interview-guide/), may prove useful. An example of a [completed VCSA for Nigeria](https://www.prepwatch.org/resources/prep-introduction-in-nigeria-value-chain-situation-analysis-2022/) is also available for viewing.

# IMPLEMENTATION FRAMEWORK

*[This introductory section outlines the vision, goal, objectives, and expected activities needed to introduce new PrEP products within existing PrEP programs. The section can be adapted to include or exclude any elements as needed. Describe the objectives and outline how they will be implemented at national and sub-national levels. Describe how this implementation plan will take into consideration the needs of key populations (MSM, SWs, PWID, transgender people) and AGYW. Relevant technical working groups (TWGs) at the national level, including the key population TWG, are critical to engage in the development and implementation of the plan.* *Describe how various components of the new PrEP product introduction will be implemented, e.g., policy updates, human resources, service delivery, supply chain management, monitoring and evaluation (M&E), pharmacovigilance and resistance monitoring, demand generation, and financing.]*

**Vision:**

*[Target population, e.g., MSM, SWs, AGYW]* at increased likelihood of exposure to HIV have choices to prevent HIV infection.

**Goal:**

*[Country]* has set a national goal to achieve [*insert national goal*] by [*end date of national goal*]. The goal of this framework is to provide guidance and strategic direction to achieve these results, and thus accelerate the impact of the combination HIV prevention strategy.

**Implementation objectives:**

*[These objectives should be focused, prioritized approaches that are informed by evidence from evaluation of programmatic gaps affecting achievement of national or sub-national goals. The objectives could be identified through data triangulation, situational analyses, or other assessments.]*

Illustrative examples include:

* To increase awareness of [*insert PrEP method*] among [*insert population*] in need of HIV prevention services, with a focus on [*insert age bands or other subcategory of interest*].
* To expand access to [*insert PrEP method*] among [insert population] at increased likelihood of exposure to HIV in [*insert country / setting*] by [*XX%*] by [*insert year*].
* To increase uptake of [*insert PrEP method*] among [*insert population*] with increased likelihood of HIV exposure to [*insert absolute number or relative target percentage*] by [*insert year*].
* To ensure facilities are staffed with providers who are trained to offer and support use of [*insert PrEP method*].
* To ensure facilities’ staff are trained in providing stigma-free and non-discriminating services for *[insert priority populations].*

## Rollout Plans and Targets

*[Develop targets based on the reason for target-setting—impact, resource allocation or other reason—and the implementation approaches that will yield those target results*. *Target-setting should include considerations for method mix by population type; estimated rates of continuation, discontinuation, and reinitiation for each method; and the proportion of product that may be wasted due to accidental contamination or spillage. Targets should be as granular as possible. Analyses can be conducted to determine where PrEP impact would be greatest across different geographies and key and priority populations, such as using the UNAIDS sub-national HIV estimates in priority populations (SHIPP) tool (*[*https://hivtools.unaids.org/shipp/*](https://hivtools.unaids.org/shipp/)*). Scenario planning can inform decisions about where to focus PrEP rollout for initial doses, during scale-up, or when product becomes available through additional funding mechanism*s.]

**For consideration:** Countries may consider use of tools such as [PrEP-it](https://www.prepwatch.org/resources/prep-it/) to support target-setting. For questions about rollout analyses or target-setting, please contact the MOSAIC Consortium at info@prepnetwork.org.

## Policy Environment

### Clinical guideline development

*[Summarize the process for developing clinical guidelines and ensuring that key and priority populations are engaged in the process. Include information about who will be involved and the timeline. Countries vary on degree of specificity in their national guidelines. At a minimum, it is suggested that the new PrEP methods and targeted populations be referenced in the guidelines; clinical details could be outlined initially in this document and/or described further in clinical training curricul*a.]

**For consideration:** Clinical guidelines are often developed by a national technical working group in consultation with relevant stakeholders. [MOSAIC Template Clinical Guidelines](https://www.prepwatch.org/resources/daily-oral-prep-event-driven-prep-prep-ring-and-cab-prep-template-guidelines/) that align with WHO recommendations are available and could be helpful. It is important to consider partnering with groups led by priority populations and youth, consulting with such groups, and/or inviting priority populations and youth to be equal partners in the guidelines development process.

