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From CAB-LA to LEN: Key Lessons and Strategic Implications

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Science, Policy and Community: the
Next Priorities for a Sustainable HIV
Response in Malawi

19-20 October 2026
Lilongwe, Malawi

- **1. Lessons Learned from the PathToScale Initiative:**
Implementation research supporting the rollout of long-acting injectable cabotegravir (CAB-LA) in Malawi.
- **2. Lessons Learned from the PrIMO Study:** Experiences and emerging evidence from pregnant women accessing CAB-LA for HIV prevention in Malawi.
- **3. Strategic Implications for Lenacapavir (LEN) Rollout:**
Applying lessons from PathToScale and PrIMO to inform the introduction and scale-up of LEN in Malawi.

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- Launched in September 2023 as a Malawi Ministry of Health and Sanitation–led implementation science initiative.
 - Supports the real world introduction and scale-up of long-acting injectable cabotegravir (CAB-LA) for HIV prevention.
 - Implemented across 36 health facilities in Lilongwe and Blantyre.
 - Led by the Ministry of Health and Sanitation in collaboration with National AIDS Commission (NAC), and Georgetown University's Center for Innovation in Global Health (CIGH) and many other partners.

1



Mixed methods:
In-depth
interviews,
DCE, & market
segmentation

Sample:
60 qualitative, 550 quantitative

**Formative research to
lay the groundwork for
implementation**

2



**36 diverse sites
in Lilongwe &
Blantyre
(public/private
health facilities
& drop-in
centers)**

Sample:
9,900 (Diverse PrEP eligible
population per Malawi National
Guidelines)

**CAB LA PrEP
implementation lead-in
and delivery channel
evaluation, roll out**

3



**Cluster
randomized trial
and sectional
survey,
qualitative
interviews,
others**

**Sample (serial cross sectional
surveys):**
~500 oral, CAB LA, and non-
PrEP users and discontinued
users,

**1:1 Cluster
randomization of
Objective 2 sites to
evaluate intensive
intervention to support
PrEP continuation**

4



**Strengthening
and adaptation
of BPS
elements**

- M&E and policy translation on cost-effectiveness analysis
- Governance, service delivery, health workforce, information systems, supply chain, financing, demand generation

**Addressing systems
and policy barriers**

What does PathToScale aim to achieve across its 4 Objectives?

- 1. Demonstrate successful programmatic introduction of long-acting injectable PrEP (CAB LA) in Malawi under real-world conditions**, led by the Ministry of Health and Sanitation and integrated within national HIV prevention systems.
- 2. Strengthen systems needed for sustainability** by reinforcing data systems, supply chains, and the health workforce to ensure client continuation and quality service delivery.
- 3. Generate evidence and lessons for national scale-up**, providing a blueprint for integrating long-acting PrEP into Malawi's broader HIV prevention platform.
- 4. Identify “must dos” for future product introductions**, including the next-generation long-acting agents such as LEN, by aligning regulatory, operational, and data systems for multi-product delivery.
- 5. Inform regional and global learning**, positioning Malawi as a model for country-led, data-driven, and health-systems-anchored introduction of new HIV prevention tools.

11

Quality improvement
learning sessions in
Blantyre and Lilongwe

10,029

clients enrolled on
injectable PrEP

180

providers trained in CAB-
LA counseling and
administration

10,700+

data errors rectified to
ensure clean CAB LA data

53+

virtual check-ins held with
providers to correct real-
time challenges and
highlight best practices

80,000+

syringes and related
consumables procured

Path to Scale Lessons from National and District-Level Implementation

01

Design with frontline experts

Involve providers, civil society/community advocates, and technical experts in guidelines, training materials, and ScanForm updates. Test and fix tools before scale-up.

02

Use local quality improvement

Combine QIC, data, and community insights to guide mentorship, engagement, and real-time troubleshooting.

03

Build sustainability into routine care

Embed PrEP delivery in the routine roles of MoH providers and pharmacists.

Path to Scale Lessons from National and District-Level Implementation

04

Scale in phases

Introduce new PrEP products and tools in stages so implementation learning strengthens capacity before scale-up.

05

Forecast together to prevent stockouts

Align national, district, and facility forecasts for PrEP, HIV tests, and other consumables.

