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GBGMC

**Long Acting HIV PrEP Market
Assessment &
Need Forecasting**

August 2025



Introduction



LA-PrEP Power: Shaping the Future of HIV Prevention for Key Populations (KP) is a three-year global initiative aimed at accelerating the introduction and uptake of long-acting pre-exposure prophylaxis (LA-PrEP) among KP.

The project is a collaboration between Global Black Gay Men Connect (GBGMC), **AVAC**, **Avenir Health**, and the **Global Key Population HIV Prevention Advisory Group**, with support from **Gilead**, **ViiV Healthcare**, and **MSD**.



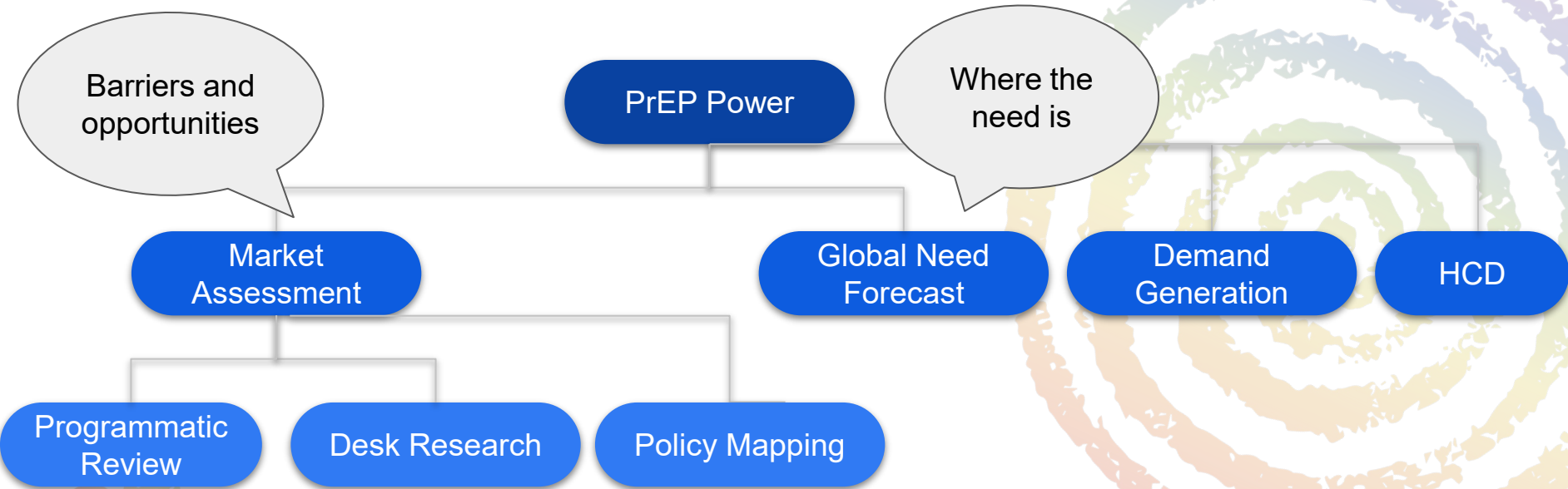
GILEAD



MSD



Components of LA PrEP Power



Current PrEP Context

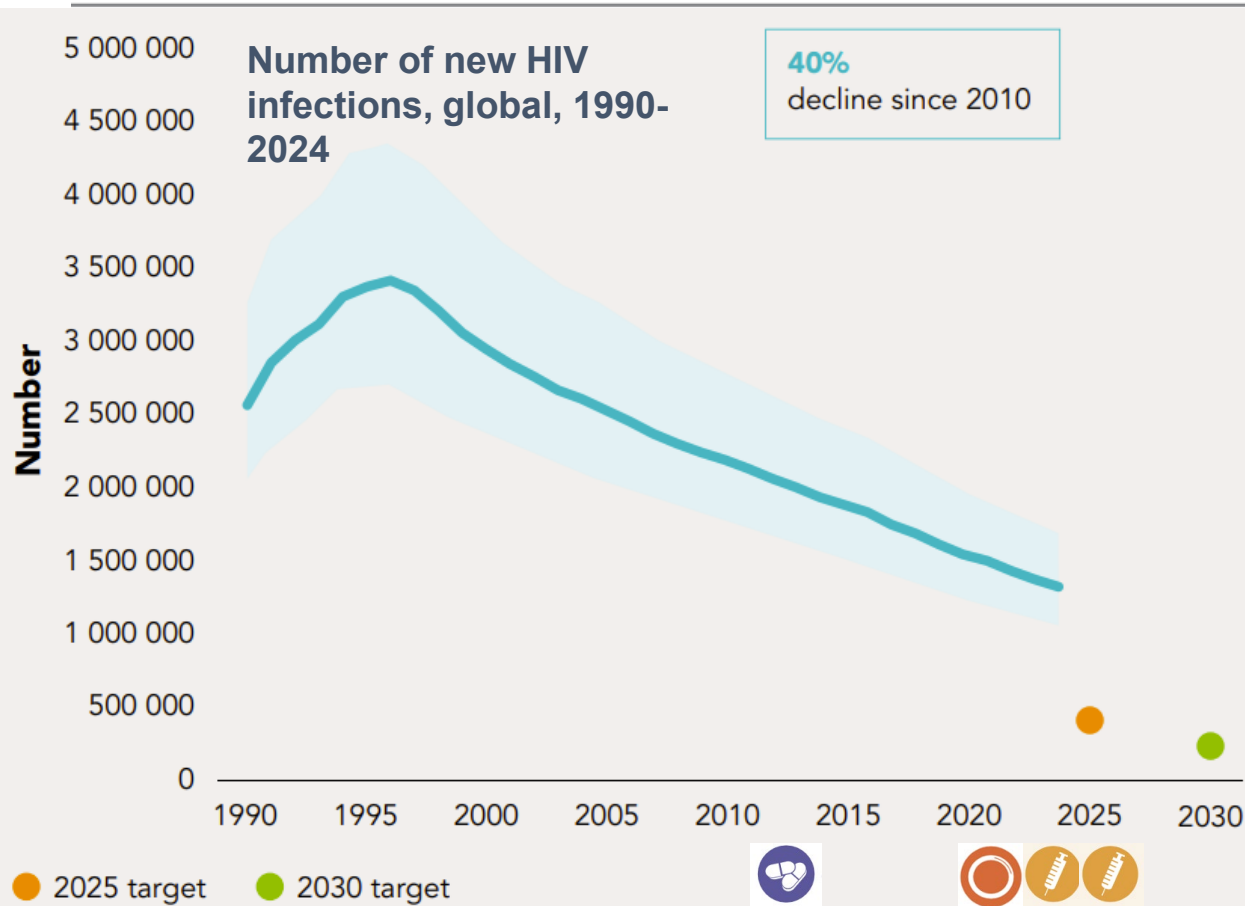
PrEP Power Market Assessment and Demand Forecast Launch