Feedback from countries that have trained providers and other clinic staff on multiple PrEP methods highlight the importance of training nonclinical staff, such as community health workers or village health team members, peer educators. and peer navigators, as part of the provider training process. Their participation ensures that clients are able to access correct information on PrEP methods at all service levels within facilities and their communities, which in turn supports informed choice and reduces provider burden.

## Human Resources

### Cadres

*[Specify who will be providing new PrEP product services (including clinicians, counselors, clerks, pharmacists, other facility staff, community dispensers, community health care workers, and outreach workers). What types of health care workers are allowed to prescribe/dispense the PrEP product? Are they the same as those dispensing oral PrEP?]*

### Provider training

*[Identify additional training/support needs for all staff involved in PrEP service delivery (e.g., clinical training, counseling, gender-based violence (GBV) screening and response, and sensitization and values clarification for serving key and priority populations). Determine how training will be rolled out and who is leading the training (e.g., trainers of trainers within the KP community). Include any nationally supported curricula (links or references) and/or provider job aids (appendices).]*

### Mentorship/Supervision

*[Describe the process for ensuring mentorship/supervision wherever services are provided (facility or community level). Examples include using service providers who are competent in KP prevention service delivery and providing additional support to M&E departments across all KP civil society organizations (CSOs). Who will provide this mentorship/supervision, what types of supervision, and how frequently? Supervision structures may already be in place. How will the new PrEP product(s) be incorporated?]*

**For consideration:** Countries may consider assessing available resources for continuous medical education for health care workers, training on differentiated models of service delivery for key populations and priority populations, and providing guidance on new prevention interventions to country TWGs. Training should be decentralized to reach providers in rural and peri-urban sites; consider building the capacity of existing youth- or KP-led CSOs to provide trainings.

## Service Delivery

### Service delivery model

*[How will PrEP be delivered? Will the new product be available in private and public health care services? In health care facilities or utilizing a community-based model? How will the new product be integrated into existing PrEP services? In what districts/states/counties and sites will it be available? Include here descriptions of the service delivery model utilized and the corresponding service delivery targets and tools used (e.g., materials that help clients and/or health care workers understand PrEP). What are the mitigating plans to address GBV and human rights violations, especially for key populations? Include tools in the* appendix.]

**For consideration:** Countries may consider strengthening community drop-in centers, through engagement with key and priority populations, to provide PrEP.

### Site readiness

*[What internal systems are in use to support PrEP product delivery (labs, filing, technology)? What external systems exist to support PrEP services (e.g., labs, continuous quality improvement, oversight)? What infrastructure is in place to support PrEP implementation (e.g., private rooms for counseling)? Will any modifications be needed to support the new PrEP product delivery? Describe any activities that will occur to support service delivery sites to build/enhance these systems/infrastructure, if applicable*.*]*

### Counseling components

*[Identify who will be conducting PrEP counseling and how PrEP counseling (and counseling on choice of PrEP method, including product switching) will be integrated into existing counseling (e.g., not just pre- and post-test counseling). Identify any tools that will be used to enhance choice counseling and include the tools in the appendix. Describe plans to support appropriate client continuation/effective use of the PrEP method (including discussion of potential side effects and their management), as well as regular HIV testing in accordance with guidelines that reflect the unique needs of different populations, including key populations. Explain how counseling and support will be provided and maintained throughout the users’ experiences with PrEP.]*

**For consideration:** Counseling materials are usually developed and tested by members of technical working groups. MOSAIC tools, including the [HIV Prevention Ambassador Training Package and Toolkit](https://www.prepwatch.org/resources/ambassador-training-package-toolkit/), the [HIV Prevention User Journey Tool and infographics](https://www.prepwatch.org/resources/hiv-prevention-user-journey-tool/) , and the [choice counseling provider training](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.prepwatch.org%2Fwp-content%2Fuploads%2F2023%2F10%2Fchoice-counseling-training.pptx&wdOrigin=BROWSELINK), are available and could be helpful. It is important to consult with key and priority populations and youth and/or invite them to be equal partners in developing and testing counseling materials. Consider developing a counseling charter for KPs and availing more resources for mental health support.