06

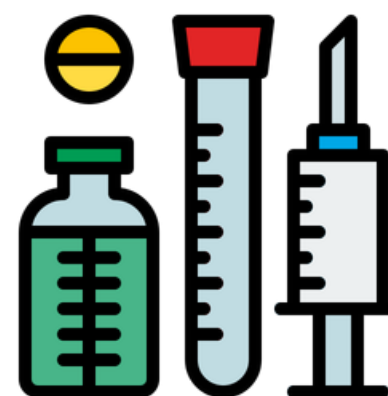
Let data guide access

Use automated monitoring to improve data quality, guide LEN scale-up, and assess value for money in real time.

Recommendations from Providers to Help Inform LEN Rollout



Offer **ongoing, on-demand training** on PrEP options, particularly LEN, with structured peer learning to complement formal training.



Ensuring **clear and real-time communication** around stock availability between facilities, with district coordinators, and with national level colleagues.



Document which demand-creation activities **bring in clients** and adapt those that are no longer working.

Recommendations from Providers to Help Inform LEN Rollout



Clients should select their **own PrEP** follow-up visit dates, within the permitted visit window, to account for their schedules and to promote ownership and shared responsibility.



Counsel clients on **dosing, benefits, and side effects** across PrEP options so they know what to expect.

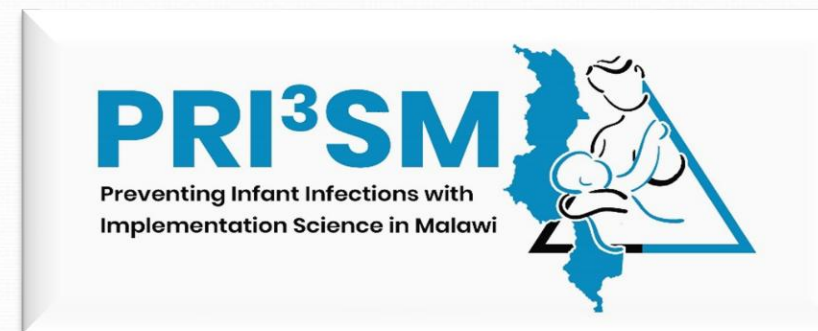


Using the **same PrEP ID** across visits and link testing and PrEP records to track continuation and document seroconversions.

PrIMO

PrIMO is an prospective observational study in Lilongwe, Malawi evaluating the safety of oral PrEP and long-acting injectable cabotegravir (CAB-LA) during pregnancy, analyzing maternal and infant outcomes.

PrIMO Prospective Cohort



Enrollment

Pregnant women attending ANC visits at Bwaila District Hospital in Lilongwe, Malawi

- Demographics
- Baseline health assessment
- Ultrasound scan
- Informed consent

As of May 2026, we have reached the **target enrollment of 621 women.**

Choose Oral PrEP (target n=207)

- Group 1a: Initiate Oral PrEP during pregnancy
- Group 1b: Continue Oral PrEP started before pregnancy

Choose CAB-LA (target n=414)

- Group 2a: Initiate CAB-LA during pregnancy
- Group 2b: Continue CAB-LA started before pregnancy



Interim analysis: baseline characteristics and relative risk of adverse pregnancy outcomes observed in the first two years of the study (17 April 2024-2026)

Objectives

Compare CAB-LA vs. Oral PrEP:

- Composite adverse birth outcomes
- Maternal and infant adverse events
- Growth and neurodevelopment
- Acceptability of PrEP options

Association between PrEP regimen (CAB-LA vs. oral PrEP) and adverse pregnancy outcomes

Saidi F, et al. AIDS 2026. Abstract OAC1306LB

	Composite Adverse Pregnancy Outcome		Unadjusted RR (95% CI)	p-value	Adjusted RR (95% CI)	p-value
	No N (%)	Yes N (%)				
Oral PrEP	154 (92)	13 (8)	—		—	
CAB-LA	264 (90)	29 (10)	1.27 (0.68, 2.53)	0.50	1.42 (0.72, 3.03)	0.30

CI = Confidence Interval, RR = Risk Ratio
RR and 95% CIs were estimated using modified Poisson regression with robust standard errors.
The adjusted model included PrEP duration, gestational age at enrollment, gravida, parity, education level, marital status, number of sexual partners, partner HIV status, occupation, and total earnings.

