

Preventing Incident HIV
Infection Among Pregnant
and Breastfeeding Women
Integrating Pre-Exposure
Prophylaxis Within Antenatal and
Postnatal Services

Thursday, 31st July 2025









#### Welcome & Introductions

Maureen Syowai
Interim Project Director (CQUIN/HIVE),
ICAP at Columbia University



#### Agenda

- Welcome and Introductions Maureen Syowai, ICAP at Columbia University
- Framing Presentation WHO PrEP Recommendations for Pregnant and Breastfeeding Women – Michelle Rodolph, WHO
- Country Presentations:
  - Integrating PrEP Into Antenatal and Postnatal Services to Prevent HIV Among Pregnant & Breastfeeding Women – Hasina Subedar, South Africa
  - Preventing Incident HIV Infections Among Pregnant and Breastfeeding Women in Zambia: Tackling Barriers to PrEP Uptake and Continuity – Chimika Phiri, Zambia
- Panel Discussion/Q&A
- Closing and Next Steps Franklin Emerenini, ICAP at Columbia University



#### **Presenters**



Michelle Rodolph

Act. Unit Head

HIV Testing, Prevention, and Populations,
Global HIV, Hepatitis, and STI Programs,
WHO, Geneva



Hasina Subedar
Senior Technical Advisor,
NDOH, South Africa



Chimika Wilson Phiri HIV Prevention Lead, Ministry of Health, Zambia





Framing Remarks

Michelle Rodolph

World Health Organization,
Geneva



## Preventing Incident HIV Infections:

WHO recommendations on PrEP for pregnant and breastfeeding women

Michelle Rodolph WHO Geneva rodolphm@who.int

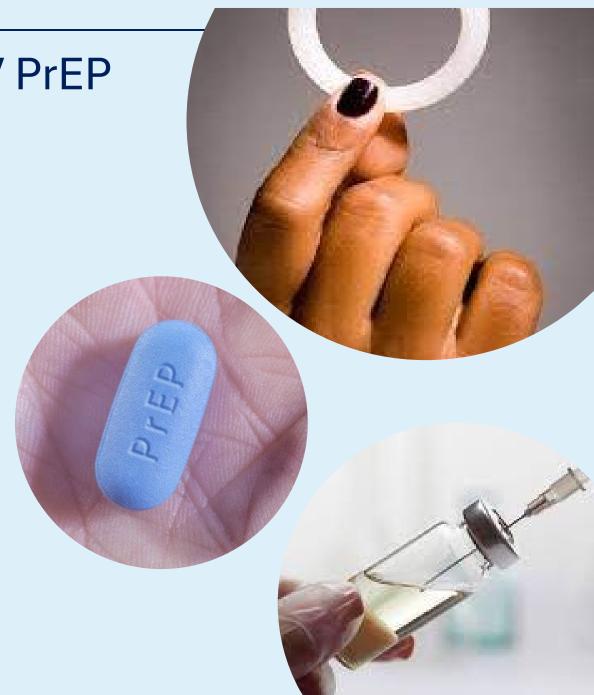


WHO recommendations on HIV PrEP

WHO has recommended four products for use as PrEP:

- 1. Oral PrEP containing tenofovir disoproxil fumarate (TDF) (2015)
- 2. Dapivirine vaginal ring (DVR) (2021)
- 3. Long-acting injectable cabotegravir (CAB-LA) (2022)
- 4. Long acting injectable lenacapavir (LEN) (2025

As part of comprehensive HIV prevention approaches, based on evidence for effectiveness, safety, community values and preferences, likely cost effectiveness etc.

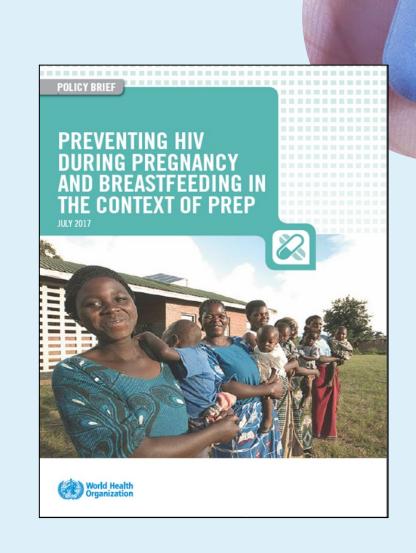




# Oral PrEP containing TDF - OK in pregnancy

- No safety risk for initiating or continuing PrEP during pregnancy and breastfeeding
- Risk of HIV acquisition and accompanying increased risk of mother-to-child HIV transmission far outweigh the potential risk of fetal and infant exposure to TDF used for PrEP.
- Decision on whether to continue PrEP during pregnancy and BF should be made by the pregnant woman in consultation with her health provider, balancing risks on HIV acquisition against potential harms
- Additional surveillance is important





#### Dapivirine vaginal ring

#### used to be additional data needed

The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches.

(conditional recommendation; moderate-certainty of evidence)

In RCTs and OLEs, **no difference** in the treatment and placebo arms **of AEs** related to pregnancy, fetal outcomes and/or infant outcomes.