### Package of services offered with PrEP

*[Specify the package of services that is currently provided alongside PrEP (e.g., HIV testing services, post-exposure prophylaxis, HIV treatment, contraception, condoms and lubricants, sexually transmitted infection (STI) testing and management, family planning, GBV screening and support, mental health support). Will this be different for new PrEP products? Describe these differences, if applicable.]*

**For consideration:** Additional services could include support services such as legal counsel, safety and security, and mental health support.

### Integration with other services

*[Specify current entry/service delivery points for PrEP service delivery within other program­ming (e.g., HIV testing services, sexual and reproductive health, antenatal care, antiretro­viral therapy), as appropriate. Highlight any changes for new PrEP products, as needed.]*

### Key and priority populations

*[Describe which populations will be considered priority populations for the new PrEP products. Are these the same populations currently receiving PrEP services or are there any differences? How will services be tailored specifically for specific populations, including AGYW ages 15–24, as well as other key and priority populations?]*

## Supply Chain Management

### Product profile

*[Describe the profile of current PrEP products available in the country. Table 2 outlines those of oral PrEP, the PrEP ring, and CAB PrEP.]*

**Table 2. PrEP product profiles**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PrEP Product** | **Dosage and Administration (Adults)** | **Shelf Life** | **Storage** | **Packaging**  |
| **Oral PrEP** | Fixed-dose tablet taken daily; tenofovir (TDF) 300 mg with **either** emtri­cita­bine (FTC) 200 mg **or** lamivudine (3TC) 300 mg | 2–4 years | 20°–25°C (68°–77°F); excursions permitted 15°–30°C (59°–86°F) | Bottles of 30 tablets |
| **Dapivirine ring** | Monthly ring removal/insertion (self-administered but can be supported by a health provider); 25 mg of dapivirine | 5 years | 15°–30° (59°–86°F); exposure up to 40°C (120°F) permitted for up to 56 days | Rings are individually packaged in one-month or three-month packaging  |
| **Long-acting injectable cabotegravir** | Gluteal injection: the first two injections are one month apart, followed by injections every two months; cabotegravir extended-release injectable suspension (3 mL) at a dose of 600 mg. Recom-mended administration is with a 6ml syringe. | 3 years | 2°–25°C (36°–77°F); exposure up to 30°C (86°F) permitted (length unknown) | Single-use vials with 3ml (600mg) of CAB PrEP are packaged in boxes of 25 vials |

### Commodities associated with PrEP implementation

*[Identify additional commodities that need to be in place for successful HIV prevention product introduction and scale-up within existing PrEP programs in the country. These commodities could include supplies for additional laboratory testing requirements, HIV and STI testing, lubricant and condom provision, and/or pregnancy testing or commodities needed to provide the product during PrEP initiation and continuation. Consider additional consumables necessary for the new products, e.g., CAB PrEP administration requires non-sterile gloves, alcohol wipes, gauze pads, a sharps container, needles and syringes, and potentially longer needles for injection for clients with BMI > 30kg/m2.]*

### Product registration

*[Describe registration status for each PrEP product, including timelines for anticipated registration if a product is not registered. If the product is not registered, an import waiver, issued in accordance with requirements of national regulatory authorities, may be required.*]

### Commodity forecasting and procurement processes and systems

*[Describe the processes (tools, timelines, roles, and responsibilities) that are currently in place for forecasting and procurement of HIV prevention products. Identify any adjustments that may be needed for forecasting and procurement of new HIV prevention products and related consumables (e.g., HIV tests, consumables for CAB PrEP administration). These adjustments may include activities such as off-cycle forecasting and consultations with donors to identify funding for procurement.]*

**For consideration:** Consider use of tools such as [PrEP-it](https://www.prepwatch.org/resources/prep-it/) to support commodity forecasting. For questions about PrEP-it, please contact the MOSAIC Consortium at info@prepnetwork.org.