Catherine Verde Hashim

Programme Manager, Product Introduction and Access, AVAC

12 August 2025

Tracking incidence against UNAIDS 2025/2030 targets



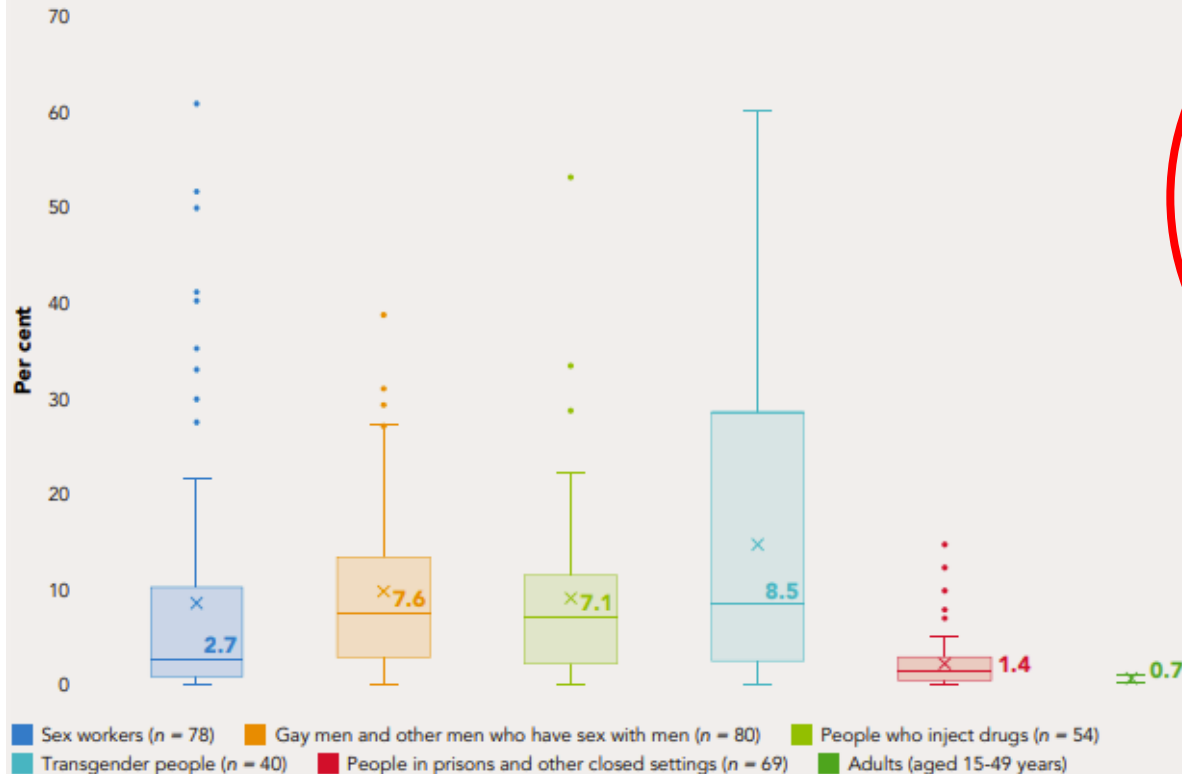
Significant declines
since 1995...

...but slow progress, and
way off target



Key Populations continue to be most impacted

Figure 1.3. HIV prevalence among people from key populations compared with adults (aged 15–49 years), global, 2020–2024



The median HIV prevalence among countries that reported these data was:

2.7% among sex workers

7.6% among gay men and other men who have sex with men

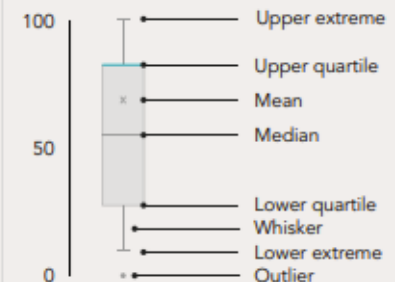
7.1% among people who inject drugs

8.5% among transgender people

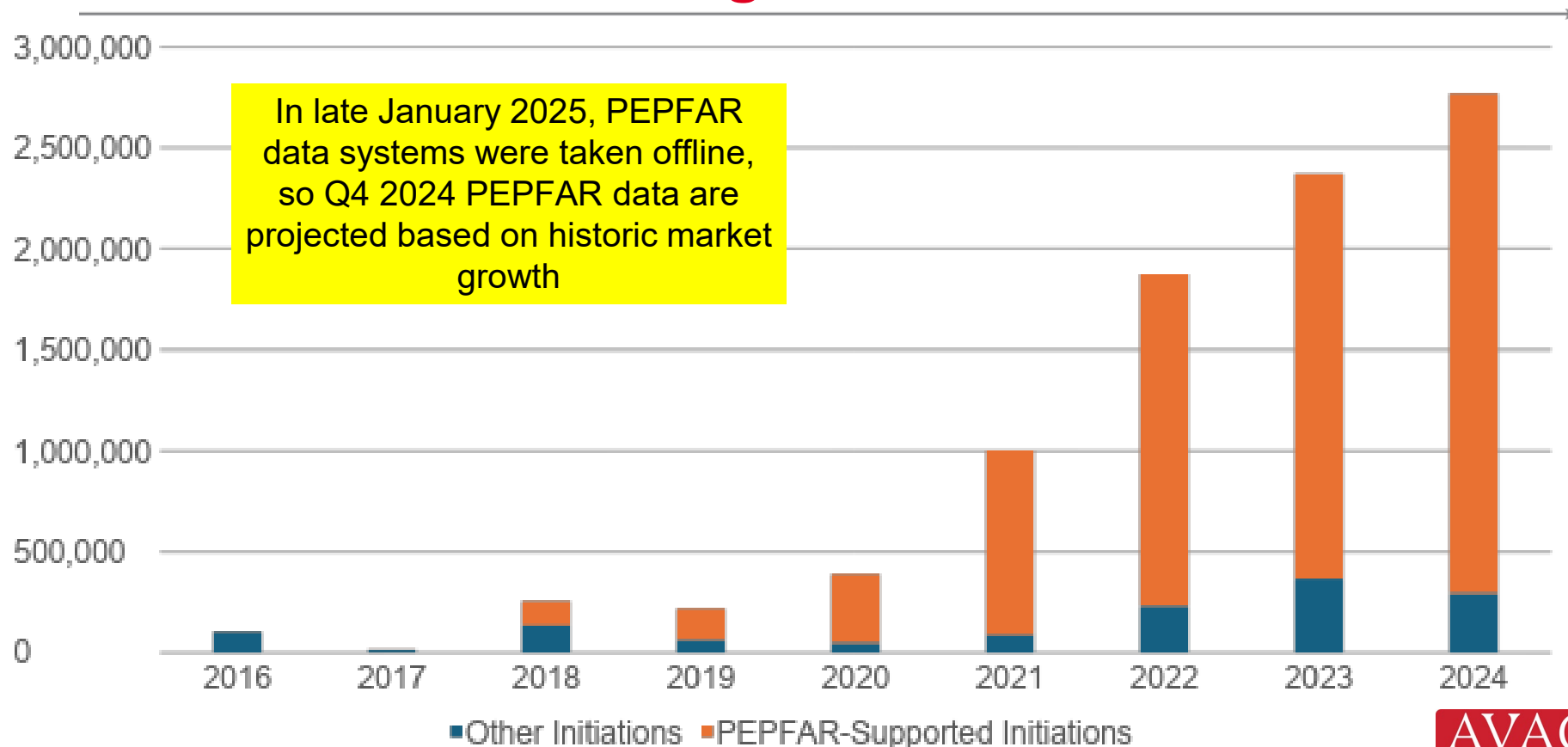
1.4% among people in prisons and other closed settings

The estimated HIV prevalence among adults (aged 15–49 years) was 0.7% [0.6–0.8%].

How to read it



PrEP Initiations through 2024



PEPFAR Stop Work Orders: Major Impacts

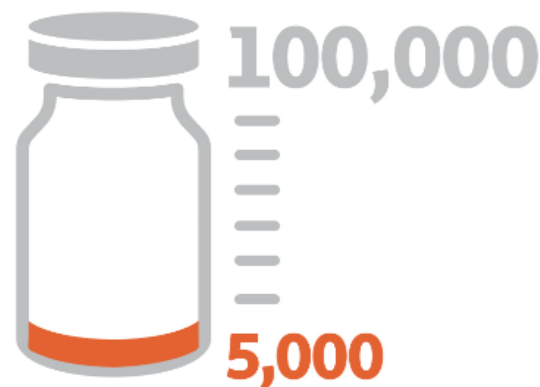
<https://www.prepwatch.org/pepfar-stop-work/>



Number of new **PrEP users** in 2024 who have **lost access to PEPFAR-supported PrEP services**