Funny Kamanga¹, Madeleine A. Squibb², Watipa Nyangulu³, William Wu³, Jiehua Chen³, Chatonda Ngwira³, Anna Drabko³, Wiktor Garbarek³, Maciej Pomykala³, Dominik Bilicki³, Charity Nakanga¹, Gladwell Masiye¹, Lameck Chinula¹, Tisungane Mvalo¹, Maganizo B. Chagomerana¹, Mitch M. Matoga¹, Wiza Kumwenda¹, Tawonga Mkochi¹, Ernest Matola¹, Peter Dias¹, Nomthata Mkochi¹, Virginia Thonyiwa⁴, Rose K. Nyirenda⁵, Linley Chewere⁶, Washington Ozituosauka⁶, Andreas Jahn⁶, Joe Nkhonjera⁶, James Odek⁷, Deborah Hoege⁷, Sheree Schwartz⁸, Felluna Chauwa⁹, Sufia Dadabhai⁹, Sam Phiri¹⁰, Sarah E. Rutstein¹¹, Michael Herce¹¹, Irving Hoffman¹¹, Sara Allinder⁷, Charles B. Holmes⁷, Mina C. Hosseinipour¹ and Friday Saidi^{1*}

What PrIMO has Taught us About CAB-LA

Feasibility in routine ANC

Women can choose and initiate long-acting PrEP within antenatal services when **delivery systems and counselling** are in place.

Safety evidence is emerging

Interim observed birth outcomes have shown no statistically significant differences between CAB-LA and oral PrEP groups; **continued follow-up** remains essential.

Initiation alone is insufficient

Risk perception, partner influence, stigma and postpartum transitions shape continuation.

Systems are essential

Prospective maternal–infant follow-up and the **pregnancy registry** make real-world safety monitoring and policy dialogue possible.

IAS From CAB-LA to LEN for pregnant clients: what must evolve?



1) Broaden product choice

Integrate LEN into **counselling** and **shared decision-making**.

Support **switching** and **continuation** across pregnancy and postpartum.

2) Strengthen safety science

Capture **timing of exposure**, **maternal outcomes**, **birth outcomes**, **infant growth** and **neurodevelopment**.

Add **Pharmacokinetics** and **infant exposure** measures.

3) Adapt delivery systems

Update **registers**, **SOPs**, **provider training** and **pharmacovigilance**.

Prepare for product-specific supply chain needs, visit frequency, and follow-up/continuation needs.

Key shift: from documenting CAB-LA implementation to a platform that can evaluate multiple PrEP options in pregnancy.



Overall Strategic Implications for PrEP in Pregnancy Malawi and the Region

POLICY

Use **emerging local evidence** to inform **inclusive, responsive PrEP guidance** while clearly communicating uncertainty.

IMPLEMENTATION

Prioritize **high-volume ANC/PNC sites**; embed **choice-based counselling, retention support** and **postpartum follow-up**.

SURVEILLANCE

Expand the **pregnancy registry** for LEN, **harmonize exposure/outcome definitions** and **strengthen safety signal** review.

RESEARCH

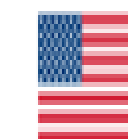
Use the expanded PrIMO cohort to **address LEN maternal/infant safety, PK, growth, neurodevelopment** and **switching questions**.

Expand access and choice together with rigorous pregnancy-specific evidence generation.

- 1. Real-world implementation is feasible:** PathToScale demonstrates that long-acting PrEP can be introduced through routine health services with strong government leadership and health system support.
- 2. Pregnancy safety evidence is encouraging:** PrIMO interim findings show no statistically significant differences in adverse birth outcomes between CAB-LA and oral PrEP, although continued monitoring is essential.
- 3. Lessons from CAB-LA should inform LEN rollout:** Strengthen provider capacity, supply chains, data systems, client-centred counselling and support for PrEP continuation
- 4. Integrate implementation and safety research into national scale-up:** Expand prevention choices while generating evidence on maternal and infant outcomes to guide policy and sustainable HIV prevention programmes.

The transition from CAB-LA to LEN is an opportunity to build a stronger, integrated and evidence-driven HIV prevention programme in Malawi.

Thank you!



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