Inventory management and distribution processes and systems

*[Describe any updates to inventory management and distribution processes and systems. For example, consultations with central medical stores may be needed to incorporate the new products into inventory management and distribution processes and systems. Stock may need to be pre-positioned at storage levels or at site level for new products.]*

*[Describe the processes and identify who is responsible for tracking PrEP commodity distribution and stock levels and for monitoring consumption at all levels of the supply chain. Identify any updates to standard operating procedures (SOPs) for inventory management practices and systems (e.g., minimum/maximum levels). Updates to SOPs for all logistics systems, including digital systems such as an electronic logistics management information system (LMIS), may be needed as new HIV prevention products are introduced. Updated trainings and/or supportive supervision guidelines or processes may be needed for pharmaceutical and/or supply chain managers at all supply chain levels to ensure timely and accurate reporting, ordering, and distribution practices.]*

## Monitoring and Evaluation

Routine M&E of PrEP program implementation should provide PrEP providers, program implementers, policymakers, and donors with data on the scale of the PrEP program, whether the program is expanding and reaching new clients, the extent to which the program is reaching key and priority populations, and whether adverse events are occurring. These data should allow stakeholders to: (1) assess progress toward targets; (2) monitor PrEP method choice; (3) assess resources used against program outputs; (4) project resource needs; (5) estimate the coverage of the PrEP program; and (6) estimate the epidemiological impact of the PrEP program.

**For consideration:** The introduction of new PrEP products does not require the development of unique indicators, data collection tools, or data systems. PrEP introduction is generally occurring in the context of existing indicators, tools, and systems designed to monitor and evaluate oral PrEP programs. However, M&E indicators, tools, and systems designed to collect data on oral PrEP may require revision to ensure that data on new PrEP methods can be collected and incorporated. The introduction of new methods of PrEP provides an opportunity to revisit existing PrEP M&E indicators, tools, and systems to ensure they are functioning as intended and providing useful information without overburdening providers and data collectors. It can also allow for improvements (e.g., introduction of new indicators, improved data collection tools, and streamlined systems) based on lessons learned from oral PrEP implementation.

### National core indicators for PrEP

*[Insert country-specific core indicators for PrEP implementation here with details on how new PrEP methods will be incorporated. Please include indicator reference sheets where possible*.*]*

**For consideration:** While adapting data collection tools to reflect the full array of PrEP methods, ensure tools (such as client health records, PrEP registers, and reporting forms) include space to designate the method of PrEP provided and allow for the disaggregation of existing indicators by PrEP method. Changes should take into account the possibility of the introduction of additional PrEP methods in the future and should be flexible enough to incorporate those methods without substantial structural change. In a paper register, this may mean adding a column in which the PrEP method can be entered, adding additional codes for new PrEP methods, or incorporating space to designate the product volume and type associated with each client interaction. In a monthly reporting form, this may mean duplicating data entry structures for each separate PrEP method available to allow the same aggregate reporting of existing oral PrEP indicators/data elements for other methods. In a context with electronic health records, ensure that any indicators gleaned from electronic health records incorporate all PrEP methods and can be disaggregated by PrEP method. Within DHIS2, ensure that any calculated PrEP indicators incorporate data elements for all PrEP methods, maintain linkages to existing indicators for oral PrEP to ensure continuity, and allow for disaggregation by PrEP method for reporting and analysis.

**For consideration:** Currently core indicators for PrEP vary by global funder/organization, with each funder requiring or recommending slightly different indicators for monitoring PrEP programs. Each country also may have its own PrEP indicators that align with country-specific priorities or data collection systems and may differ from those required or recommended by global funders/organizations. Given lessons learned in PrEP M&E through oral PrEP implementation and the need for revisions to accommodate new PrEP methods, MOSAIC suggests use of a new set of PrEP indicators that are easy to collect, simple to incorporate into existing systems, and more useful for monitoring PrEP programs, projecting resource needs, and estimating the coverage and impact of PrEP programs. These proposed indicators align with recommendations in WHO’s Consolidated Guidelines on Person-Centered HIV Strategic Information. The full proposal outlining these indicators can be found [here](https://www.prepwatch.org/resources/proposed-new-national-level-indicators-for-me-for-all-forms-of-prep/). At a minimum, MOSAIC recommends that ministries of health consider adopting Volume of PrEP Prescribed (or PrEP Dispensed) as a new indicator in national M&E systems, based on updated WHO guidelines. For questions about these indicators, please contact the MOSAIC Consortium at info@prepnetwork.org. However, recognizing that these are suggested indicators, countries may wish to align their indicators with current donor requirements.

