

# Supply chain management for PrEP – complexities and key considerations

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MOSAIC Project Director

September 2024



# 2012–16: Oral PrEP!



July 2012

## FDA approves first drug for reducing the risk of sexually acquired HIV infection

Content From: [HIV.gov](http://HIV.gov) • Published: July 16, 2012 • ⌚ 5 min read

**aidsmap**

News

About HIV

PrEP programmes & uptake

### PrEP spreads across Africa – slowly

Numerous PrEP initiation projects started in the last year – but retention is a problem

Gus Cairns | 6 August 2018 | Estimated reading time 12 minutes

**AIDS 2018**



POLICY BRIEF

PRE-EXPOSURE PROPHYLAXIS (PrEP)  
WHO EXPANDS RECOMMENDATION ON ORAL PRE-  
EXPOSURE PROPHYLAXIS OF HIV INFECTION (PrEP)

NOVEMBER 2015

November 2015



# 2016–21: PrEP Ring!



January 2021



The NEW ENGLAND  
JOURNAL of MEDICINE

December 2016

SPECIALTIES ▾ TOPICS ▾ MULTIMEDIA ▾ CURRENT ISSUE ▾ LEARNING/CME ▾ AUTHOR CENTER PUBLICATIONS ▾

ORIGINAL ARTICLE



## Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women

**Authors:** Jared M. Baeten, M.D., Ph.D., Thesla Palanee-Phillips, Ph.D., Elizabeth R. Brown, Sc.D., Katie Schwartz, M.P.H., Lydia E. Soto-Torres, M.D., M.P.H., Vaneshree Govender, M.B., B.Ch., Nyaradzo M. Mgodini, M.B., Ch.B., +45, for the MTN-020–ASPIRE Study Team\* [Author Info & Affiliations](#)

Published December 1, 2016 | N Engl J Med 2016;375:2121-2132 | DOI: 10.1056/NEJMoa1506110

VOL. 375 NO. 22

Health Topics ▾ Countries ▾ Newsroom ▾ Emergencies ▾ Data ▾

/ News / WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection



### WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection

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Turning Discovery Into Health

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NEWS RELEASES

July 2019

Tuesday, July 23, 2019

### Most women use vaginal ring for HIV prevention in open-label study



# 2020-22: CAB PrEP!

**aidsmap**

News

About HIV

Injectable & long-acting PrEP

## US approves injectable cabotegravir for PrEP

Liz Highleyman | 24 December 2021 | Estimated reading time 8 minutes



Home » News and Events » Press Releases » Long-acting Injectable Cabotegravir Is Highly Effective For The Prevention of HIV Infection In Cisgender Men and Transgender Women Who Have Sex With Men

May 18, 2020

ABOUT RESEARCH COMMUNITY NEWS & EVENTS RESOURCES CONTACT



Home » News and Events » Press Releases » HPTN 084 Study Demonstrates Superiority of CAB LA To Oral TDF/FTC For The Prevention of HIV

FDA NEWS RELEASE

## FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

*Drug Given Every Two Months Rather Than Daily Pill is Important Tool in Effort to End the HIV Epidemic*



## WHO recommends long-acting cabotegravir for HIV prevention

New WHO guidelines advise countries to deliver long-acting cabotegravir as part of comprehensive approach to HIV prevention

# 2024: LEN PrEP!






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SPECIALTIES ▼ TOPICS ▼ MULTIMEDIA ▼ CURRENT ISSUE ▼ LEARNING/CME ▼ AUTHOR CENTER PUBLICATIONS ▼

ORIGINAL ARTICLE



## Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women

Authors: Linda-Gail Bekker, M.B., Ch.B., Ph.D. , Moupali Das, M.D., M.P.H., Quarraisha Abdool Karim, Ph.D. , Khatija Ahmed, M.B., B.Ch., Joanne Batching, M.B., Ch.B., D.F.S.R.H., D.R.C.O.G., Dip. HIV Man., William Brumskine, M.B., Ch.B., Dip. HIV Man., Katherine Gill, M.B., Ch.B., M.P.H., , for the PURPOSE 1 Study Team\* [Author Info & Affiliations](#)

Published July 24, 2024 | DOI: 10.1056/NEJMoa2407001

The New York Times

## *New Drug Provides Total Protection From H.I.V. in Trial of Young African Women*

An injection given just twice a year could herald a breakthrough in protecting the population that has the highest infection rates.