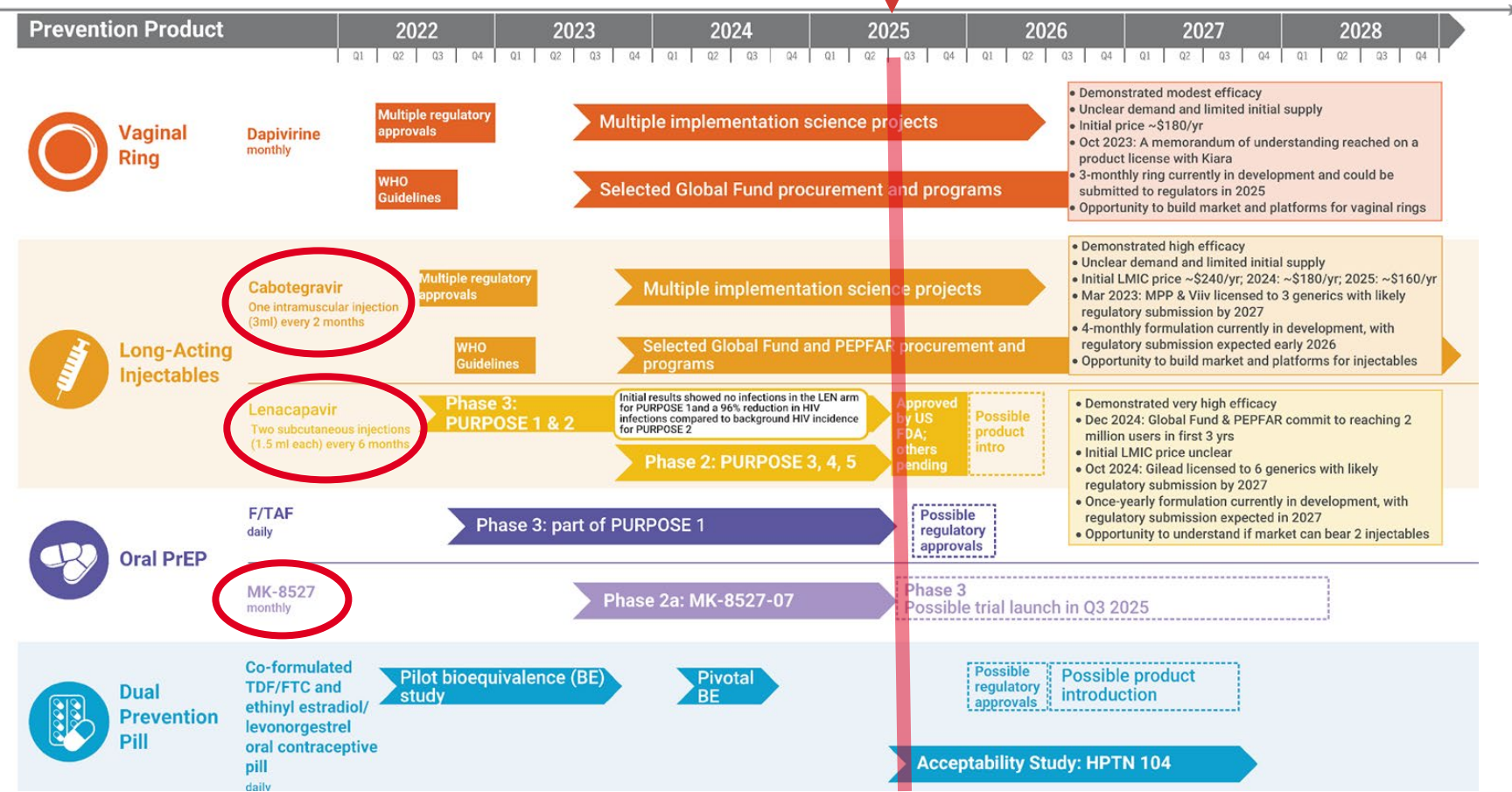


Number of people identifying as **Key Populations who have lost access to HIV prevention programming** under PEPFAR



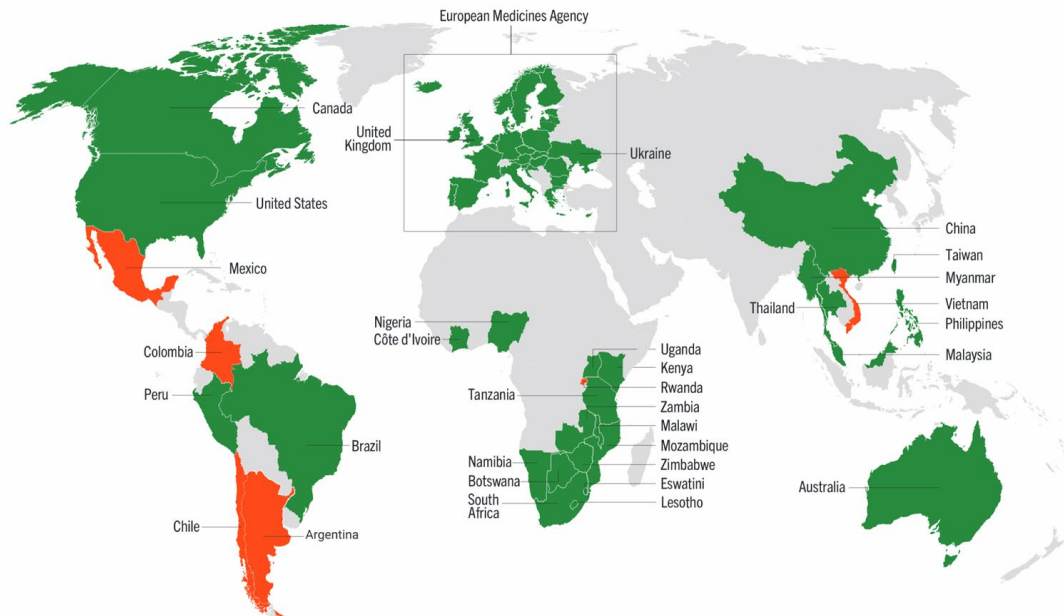
Off Target: The PEPFAR goal of **people initiating CAB for PrEP** in 2025 is falling far short – **5k instead of 100k**

PrEP Pipeline



Cabotegravir for PrEP (Two Month Injectable)

26 regulatory approvals (57 countries in total), 6 pending for CAB as of June 2025



CAB for PrEP Regulatory Approvals

- Approved in 25 countries + EMA and recommended by WHO
- Not yet widely available outside of implementation studies and small scale PEPFAR implementation
- Early PEPFAR implementation in 13 countries disrupted or suspended by stop work orders earlier this year
- Several countries have resumed, though overall numbers are small- about 10k users per country (or less)
- With LEN, unclear what a multi injectable market might look like
- Current price \$160 USD/year- roughly 4x oral PrEP
- Generics expected 2027

