

CATALYST Interim Learnings (May – November 2023)

Topline findings from the first CATALYST interim analysis have important implications for PrEP programming in the context of choice.

CATALYST Overview

The CATALYST study, under the MOSAIC project, uses mixed methods to characterize and assess the implementation of an enhanced service delivery package providing choice of PrEP products among women across 28 PEPFAR delivery sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe. Data collection began in May 2023. By November 30, 2023, 2,407 women were enrolled in the study. During this timeframe, CATALYST was implementing stage I of the study, in which participants were offered a choice of oral PrEP or the PrEP ring. Injectable cabotegravir for PrEP (CAB PrEP) will be added in stage II once the product is approved and available in country.

In this first interim analysis, the MOSAIC team provides key learnings from preparing for the delivery of PrEP choice, a summary of challenges experienced in implementing the enhanced service delivery model and the solutions introduced, programmatic considerations for countries preparing to introduce new PrEP methods, and a list of publicly accessible tools and resources used in CATALYST and that are relevant for program planning. Data from the interim analysis are not yet publicly available; this brief focuses on key learnings from study start-up and early implementation that can inform programmatic rollout of PrEP choice. While CATALYST study participants are women, many of the lessons learned to date are applicable to national PrEP programs.

KEY TAKEAWAYS THROUGH NOVEMBER 2023

Participants take advantage of choice. Substantial numbers of CATALYST participants choose the ring, including sex workers and previous oral PrEP users (not using PrEP at the time of enrollment).

It is important to invest time in routinely training providers on choice counseling, oral PrEP, and new PrEP methods.

Most providers find delivering PrEP choice counseling to be appropriate, feasible, and acceptable.

Many clients have not heard about PrEP before and should be counselled accordingly.

Quality improvement methods can be used to tailor and strengthen the delivery of PrEP choice in each service delivery setting as new products are introduced.

Preparing for programmatic rollout of PrEP choice

For CATALYST to launch, new PrEP methods needed to be approved by the national regulatory authority in each country. In addition, national clinical guidance for the new method needed to be drafted, training curricula reviewed and approved by ministries of health, and providers trained. Key learnings from these preparatory steps follow.

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GUIDELINE DEVELOPMENT

- 1) Set the format:** Determine if existing guidelines should be updated, an addendum is needed, and/or a PrEP implementation plan will be developed prior to introduction. Use available resources to expedite the process: the [guideline template](#) and [PrEP implementation plan template](#).
- 2) Plan ahead:** Begin the guideline development process prior to product approval if possible. Pilot the guidelines and allow for updates based on actual implementation experience.
- 3) Make guidance practical:** Balance the level of detail in guidelines. Keeping them PrEP-method agnostic, or inclusive of all new PrEP methods, creates space for future updates. However, having too little method-specific guidance may leave providers unprepared for addressing nuances of use, especially if an additional operational plan for delivery specifics is not developed to ensure uniform delivery across partners/facilities.

KEY QUESTIONS TO INFORM PrEP GUIDELINE DEVELOPMENT AND EARLY IMPLEMENTATION PLANNING

- Is there a minimum age or weight for use in the country registration/label of the PrEP product?
- Can minors (or emancipated minors) access products?
- Can a method be initiated or continued during pregnancy or breastfeeding?
- Are there contraceptive requirements associated with use of any new PrEP methods?
- What is the standard dispensing schedule? Is there flexibility?
- What length of time defines restarting? What procedures are required to restart (if different from initiation)?
- CAB only: Will bridging—the process of covering anticipated gaps in protection resulting from postponed CAB injections with other PrEP—be with oral TDF-based PrEP or oral CAB?
- What is the recommended HIV testing algorithm for initiation and use, if different from the standard algorithm?
- What are the recommendations for HIV testing following discontinuation?
- What safety testing will be required prior to PrEP initiation, if any? Is any continued safety monitoring required?
- What considerations should be addressed regarding switching between methods?
- What factors related to administration or disclosure should be

PROVIDER TRAINING

Most providers have experience providing oral PrEP, but the interim analysis identified some oral PrEP knowledge gaps that warranted refresher training. Further discussions with teams about how to improve provider attitudes on some aspects of PrEP provision—especially for adolescent girls and young women—should also take place. Providers are primarily concerned about clients' ability to return on time and take oral PrEP on schedule and about the efficacy of the ring. However, most providers find delivering PrEP choice counseling to be appropriate, feasible, and acceptable.

PROVIDER TRAINING LEARNINGS

- First impressions/introduction to products sets the tone for provider acceptance and knowledge base.
- Develop a training plan that fits best: site-based vs. centralized; full days vs. half-days. Consider how to minimize disruptions to service provision.
- Dedicate enough time to cover clinical trainings on new methods, as well as choice counseling and any necessary refreshers (e.g., oral PrEP boosters, LIVES/first-line violence response support).
- Recommend competency-based training (pre- and post-knowledge/attitude testing).
- Incorporate scenarios and role-plays to engage participants and enable them to demonstrate aptitude, including non-judgmental, client-centered counseling skills.
- Anticipate high staff turnover—develop a plan to rapidly train and on-board new providers.
- Note that continued training is essential. Monitor early implementation and provide refreshers through in-service training or offer Continuing Medical Education (CMEs) to address knowledge gaps.

CATALYST Enhanced Service Delivery Model

As shown in Figure 1, the CATALYST enhanced service delivery model for provision of PrEP choice consists of inputs at multiple levels. Across CATALYST’s 28 service delivery sites, teams have encountered challenges to implementing PrEP choice and identified solutions that they will introduce as the study progresses.