Health Topics ▼

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Home / News / Long-acting injectable lenacapavir proves effective in HIV prevention for women



## Long-acting injectable lenacapavir proves effective in HIV prevention for women

26 July 2024 | Departmental update | Reading time: 2 min (587 words)



# What's taking so long?

**aidsmap** News About HIV

PrEP programmes & uptake

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Gus Cairns | 6 August 2018 | Estimated reading time 12 minutes

**AIDS 2018**



10 Jun

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## In The Spotlight - HIV prevention injections exist, but hardly anyone can get them

Catherine Tomlinson

**spotlight**

Comments

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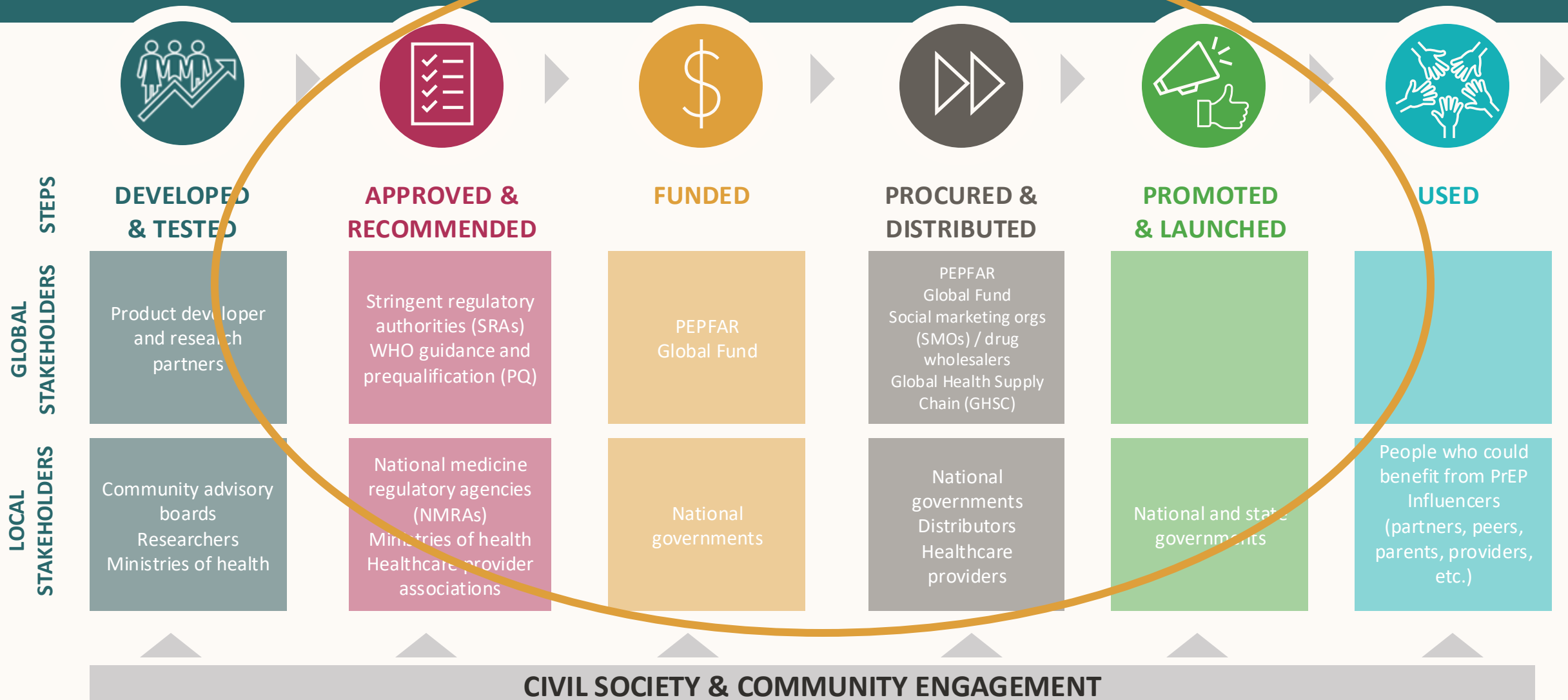
GLOBAL HEALTH

**The New York Times**

*A New Shot Guards Against H.I.V., but Access for Africans Is Uncertain*

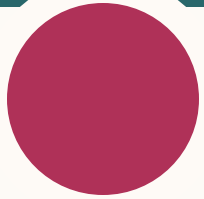


# What does it take to move from R&D to users?





# Product must be approved and recommended



## APPROVED & RECOMMENDED

Stringent regulatory authorities (SRAs)  
WHO guidance and prequalification (PQ)

National medicine regulatory agencies (NMRAs)  
Ministries of health  
Healthcare provider associations

- The product developer develops regulatory strategy in consultation with various stakeholders – they often prioritize registration in countries where the clinical trials took place to facilitate post-trial access.
- The local approval process varies by country – some countries have NMRAs, others use a regional approval, others move ahead with securing import permits once WHO PQ is in place.
- An import waiver can be requested by the MOH to bring product into the country prior to NMRA approval.
- Additional steps may be needed prior to programmatic access in a country, e.g., the product being put on the Essential Medicines List (EML).
- Countries often wait to begin planning (updating national policies etc.) until WHO guidance is issued.