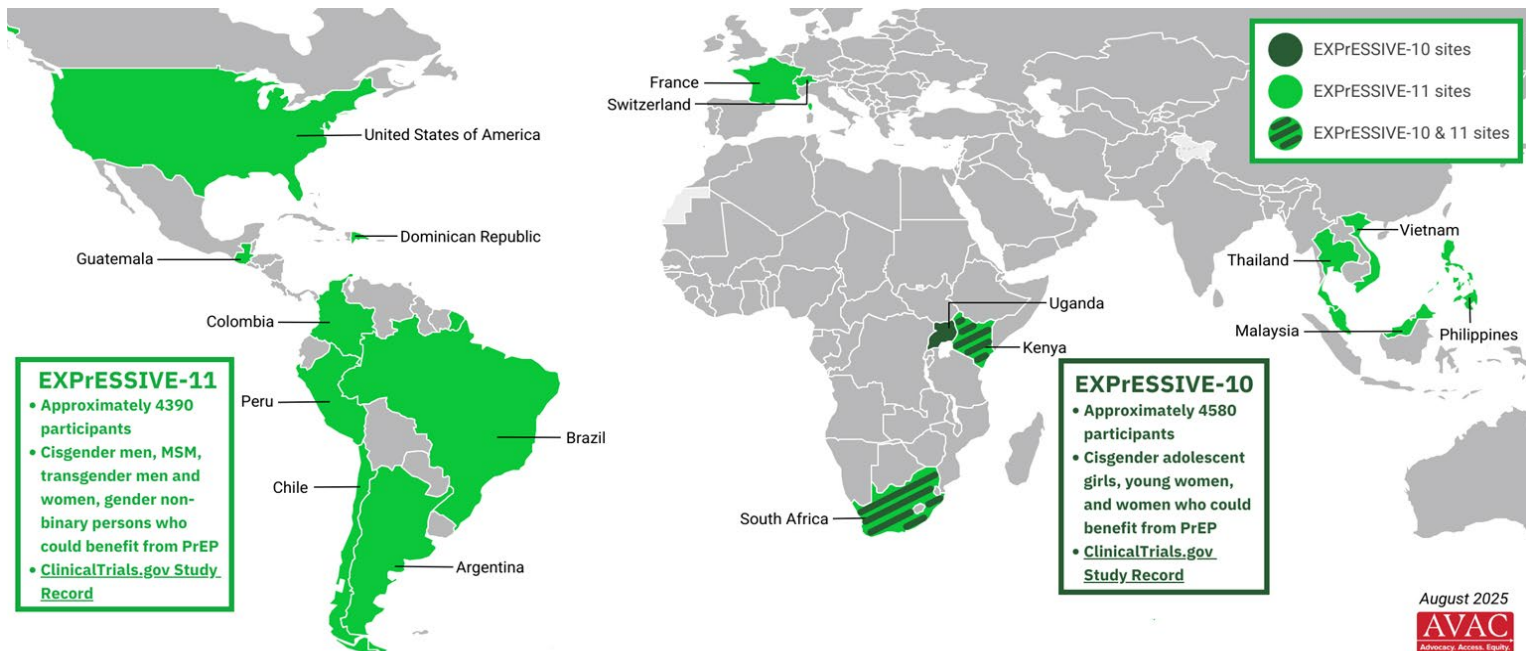
Lenacapavir for PrEP (Six Month Injectable)

Global Fund/CIFF LEN Early Adopter Countries



- Approved by US FDA and recommended by EMA
- Not yet commercially available outside of US- pending in Brazil and South Africa
- Recommended by WHO in July 2025
- Global Fund and CIFF funding early LEN adoption in nine African countries
- First implementation in early adopter countries anticipated January 2026
- LMIC price not yet known
- Generics expected 2027
- One year formulation also in development, expected 2027

MK-8527 (Monthly Pill)



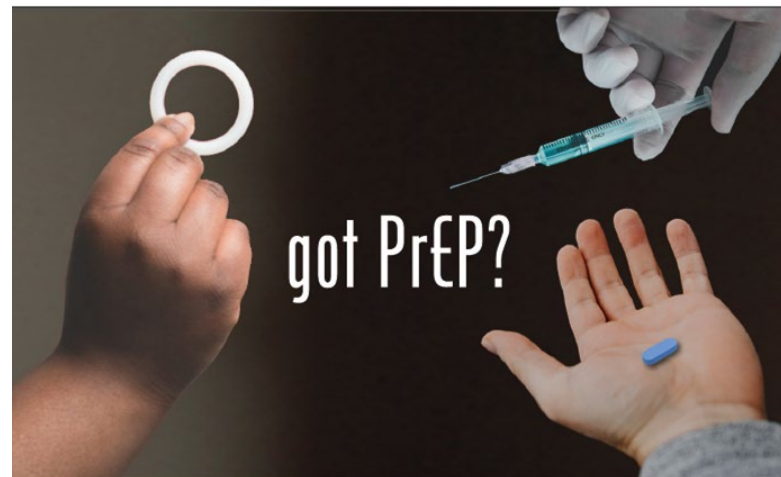
- Found to be safe and well-tolerated in Phase II clinical trial
- Phase III clinical trials (EXPrESSIVE) due to start enrolling this month and run through 2027/2028
- Would be first long-acting oral product if trials are successful

Key Takeaways

- Despite significant increases in PrEP uptake since 2021, we are **still far off** from reaching UNAIDS targets for **incidence reduction, especially for KPs**
- New, **longer-acting PrEP products** are beginning to come to market- providing users with additional options like these can help them find a product that best fits their lifestyle and **facilitate uptake and continuation**
- **CAB for PrEP** is available in limited contexts and has **not yet been fully scaled up**
- **LEN for PrEP** is currently only available in the US and will become available in **nine African countries early next year**
- **MK-8527** was found safe in Phase II trials and will **begin Phase III (efficacy) trials this month**
- The global community needs to **act now** to make these products **available to key populations**

Further Resources

- [All things CAB](#)
- [All things LEN](#)
- [All things MK-8527](#)
- [Getting Rollout Right This Time](#) – insights and best practices for successful PrEP rollout
- [Global PrEP Tracker](#) – tracking PrEP initiations by country over time
- [PrEPWatch.org](#) – data, information, and PrEP resources



For the last 8 years, AVAC has proudly worked with PEPFAR to document PrEP uptake and its impact around the world. That stopped in January with a stop work order from the US government. But protecting access to PrEP is vital. Are you leading a PrEP program? Whether supported by PEPFAR or not, we invite you to work with us to ensure global data on PrEP is not lost.

Brief Context



- 55% of new HIV infections globally are among KP, increased from 44% in 2010.
- 25% of new infections among KP are in sub-Saharan Africa with high regional variability - eg 64% in West and Central Africa, 25% in East and South.
- **As of 2024, only 40-50% of KP at risk were accessing effective prevention.**



Key populations will drive the future of the epidemic

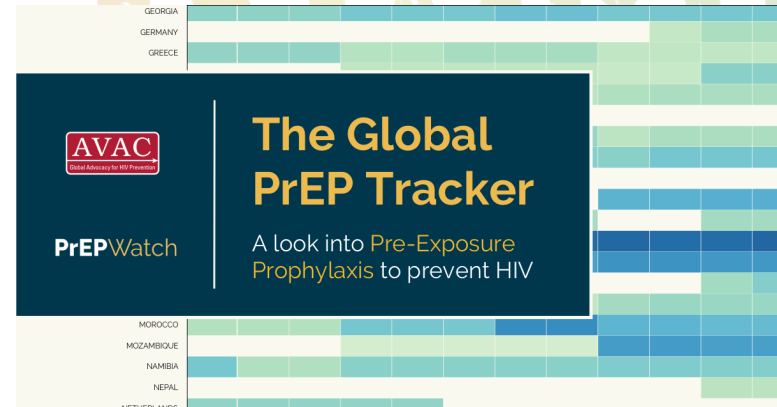
https://www.unaids.org/sites/default/files/media_asset/new-hiv-infections-data-among-key-populations-proportions_en.pdf



Market assessment methods

This market assessment draws on a landscape analysis combining a range of publicly and privately available data sources:

- KP population size estimates (UNAIDS Technical Reference Group)
- programmatic review (PrEP Watch)
- desk research review (PubMed & Scholar)
- policy mapping (Georgetown HIV Policy Lab)



Primary Questions for the Market Assessment



1. What are the total population size estimates for key populations globally?
2. What are primary barriers and facilitators for LA-PrEP?
3. What key criteria should be considered for LA-PrEP country prioritization?
4. What are the current policy and funding risks for LA-PrEP rollout?