Figure 1. CATALYST enhanced service delivery model.

CHALLENGES	SOLUTIONS
Individual level	
<ul style="list-style-type: none"> Individualized PrEP choice counseling sessions are lengthy Limited resources for PrEP follow-up and PrEP use support options 	<ul style="list-style-type: none"> Increase PrEP choice sensitization with clients prior to seeing provider to increase efficiency in counseling sessions Counsel clients on potential side effects, benefits, and adherence challenges to ensure informed choice Refine and strengthen IEC materials for clients
<ul style="list-style-type: none"> Gaps in integrated service delivery 	<ul style="list-style-type: none"> Utilize QI to strengthen integrated services and expand PrEP support strategies
Provider level	
<ul style="list-style-type: none"> Time and practice necessary to master choice counseling and provision of new PrEP methods Staff turnover requiring training new providers 	<ul style="list-style-type: none"> Adequate provider training, including sufficient time spent on choice counseling, supported by district and facility managers Refresher training on existing PrEP methods to identify knowledge gaps before new product introduction Continued training and follow-up mentorship for providers on PrEP choice job aids and messaging tools Capacitate master trainers within districts and facilities
<ul style="list-style-type: none"> Providers have limited time to add on additional services Complex job aid tools 	<ul style="list-style-type: none"> Refine and strengthen choice counseling tools, simplify job aids
Facility level	
<ul style="list-style-type: none"> Current registers only accommodate oral PrEP 	<ul style="list-style-type: none"> Develop standardized monitoring and reporting systems, including PrEP choice indicators and accommodate switching between multiple methods
<ul style="list-style-type: none"> Consistency in test kit supplies and need for quality assurance PrEP stockouts 	<ul style="list-style-type: none"> Develop/strengthen adherence to commodity management policies and procedures, including accurate forecasting and timely reordering
<ul style="list-style-type: none"> Inefficient client flow and long queues 	<ul style="list-style-type: none"> Establish a feedback mechanism for continuous improvement Consider user-friendly, differentiated service delivery models that welcome diverse backgrounds and lifestyle choices
Community level	
<ul style="list-style-type: none"> PrEP stigma Knowledge gaps and misinformation 	<ul style="list-style-type: none"> Debunk prevalent myths and misconceptions about HIV and PrEP with widespread, targeted community education efforts Conduct stakeholder mapping and form community and youth advisory boards to address stakeholder concerns Engage community leaders and youth networks in new PrEP product advocacy and education

CATALYST Tools & Resources Available for Programmatic Adaptation

Unless otherwise indicated, resources can be found on the [CATALYST Study Implementation Materials](#) page on PrEPWatch.

Tool/Resources	Description
Guideline and Implementation Plan templates	The PrEP guideline template intends to expedite policy updates to include new PrEP methods and is reflective of all WHO guidance on PrEP. The PrEP Implementation Plan template was designed to help expedite the operational next steps for PrEP planning, to clearly outline PrEP delivery plans for the country. These templates were co-developed by MOSAIC, USAID, Global Fund and WHO.
PrEP ring clinical training	Slide deck , easily adaptable, classroom based <ul style="list-style-type: none"> • Consider developing into self-led modules • Ideal to have pelvic models and demo rings for hands-on learning • Consider integrating supervised insertions on early clients
CAB PrEP clinical training	Tool kit , adaptable for self-led and/or classroom-based <ul style="list-style-type: none"> • Completion of self-led training prior to classroom recommended; may not be feasible in all settings • Intensive training of trainers (TOT) provided to capacitate master trainers • Consider offering a TOT to key MOH staff and implementing partners as a kickoff to CAB PrEP program discussions and prior to guideline development to increase knowledge of the new PrEP method to guide decision making
PrEP Factsheets	This includes clinical information factsheets for oral PrEP, CAB PrEP, and PrEP ring as well as factsheets on product use considerations specifically for pregnant and breastfeeding populations and prevention HIV as a transgender or nonbinary person.
Pelvic models	The CATALYST model has found this model to be most helpful to support PrEP ring counseling and educate potential users about where the ring is situated in the body.
Demo ring kits	A placebo/demonstration ring is provided in this kit alongside product use instructions and a demonstration video.
Job Aid: Acute HIV Infection Screening	These job aids can assist providers in ruling out HIV infection by offering guidance through three steps: HIV testing, HIV recent exposure assessment: determining need for PEP instead of PrEP, and acute HIV infection assessment. The job aids cover ruling out HIV acquisition for new or returning adherent or non-adherent clients using oral PrEP, PrEP ring, or CAB PrEP.
Job Aid: PrEP Use Support	This template intends to support sites in determining which PrEP support options are offered to clients, and once adapted locally, support providers in discussing options with their clients to find options that might work best for them.
Job Aid: GBV Screening and Disclosure Counseling	This tool is useful in GBV screening and guiding conversations on PrEP use disclosure.
Job Aid: PrEP ring initiation steps and counseling messages	This job aid outlines initiation steps and counseling messages for the PrEP ring.
Job Aid: CAB PrEP initiation steps and counseling messages	This job aid outlines initiation steps and counseling messages for CAB PrEP.
HIV Prevention User Journey Tool	The HIV Prevention Journey Tool was developed to support informed choice: <ul style="list-style-type: none"> ▪ Making clients and providers aware of their options ▪ Providing use, effectiveness, and attributes details ▪ Supporting clients in their journey to select the most appropriate HIV prevention plan It is being used across CATALYST sites as a part of informed choice counseling.