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# Product must be funded



- Price negotiations between procurers and the product developer are a first step.
- Product eligibility for PEPFAR funding is determined by multiple factors such as US Government legislation, policy, and quality assurance rules.
- For both PEPFAR and Global Fund, countries submit proposals (or implementation plans) that include commodity requests and are based on technical guidance from the donor, e.g., PEPFAR country and regional operational plan (COP/ROP) guidance.
- Product eligibility for national government funding is also dependent on multiple factors, e.g., EML.

# Product must be procured and distributed



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## PROCURED & DISTRIBUTED

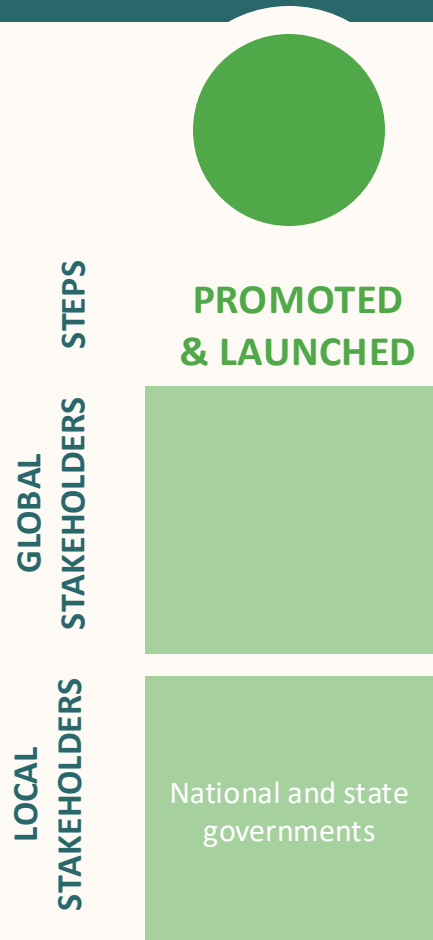
PEPFAR  
Global Fund  
Social marketing orgs (SMOs) / drug wholesalers  
Global Health Supply Chain (GHSC)

National governments  
Distributors  
Healthcare providers

- For PEPFAR, the Global Health Supply Chain (GHSC) manages the importation process in most countries.
- Shipping requirements are unique to each product, e.g., CAB PrEP must be shipped within a set temperature range.
- Once product arrives in country, the customs clearance and importation process begins, as well as any product import testing requirements that may be in place.
- CAB PrEP requires additional commodities like needles and syringes, which must be procured in sufficient quantities and distributed alongside the product.
- Forecasting of CAB PrEP quantities and initiations must be carefully managed to ensure continued access for those who initiate.



# Product must be promoted and launched



- Country preparations include updates to national PrEP guidelines, implementation plans (prioritizing geographies and/or populations), M&E systems and registers, provider curricula and job aids, and selection of implementing partners (IPs). Activities usually coordinated through national technical working groups (TWGs).
- Provider training often starts with a training of trainers (ToT) in advance of launch so the MOH and IPs are well trained in the new product and can inform guideline updates. Training is usually cascaded to facilities right before the product is available.
- National demand generation strategies and campaigns may need to be updated to address the expansion of PrEP as a category that now includes choice across multiple products.
- Many countries prefer to start small (pilot program) and then expand based on early learnings.