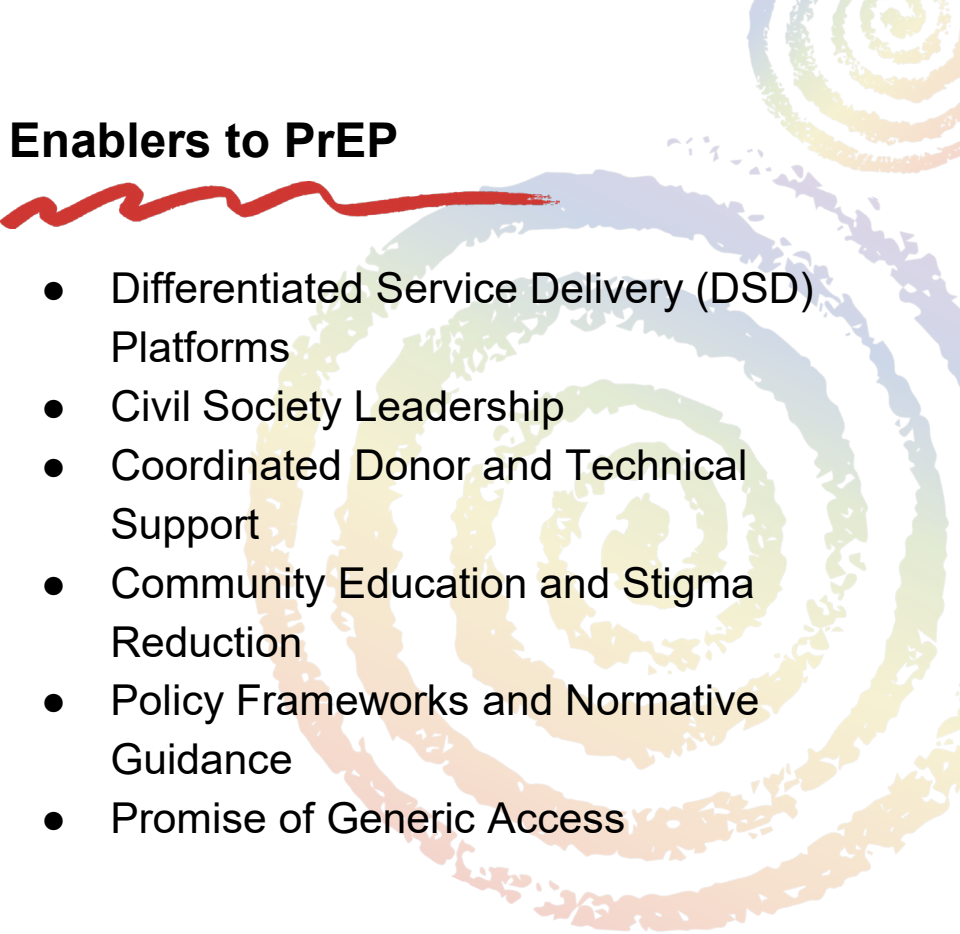
Barriers to PrEP



- Lack of access points
 - Cost and Procurement Constraints
 - Regulatory and Policy-Practice Gaps
 - Health System Capacity and Delivery Design
 - Low Awareness and Provider Readiness
 - Legal, Structural, and Social Barriers
 - Donor Instability and Limited Domestic Financing
- 

Enablers to PrEP



- Differentiated Service Delivery (DSD) Platforms
 - Civil Society Leadership
 - Coordinated Donor and Technical Support
 - Community Education and Stigma Reduction
 - Policy Frameworks and Normative Guidance
 - Promise of Generic Access
- 

Country Prioritization Criteria

**Country
prioritization
matrix**

**Total population and proxy for
PrEP eligible population (20%)**

HIV Prevalence (20%)

HIV Incidence among KP (20%)

**PrEP Initiations and proxy for
health system readiness) – (20%)**

Policy index score (20%)



Countries with Top Composite Scores - recommended for investment



United States

South Africa

Brazil

Nigeria

Zambia

Vietnam

France*

Philippines*

Countries were ranked using a composite scoring framework to ensure regional diversity and representation of critical implementation contexts.

Note: Philippines (12th) and France ranked lower (19th) on the quantitative prioritization score; these were included in the final list based on strategic relevance identified by GBGMC and funders.

Global Fund countries: Eswatini, Kenya, Lesotho, Mozambique, Nigeria, South Africa, Uganda, Zambia, Zimbabwe



PrEP need forecast for key populations

Katharine Kripke and Matthew Hamilton
Avenir Health
11 Aug 2025

The context for this forecast

- This is not a demand forecast. The purpose of this forecast is to tell us where and how big the *need* is.
- The funding environment for PrEP is changing rapidly. Which countries will adopt new methods, and the timing of method introduction, are uncertain.
- Client preference for current and potential long-acting PrEP products is unknown.
- Final prices for the new methods are unknown and will largely determine their availability.



This forecast vs WHO Global PrEP Forecast

- This forecast is for key populations only.
- This forecast uses the new UNAIDS PrEP target setting methodology incorporating population-specific incidence.
- WHO Global PrEP Forecast anchored demand in 2025 to reported PrEP implementation as of 2023. This forecast focuses only on need for PrEP, not on demand or program capacity (no scale up from prior implementation).



Methods

- Based on the revised UNAIDS Global PrEP Targets methodology. Need is based on incidence and KP size estimates for 172 countries.
- Four key populations: FSW, MSM, TGW, and PWID
 - Need is assumed to be static over time, with new methods adding to fulfillment.
- Five PrEP methods: Daily oral, DVR, CAB PrEP, LEN PrEP, and monthly oral
 - Specific years of introduction of injectable CAB and LEN PrEP for each country
 - Monthly oral introduction in 2030 for all countries that are assumed to introduce injectable PrEP
- As this is a forecast of need for PrEP, we do not scale up from actual PrEP uptake.
 - Actual PrEP uptake does inform assumptions in one respect: Among the 118 countries that report to PEPFAR or GAM, only those that reported past oral PrEP uptake are assumed to implement long-acting PrEP methods.

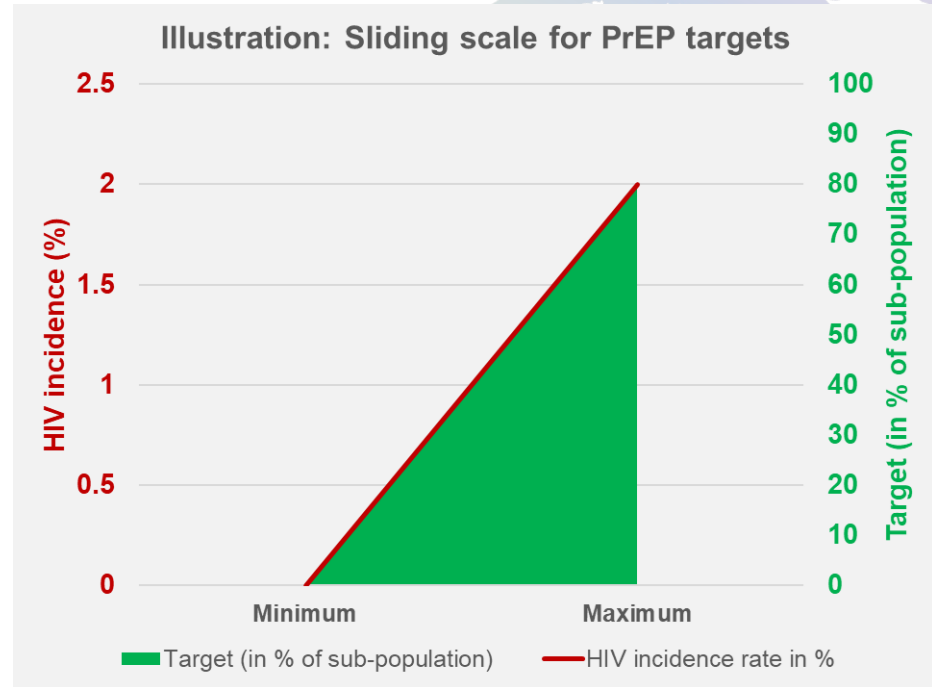


New UNAIDS methodology: PrEP targets and needs estimation assumptions use a sliding scale

- General rationale: Need for PrEP is predicted by level of HIV incidence in specific sub-populations and their population sizes.
- Target coverage is calculated on a sliding scale from a minimum value at 0% incidence to a maximum value at 2% incidence and above.

	FSW	MSM	TGW	PWID
Minimum	0	20	20	0
Maximum	80	80	80	50*

*PWID: In most countries, roughly half of people who inject drugs use safe injecting equipment, therefore a maximum target of 50%. Country-specific coverages of safe needle and syringe programs were used to determine the max where available.



