

The CATALYST study (Catalyzing Access to New Prevention Products to Stop HIV) is an implementation study that will characterize and assess the implementation of an enhanced service delivery package providing **informed choice** of pre-exposure prophylaxis (PrEP) products among women¹ at PEPFAR sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe.

Informed choice means individuals have the autonomy, knowledge, and freedom from coercion at any given time to select the best HIV prevention method for them among options available in a specific market.

Background

Although oral PrEP initiations have increased globally, uptake and effective use remain suboptimal among many populations. HIV incidence remains high in eastern and southern Africa, particularly among adolescent girls and young women (AGYW) younger than 25, pregnant and breastfeeding people (PBF), female sex workers (FSWs), and transgender people. New PrEP methods are currently in development or nearing market entry. Two methods soon to enter the market are the dapivirine vaginal ring (PrEP ring) and injectable cabotegravir for PrEP (CAB PrEP). CATALYST is designed to generate evidence to accelerate access to a choice-based HIV prevention portfolio and ensure new prevention products reach and can be used by those who need them most.

Study Overview

Implemented through Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC), a five-year global project funded by the U.S. President's Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID), the CATALYST study will deliver an enhanced service delivery package providing choice of oral PrEP, the PrEP ring, or CAB PrEP among women in real-world service delivery settings at 28 sites across five countries. In each country, CATALYST will be implemented by a local partner and in partnership with the Ministry of Health. CATALYST will introduce a service delivery package (Figure 1) that supports PrEP choice; addresses needs at the individual, provider, facility, and community levels; and uses quality improvement methods to refine the components of the delivery package.

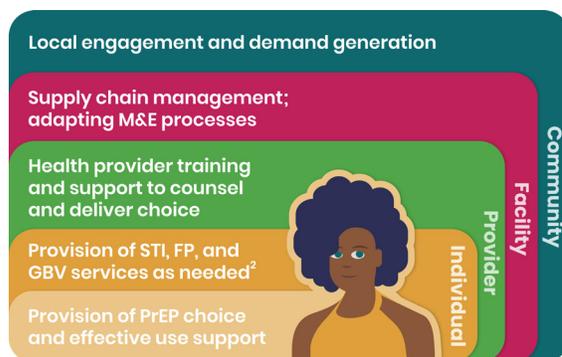


Figure 1. Enhanced service delivery package elements, delineated by individual, provider, facility, and community levels

Study Objectives

- **Objective 1:** Characterize the implementation of an enhanced service delivery package for informed PrEP choice for women in public health service delivery sites and assess facilitators of and barriers to implementation for individuals, providers, facilities, communities, and health systems.
- **Objective 2:** Describe patterns of PrEP use and use effectiveness in the context of informed PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns.
- **Objective 3:** Describe clinically relevant indicators among PrEP users, including rates of HIV infection and drug resistance among PrEP users who acquire HIV following PrEP initiation or had undetected HIV prior to PrEP initiation.

¹ For this study, the term “women” is inclusive of individuals assigned female at birth of any gender identity or individuals assigned male at birth who identify as women

² Provision of sexually transmitted infection (STI), family planning (FP), and gender-based violence (GBV) services as needed

Stages of the CATALYST study



Figure 2. Stages of the CATALYST study. Stage I will offer oral PrEP and PrEP ring, which are currently approved for use. In each country, Stage II will add CAB PrEP once it has been approved by the national regulatory authority and donated product is available on site.

Study Design

The CATALYST study includes two main components, in addition to several smaller, nested studies. The evidence generated from these studies will guide HIV prevention programs and policy tailored for real-world settings.

Component I – In a prospective cohort study, a group of HIV-negative women will be followed over time to learn about their preferences, choices, and effective use of the PrEP products offered.

Component II – A process evaluation will document the implementation of informed PrEP choice and the improvements made during the life of the CATALYST study and will inform a core implementation package for scale-up. This study component involves periodically gathering service site data and conducting qualitative interviews about the acceptability, feasibility, and cost of implementing informed PrEP choice.

Additional nested studies that are part of CATALYST include:

- An acceptability study with community members and influencers (parents and partners) to understand perceptions of and support for PrEP choice in local contexts
- A “prevention effective use” study to evaluate individuals’ effective use of their chosen PrEP method in relation to their potential exposures to HIV
- A costing study to evaluate the cost of implementing each PrEP product in real-world contexts
- A study on HIV testing to explore the use of rapid antigen and DNA and RNA tests to identify delayed HIV seroconversion among CAB users and to assess HIV drug resistance among those who become HIV positive while using any PrEP product

Cohort participants will be followed in Stage I until CAB PrEP becomes available (up to 18 months) and for up to 24 months in Stage II. All other study activities will be completed within this time frame.

Intended Use of Study Results

CATALYST study results are intended to inform the rollout of new PrEP methods and to strengthen PrEP service delivery. Interim data analyses will be conducted every six to nine months, and results will be shared with ministries of health to inform national PrEP implementation plans. The quality improvement component of the study will facilitate rapid learning and sharing of evidence-based improvements across sites and will inform development of a refined and scalable service delivery package for offering PrEP choice.

Study Populations

Component I – HIV-negative women attending PEPFAR delivery sites who are interested in learning about HIV prevention, including:

- AGYW ages 15–24
- FSWs ≥18 years old
- Transgender individuals and nonbinary people assigned female at birth
- PBFP ≥15 years old

Component II – Implementers and stakeholders involved in informed PrEP choice implementation, including:

- Policymakers
- Providers and site staff
- Community leaders
- Partners, parents, caregivers