# 2024: Where are we now?

## Injectable HIV-prevention Drug Launches in Zambia

February 13th, 2024 | NEWS



Photo Credit: JSI

The Herald

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The Herald Classified

April 11, 2024

### Zimbabwe introduces injectable HIV drug

SCIENCEINSIDER | AFRICA

## Long-lasting, injectable HIV prevention drug set for “aggressive” roll-out in Africa

U.S. government agency plans to make inexpensive shots widely available for people at risk

25 MAR 2024 • 2:30 PM ET • BY [JON COHEN](#)

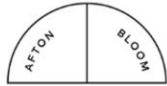






# ACKNOWLEDGMENTS

Many thanks to Katie Schwartz (FHI 360)



*MOSAIC is made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID) cooperative agreement 7200AA21CA00011. The contents of this presentation are the responsibility of MOSAIC and do not necessarily reflect the views of PEPFAR, USAID, or the U.S. Government.*

*Photo Credit: MOSAIC Consortium*



# Forecasting PrEP products in the context of choice

KATHARINE KRIPKE, AVENIR HEALTH



# National commodity forecasting exercises

- Intended to ensure clients receive the health products they need
- Help avoid shortages or stock-outs
- Inform budgeting and guide advocacy for and allocation of scarce resources for HIV prevention programming
- For new products: help provide manufacturers and suppliers with the information they need to scale up production and ensure adequate supply



# What do we need to know?

- Trends in product use over time and how that relates to national PrEP indicators
- Stock on hand and shelf life
- Minimum stock on hand requirements (inventory control levels)
- Plans for program scale-up
- Timelines for new product introduction
- Uptake, patterns of use over time → method mix
- Size of population(s) in need of PrEP

# Challenges with PrEP forecasting

- Countries have been applying tools developed for treatment, which don't take into account the specific considerations of the PrEP program
- Routine indicators for PrEP not informative for forecasting
  - Countries are not routinely collecting / analyzing the amount of PrEP products dispensed alongside indicators tracking the numbers of people using PrEP
  - For oral PrEP, products can be used for PrEP, ART, and hepatitis treatment, so difficult to know how much was dispensed for PrEP (may also become true for long-acting injectable forms of PrEP)
- Difficult to estimate the size of the population in need
- Difficult to project uptake/method mix, especially with new methods and ED PrEP
- Impact of CAB PrEP tail – stockouts can lead to drug resistance
- Resource (funding and commodity) limitations

# PrEP—it can help with estimating PrEP commodity need based on targets

1. Define populations in need of PrEP
    - Size of subset of each population that is in need of PrEP (HIV-negative and likely to be exposed to HIV)
  2. Specify PrEP methods to be considered
  3. Enter data/assumptions on PrEP patterns of use
  4. Enter PrEP monitoring data to characterize past trends
  5. Define visit schedules for each PrEP method and population
  6. Project scale-up curves for each method/population
  7. Set targets by % coverage, funding or product constraints, or numbers of initiations
- Estimates of commodity needs by method and month over target-setting period



# Using PrEP-it to Inform Commodity Forecasting for HIV Prevention Products: Lessons Learned from Kenya

[www.prepwatch.org/resources/using-prep-it-for-commodity-forecasting](http://www.prepwatch.org/resources/using-prep-it-for-commodity-forecasting)

The screenshot shows the PrEPWatch website interface. At the top, there are navigation links for AVAC.ORG, HIVRESOURCETRACKING.ORG, STIWATCH.ORG, ENGAGE, and DONATE. Below this is the PrEPWatch logo, described as an initiative of AVAC. A secondary navigation bar includes links for PRODUCTS, NEWS & STORIES, COUNTRY DATA, BEST PRACTICES, EVENTS, and RESOURCES, along with a search icon. The main content area features a blue header with a link to '< Back to Resource Library' and the title 'Using PrEP-it for Commodity Forecasting'. The document preview shows the title 'Using PrEP-it to Inform Commodity Forecasting for HIV Prevention Products: Lessons Learned from Kenya' dated 31 JANUARY 2024. It includes sections for Introduction and Background. The footer of the document lists logos for PEPFAR, USAID, and MOSAIC.

31 JANUARY 2024

This brief describes how PrEP-it was used to inform commodity forecasting for PrEP products in Kenya and highlights lessons learned.

Topic(s): [Financing & Costing](#)

Product(s): [Cabotegravir](#), [Dapivirine](#)  
[Vaginal Ring](#), [Oral PrEP](#)

## Stay tuned for future sessions:

- **Wednesday 2 – 3 p.m.**
  - How we can improve PrEP M&E so we can improve our commodity forecasts (among other things)
  
- **Thursday 1:30 – 3 p.m., Room 3**
  - PrEP-it walkthrough

# ACKNOWLEDGMENTS

These slides were largely based on the brief about the use of PrEP-it to inform commodity forecasting in Kenya, drafted by Susan Duberstein with input from Janet Mugambi, Moses Otieno, and Katharine Kripke



*MOSAIC is made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID) cooperative agreement 7200AA21CA00011. The contents of this presentation are the responsibility of MOSAIC and do not necessarily reflect the views of PEPFAR, USAID, or the U.S. Government.*

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