Method mix: three scenarios

We lack information about uptake in the context of multiple long-acting methods. However, we can hypothesize three scenarios of method mix at full scale (with all methods introduced). These can be changed in the forecasting tool by the user.

1. Low innovation adoption: limited shift to long-acting methods
2. Balanced adoption: moderate shift to long-acting methods
3. Long-acting dominant future: strong preference for long-acting options

Three scenarios	Daily Oral	Ring	CAB PrEP	LEN PrEP	Monthly Oral
1. Low Innovation Adoption	75.0%	0.0%	10.0%	10.0%	5.0%
2. Balanced Adoption	40.0%	0.0%	20.0%	20.0%	20.0%
3. Long-Acting Dominant Future	20.0%	0.0%	30.0%	30.0%	20.0%

• The forecast tool allows method mix to vary by population. In results shown here, we assume the same mix for all pops.

• It is unclear what the relative uptake of CAB and LEN PrEP will be in a two-injectable market. We have assumed equal uptake in each scenario.



Long-acting PrEP introduction

- The forecast tool allows users to specify which countries receive which methods and in what years.
- Some countries have already begun to deliver CAB PrEP. We assume implementation begins slowly, so our forecast for each new PrEP method begins the year after it is first received.
- Assume full implementation starts in 2025 (color coding in notes):
 - 9 countries that started CAB PrEP in 2024: Botswana, Eswatini, Ethiopia, Lesotho, Malawi, Mozambique, Ukraine, Zambia, Zimbabwe
 - 4 countries that were due to start in 2024 or 2025: Rwanda, Nigeria, South Africa, Namibia
 - Assume LEN PrEP for these counties starts in 2026
- Assume full implementation of CAB and LEN PrEP starts in 2026:
 - 4 countries that hoped to receive CAB PrEP in 2025: Cambodia, Kenya, Myanmar, Nepal
 - 4 additional countries that we suspect could potentially receive CAB and LEN PrEP: Philippines, Uganda, Vietnam, Thailand



Long-acting PrEP introduction

- Generic CAB and LEN PrEP are expected to be available by 2027. We assume CAB PrEP and LEN PrEP scale up begins in 2027 for 63 countries and 50 countries, respectively, which we assume are waiting for generic and have reported oral PrEP use in past years (if they report).
- We assume CAB PrEP will be introduced in 6 more: Argentina, Brazil, China, Mexico, Pakistan, and Peru.
- We assume LEN PrEP will be introduced in 3 more: Argentina, Pakistan, and Peru.
- We also assume CAB and LEN PrEP will become available by 2027 for 33 high-income countries for which CAB PrEP is approved per the PrEP Tracker.
- Under these assumptions, a total of 123 countries and 107 countries are assumed to implement CAB PrEP and LEN PrEP respectively. All are assumed to introduce monthly oral PrEP in 2030. The remaining 44 of the 172 countries are assumed not to introduce any of the three long-acting methods.



PrEP targets calculated for 172 countries



82 countries reported previous PrEP implementation to PEPFAR and/or GAM, plus 33 high-income countries which do not report, plus 2 others (China and Pakistan)



123 countries assumed to introduce injectable PrEP

- 21 countries that have already introduced or plan to introduce CAB PrEP and LEN PrEP
- 63 countries eligible for generic CAB that have reported oral PrEP implementation, if they report
- 50 countries eligible for generic LEN that have reported oral PrEP implementation, if they report
- 33 high-income countries which do not report but have approved CAB
- 6 additional countries that may also introduce injectable CAB or LEN PrEP (Argentina, Brazil, China, Mexico, Pakistan, and Peru)

Which countries will adopt injectable PrEP?



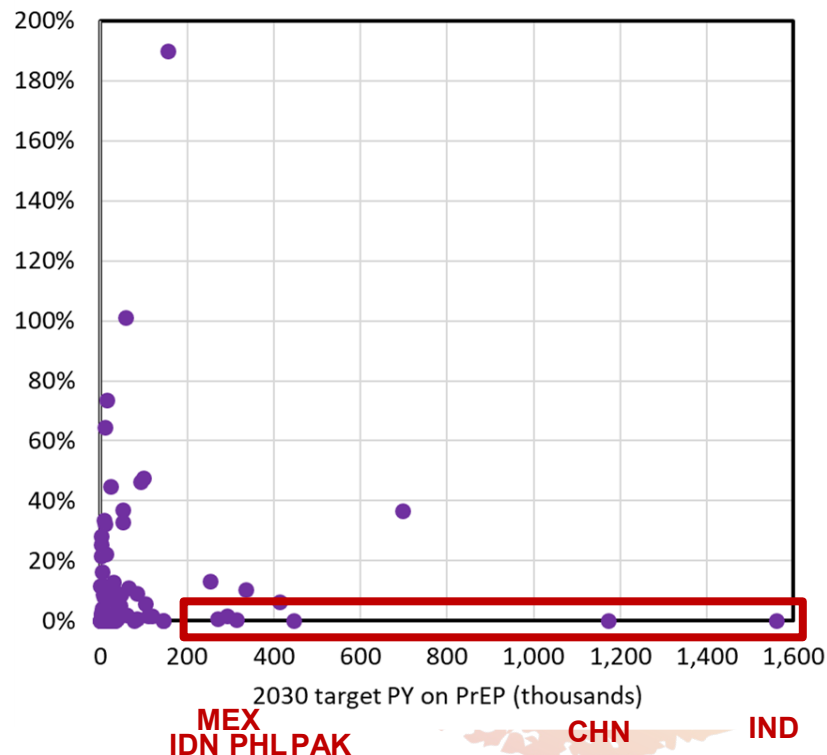
Target vs. implementation

- 6 countries with large 2030 PrEP targets (>200k PY on PrEP), yet little/no PrEP use reported in 2023
 - Indonesia (270k, 0.8%)
 - Mexico (291k, 1.6%)
 - Philippines (314k, 0.3%)
 - Pakistan (445k, 0.0%)
 - China (1173k / 0.0%)
 - India (1560k, 0.0%)

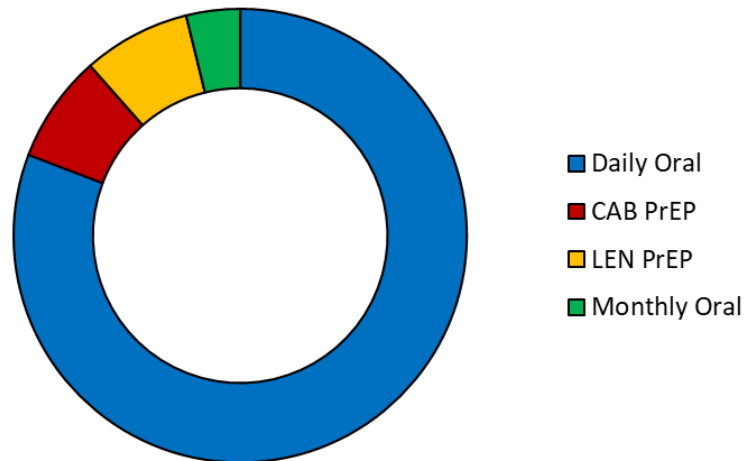
● Assume 25% of KP need will be met for these countries



% of 2030 target reached in 2023,
relative to target



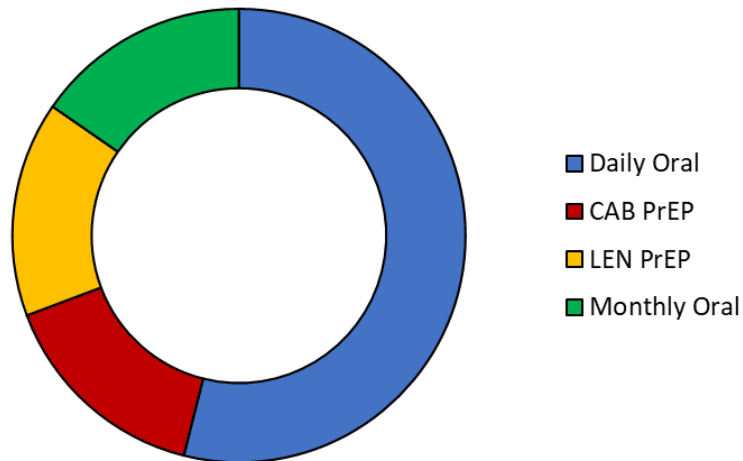
Scenario 1, Low innovation



2030 PY on PrEP (millions)	Daily Oral	CAB PrEP	LEN PrEP	Monthly Oral	Total
Scenario 1 Total	9.30	0.95	0.78	0.48	11.52
Female sex workers	1.46	0.15	0.14	0.08	1.83
Men who have sex with men	6.27	0.66	0.51	0.33	7.77
Transgender women	0.53	0.06	0.05	0.03	0.67
People who inject drugs	1.04	0.08	0.07	0.05	1.24