### M&E training

*[Identify existing training/support needs of data collectors, data capturers, and other M&E staff and ensure that any trainings include guidance on data collection for new PrEP methods. Develop a plan for training and register dissemination if changes to registers and data collection systems are required to accommodate multiple methods.]*

## Pharmacovigilance and Resistance Monitoring

*[Describe the current process of reporting seroconversions for those who have used PrEP methods, escalation, testing for resistance, results capture, and relay to relevant people, including the client. Will any modification be needed for the new PrEP products? For countries offering new PrEP methods to pregnant and breastfeeding populations, consider collecting surveillance data on birth and pregnancy outcomes, particularly for CAB PrEP.]*

## Demand Generation

*[Countries may wish to create or update their communication strategies as part of their implementation plans, working with key and priority populations including MSM, transgender people, SWs, PWID, and AGYW. The communication strategy should be aligned with general HIV prevention communication, which may include PrEP, condoms and lubricants, and/or other strategies. If this section is included in the implementation plan, briefly describe the overall plan for demand generation for PrEP and refer to a separate document, as applicable (see guidance below).]*

**For consideration:** In addition to an implementation plan, a robust communication strategy should be developed to generate demand among key and priority populations. Demand generation refers to a comprehensive marketing program that generates interest in a product or service for long-term engagement. It means driving awareness of PrEP *and* generating and maintaining interest in the use of PrEP by members of a target audience. A communication strategy serves to coordinate demand generation efforts by ensuring the use of common objectives, approaches, and messages to achieve increased PrEP uptake and continuation among priority populations. Users of the strategy are program designers and implementers who refer to it when selecting communication objectives for priority audiences and designing communication activities based on those objectives.

A communication strategy should include detailed information on specific priority audiences, including AGYW, MSM, transgender people, SWs, and PWID; communication objectives based on factors influencing uptake and use of PrEP by key and priority audiences (i.e., awareness, criminalization, stigma, attitudes and perceptions, knowledge, and social norms); and specific activities (i.e., channels, tactics, and messaging) to generate demand.

Communication strategies to support PrEP uptake and use by AGYW, MSM, transgender people, SWs, PWID, and other priority populations should include analysis of and mechanisms to address legal barriers, stigma and discrimination, health care providers’ attitudes, and prevalent gender and social norms that affect PrEP use, as well as the roles of key influencers such as partners, parents, and other identified influencers. Tools such as the [PrEP Communications Accelerator](https://www.prepwatch.org/resources/prep-communications-accelerator/) and the [PrEP Category Positioning Strategy](https://www.prepwatch.org/resources/prep-category-positioning-strategy-for-adolescent-girls-and-young-women/) may be helpful in developing communication strategies to increase PrEP uptake across several audiences. An example of a communications strategy from Malawi can be found [here](https://www.prepwatch.org/wp-content/uploads/2022/07/Malawi-PrEP-Communications-Strategy-2020-23.pdf). A communications strategy template from MOSAIC will be forthcoming.

## Budgeting and Financing

*[Describe funding for PrEP overall and funding sources for the new PrEP products and associated materials. Costs will be based on the country plan for rollout and the targets, as described on page 13. Costs should include both site-level costs, which can easily be estimated using PrEP-it (*[*https://prepitweb.org/*](https://prepitweb.org/)*) if targets have been set using that tool, and above-site-level costs. Site-level costs may include staff time, commodities (including the cost of the PrEP products as well as associated materials such as syringes, sharps containers, gloves, HIV test kits), capital and equipment costs, laboratory costs, and overhead. Above-site-level costs may include costs of staff training; development and implementation of demand creation campaigns, including those informed by and for key and priority populations; systems strengthening (e.g., for M&E, supply chain management); policy and guideline development; program management; quality improvement/quality assurance processes; and commodity importation, storage, and distribution, if not included in the site-level commodity costs. When describing costs, it can be helpful to indicate whether specific line items come from the national PrEP- or HIV-specific budgets or from another funding stream, such as the general health system budget or donor funds. Describe any funding gaps and plans to fill those gaps, if appropriate.]*

# **APPENDICES**

*[Include any additional documents or data that will be used for PrEP implementation, such as job aids and demand creation materials.]*

## Appendix 1. Implementation Plan Timeline

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** | **Mar** |
| Policy Environment |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |
| Human Resources for Health |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |
|  Service Delivery |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |
| Supply Chain Management |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** | **Mar** |
| Monitoring and Evaluation |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |
| Pharmacovigilance and Resistance Monitoring |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |
| Demand Creation  |
| Activity 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| Activity 3 |  |  |  |  |  |  |  |  |  |  |  |  |

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