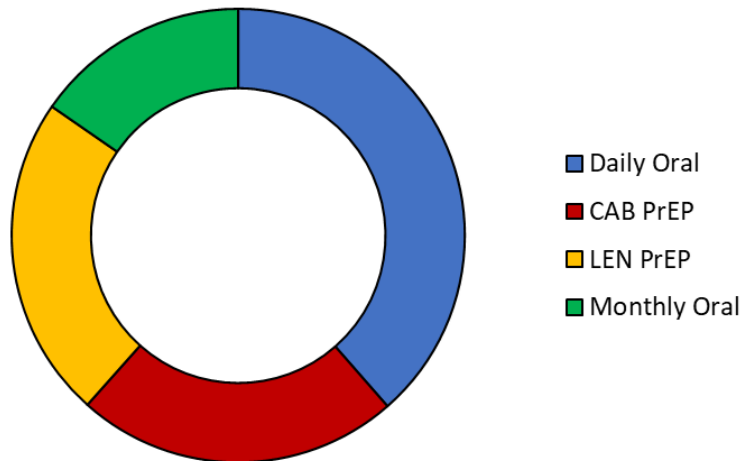
Scenario 2, Balanced adoption



2030 PY on PrEP (millions)	Daily Oral	CAB PrEP	LEN PrEP	Monthly Oral	Total
Scenario 2 Total	6.01	1.96	1.56	1.99	11.52
Female sex workers	0.92	0.31	0.29	0.31	1.83
Men who have sex with men	4.03	1.35	1.03	1.36	7.77
Transgender women	0.33	0.12	0.10	0.13	0.67
People who inject drugs	0.74	0.17	0.15	0.19	1.24



Scenario 3, Long-acting dominant future

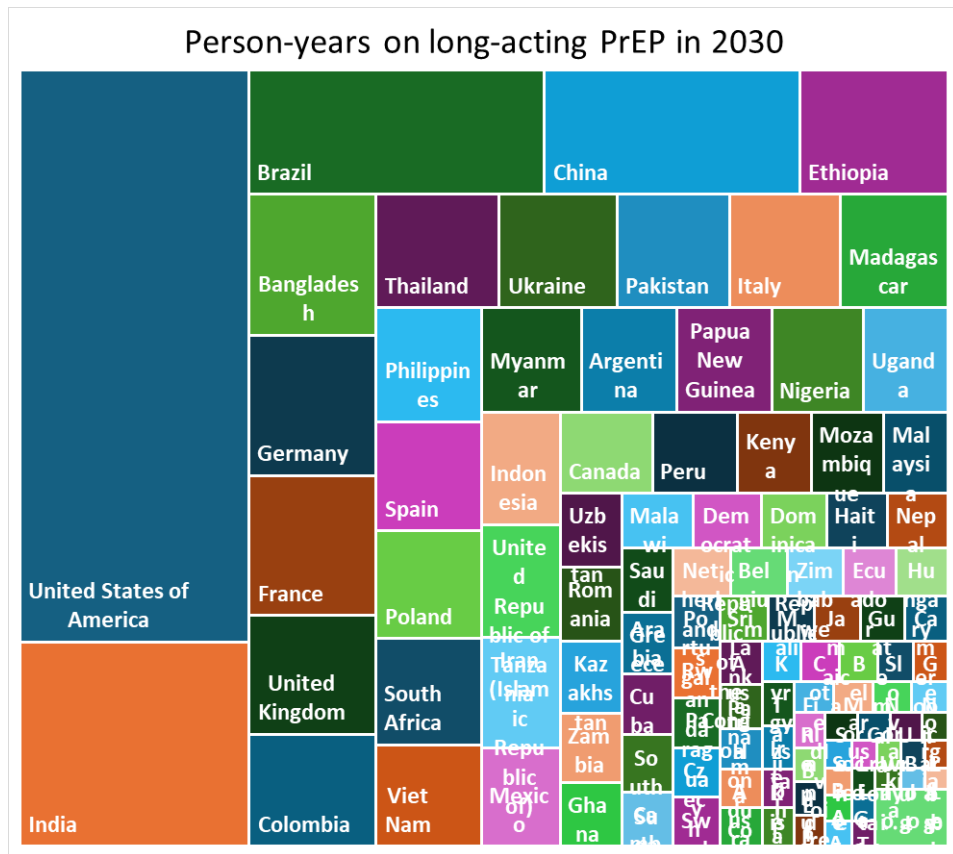


2030 PY on PrEP (millions)	Daily Oral	CAB PrEP	LEN PrEP	Monthly Oral	Total
Scenario 3 Total	4.09	3.02	2.35	2.05	11.52
Female sex workers	0.61	0.47	0.43	0.32	1.83
Men who have sex with men	2.72	2.10	1.54	1.41	7.77
Transgender women	0.21	0.19	0.15	0.13	0.67
People who inject drugs	0.55	0.26	0.23	0.20	1.24



Scenario 3, Long-acting dominant future, 2030

Top 10 HICs	% of global PY on LA PrEP	Top 10 LMICs	% of global PY on LA PrEP
USA	18.2%	India	6.5%
Germany	2.5%	Brazil	5.1%
France	2.5%	China	4.4%
United Kingdom	2.1%	Ethiopia	2.6%
Italy	1.7%	Bangladesh	2.5%
Spain	1.6%	Colombia	2.0%
Poland	1.6%	Thailand	1.9%
Canada	1.0%	Ukraine	1.9%
Romania	0.6%	Pakistan	1.8%
Saudi Arabia	0.5%	Madagascar	1.7%



Key results

- Total annual need among these four populations is 11.5 million person-years on PrEP
- Largest need is among MSM, followed by FSW and PWID
- In the long-acting dominant future scenario, the United States, Brazil, India and China alone would account for 34% of need for long-acting PrEP. The top 10 countries account for just under half of all need.
- Annual long-acting product needs by 2030 in the long-acting dominant future scenario:
 - CAB PrEP, 21.2 million injection visits
 - LEN PrEP, 4.7 million injection visits
 - Monthly oral, 24.6 million pills

Key populations will drive the future of the epidemic, and the demand for long-acting PrEP among KPs is large



Limitations

- Forecast applies the UNAIDS methodology to 172 countries, 82 of which reported past oral PrEP implementation to PEPFAR and/or GAM. However, this forecast of need for PrEP does not scale up from current oral PrEP coverage. Actual uptake of PrEP may vary for each country.
- Estimates of population size and incidence for KP are highly uncertain. We lack estimates for transgender men and nonbinary individuals.
- The forecast does not consider future change in population size or incidence.
- Uncertainty remains in method mix and the timing of new method introduction by country.
- It is unclear what the relative uptake of CAB and LEN PrEP will be in a two-injectable market. We have assumed equal uptake in each scenario.



LEN for PrEP: Current Status

Current Status

- **Global Fund & Gilead Agreement:** Access deal announced, but no public price or volume commitments.
- **Target:** Ambition to reach 2M people over 3 years : **Our forecast estimates the need for LEN among key populations at 2.35 million people.**
- **WHO Guidance:** Released new guidelines on July 14, 2025, recommending twice-yearly injectable LEN as an additional PrEP option.
- **PEPFAR:** Not part of announcement; current guidance prioritizes pregnant & breastfeeding women — discussions should continue at all levels, and key populations encouraged to engage country coordinators.
- **Regulatory:** FDA approved June 19, 2025; **EMA recommended approval on July 24, 2025** via EU-M4All pathway
- **Early Adopters:** 9 Global Fund–selected countries to submit demand forecasts — some excluding key populations despite existing needs forecast.
- **Capacity:** Gilead says it can produce for >5M users over 3 years if orders placed.



CAB LA for PrEP + MK-8527 Monthly Oral PrEP

CAB LA for PrEP (ViiV)

- **ViiV–MPP License:** Expands CAB LA prevention licensing to 133 countries — LDCs, LICs, LMICs, Sub-Saharan Africa, and countries without CAB patents.
- **Access Potential:** Enables generic production (Aurobindo, Cipla, Viatriis) pending regulatory approvals.
- Expand and accelerate demand creation and literacy to enable choice and support user centered demand creation
- **Our forecast estimates the need for CAB among key populations at 3.53 million person-years by 2030.**

K-8527 Monthly Oral PrEP (Merck)

Potential Impact: A once-monthly oral PrEP pill offering a discreet, user-friendly alternative to injectables.

Access Imperatives:

- If effective, Merck must ensure **timely, broad access**, especially in EXPrESSIVE-10 and EXPrESSIVE-11 trial countries.
- Key populations participants and their communities must benefit from the research.
- Global access planning must occur **in parallel with efficacy trials** — not just post-trial



Defend – Shield KP-led programs from political and funding harm

The March 2025 GBGMC Frozen out report documented the closure or scaling back of hundreds of KP-led clinics—critical infrastructure for delivering LAP.

- Ensure KP-led clinics are protected and funded as part of LAP introduction.
- Push back against non-KP-led organizations positioning themselves to lead demand creation, literacy programs, or technical assistance.
- Leverage the PrEP Power Project to provide tailored, KP-specific TA to all nine Global Fund access countries.

Double Down – Expand coverage, choice, and sustainability

We cannot accept a three-year, two-million target when the need—and capacity—is exponentially greater.

KP Need forecast for Long Acting product by 2030 is 11.5 million person-years on PrEP

- Use the forecasts to press donors and governments to **scale faster**, especially for Black gay men and trans communities.
- Maintain **product choice**, ensuring oral PrEP remains available alongside LAP.
- Build long-term sustainability by embedding LAP plans in national budgets and donor funding cycles.



GBGMC Advocacy Blueprint: Long-Acting Prevention for Key Populations – August 2025

A bold, strategic, and urgent plan to ensure KP-led leadership in the rollout of Long-Acting PrEP globally.

Demand – Make the case for urgent, funded LAP rollout

The LEN approvals, early adopter country list, and demand forecasts are here. The Global Fund has asked nine countries to submit plans and forecasts within weeks

- Use the 20-country GBGMC-led planning process to embed prevention and LAP targets into national HIV plans
- In Global Fund early-adopter countries, ensure KP prevention targets are included in the official **forecasts** and plans submitted to the Global Fund.
- In middle- and high-income countries, use GBGMC's KP-specific LAP need forecast to demonstrate demand to governments and donors.

Deploy – Activate early implementers with product and budgets

- Align LAP targets with existing PrEP targets so funding flows directly to KP-led delivery.
- Use early-adopter country experiences to **show readiness and build political will** for scale-up.
- Secure procurement, regulatory clearance, and trained KP-led providers within months, not



Move Now & Move Together: Call to Action

1. **Advocate** for full Global Fund replenishment & product-specific funding for LEN, CAB LA, and oral PrEP.
2. **Push** for PEPFAR inclusion for *all* populations.
3. **Demand** price & volume transparency from Gilead, Global Fund, ViiV, and Merck.
4. **Coordinate** donor strategies (Global Fund, PEPFAR, Unitaid, Gates, EJAF).
5. **Use** existing coordinating mechanisms eg Long Acting Coalition, KP Prevention Advisory Group, PrEP Power Project
6. **Ensure** countries integrate existing key population demand data and avoid redundant forecasts.
7. **Secure early access plans for MK-8527** — not just post-trial, but full national scale-up in trial-host countries.





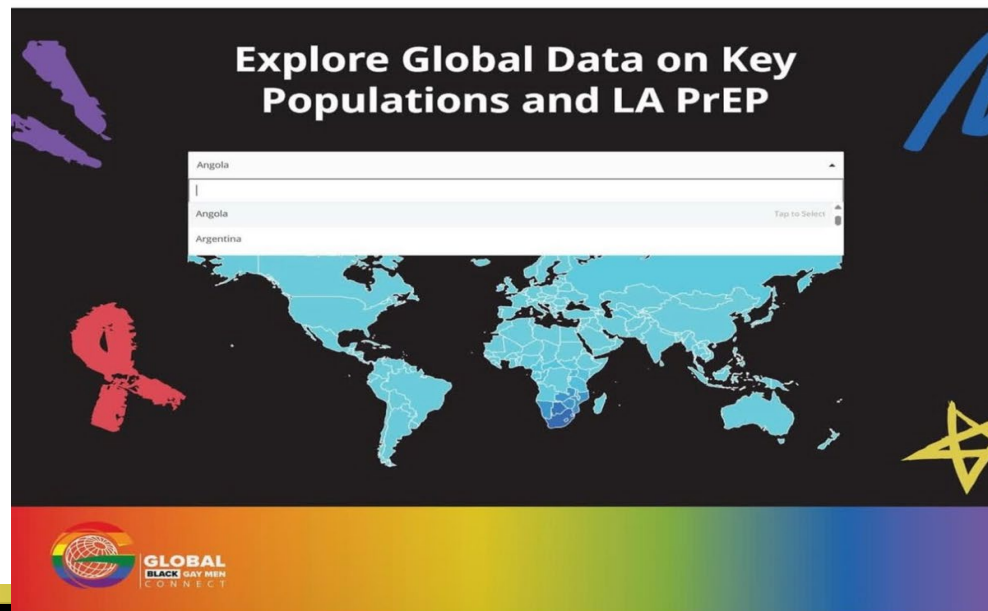
GBGMC

What You Can Explore

- **Key Population Sizes** – Country-level size estimates
- **HIV Incidence** – Where new infections are concentrated
- **LA PrEP Access** – Status of availability and rollout
- **LAP Availability** – Track early adopters and scale-up readiness

NOW
LIVE

The Long-Acting PrEP Interactive Global Map is now live and offers critical visibility into:



Leading Demand Creation and Building Awareness



GLOBAL
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Get Involved – Be Part of GBGMC's 4D Plan



Demand – Make the case for urgent, funded LAP rollout

If you are a KP advocate engaged with your government on LAP forecasting and planning and need support:

kkhanyiso@gbgmc.org

Deploy – Activate early implementers with product and budgets

To learn about the Last Mile National KP Planning Process:

mmilanga@gbgmc.org

Defend – Shield KP-led programs from political and funding harm

Join the KP Long-Acting PrEP Pre-Conference at EACS:

kylie@gbgmc.org

Double Down – Expand coverage, choice, and sustainability

Learn about the Long-Acting PrEP Access Plan Workshop for Black Gay Men & Trans Communities (US):

kylie@gbgmc.org

Human-Centered Design for KP & Long-Acting PrEP – Launching Fall 2025

RobynEakle@gbgmc.org



Friday

August 15th, 12:00 PM EDT

IG LIVE

Session

WHY THIS KP FORECAST MATTERS

JOIN US FOR OUR IG LIVE SESSION

Samuel Anyula Gorigo - Africa

Pronouns: (he/him)



Clinical Arm Lead at Hoymas
Kenya & AVAC Advocacy
Fellow 2024-2025 Kenya

Princess Jauan Durbin - USA

Pronouns: (he/she/they)



Interim Vice President of
Programs & Partnerships at
Southern Legal Center for Youth

Renae Green - Caribbean

Pronouns: (she/her)



Director of Development at
Game Changing Men



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