Number of pregnancies was small **and participants stopped ring use once pregnancy was known**. Ongoing trials are further assessing safety data during pregnancy and breastfeeding

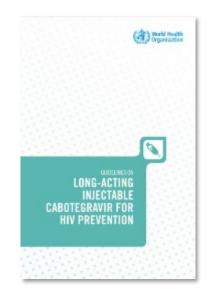
- DELIVER
- B-Protected





# Long-acting injectable cabotegravir (CAB-LA) used to be probably ok

Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (conditional recommendation; moderate certainty of evidence).



#### **Outstanding critical issues**

- Drug resistance
- HIV testing
- Limited representation of key populations
- Safety during pregnancy and breastfeeding



# Guidelines on lenacapavir for HIV prevention – **OK in pregnancy**

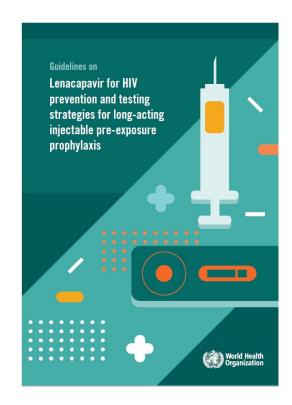
#### **New recommendations**



#### **Recommendation [NEW]**

**Long-acting injectable lenacapavir** should be offered as an additional prevention choice for people at risk of HIV, as part of combination prevention approaches. (strong recommendation, moderate to high certainty of evidence)

- **LEN showed no increase in adverse pregnancy or birth outcomes** among the 184 pregnancies reported in PURPOSE 1 so far.
- No dose adjustment is likely to be required during pregnancy, with pharmacokinetic data indicating standard dosing remains effective.





## WHO 2025 PrEP guidelines provide updates on using LA <u>PrEP</u> during pregnancy and breastfeeding



- Review pk and safety data available on LEN PreP from PURPOSE 1 showed
  - no dose adjustment during pregnancy
  - no increase in adverse pregnancy or birth outcomes among 184 pregnancies
- Review of new safety data available on
  - CAB (HPTN 084 OLE)
  - DVR (MTN-043/DELIVER, MTN-043/B-PROTECTED)

The 2025 guidelines recommend that for any of the available PrEP products:

- PrEP should NOT be discontinued during pregnancy and breastfeeding for women with a risk of exposure to HIV
- The choice to start, continue, or discontinue PrEP when becoming pregnant should be made by the individual, following discussion of the risks and benefits with a health-care provider



#### Beyond LEN: Current safety data oral PrEP, DVR and CAB-LA in pregnancy

Women can continue to use oral PrEP, the DVR and CAB-LA during pregnancy and breastfeeding.

Based on the available safety data, WHO concludes that PrEP with **any of the available** products should **not be discontinued** during pregnancy and breastfeeding for HIV-negative women with a high likelihood of exposure to HIV.

The choice to **start, continue or discontinue** PrEP when someone becomes pregnant should be **made by the woman**, indiscussion of the risks and benefits with a **health care provider**.



## More data needed for PrEP in pregnancy

However, the 2025 PrEP guidelines emphasise

 More data are needed on uncommon and rare adverse events, e.g., birth defects, neonatal mortality, and stillbirth

Surveillance programmes within PrEP programmes need to be implemented





## Simplified testing for long-acting PrEP

Background, evidence, recommendations and implementation

July 2025



#### **New WHO recommendation**



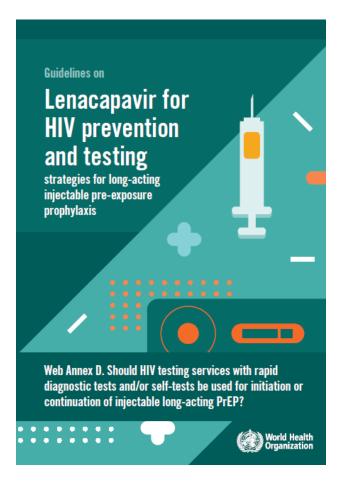
Rapid diagnostic tests may be used for HIV testing for initiation, continuation and discontinuation of long-acting PrEP

(strong recommendation, very low certainty of evidence)



- HIVST may be an important implementation consideration in some contexts, increasing programme flexibility and testing frequency
- Implementation research remains important in this area
- WHO will review emerging evidence as soon as it is available and update guidance

### Evidence\* on HIV RDTs for injectable LA-PrEP



HIV RDT supported injectable LA-PrEP compared to NAT and/or laboratory-based testing algorithms resulted in:

- Faster turnaround time and more rapid ART initiation
- Fewer delayed or missed injection visits
- Similar negative predictive value and positive predictive value
- No difference in absolute number of missed or delayed HIV infections detected or the detection of breakthrough infections
- No difference in the prevention of INSTI resistance associated mutations
- · No difference in frequency of testing
- No difference in clinical or social harm
- High acceptability and feasibility
- Substantial cost-savings ----

To detect 1 additional HIV case, missed by a rapid test, using NAT requires testing 5,305 people with estimated cost of \$46,684 - \$451,456 per test\*

Source: WHO 2025, <u>Tieosapjaroen et al</u> 2025; <u>see annex for more details</u>

\*Systematic review included 22 studies (CAB-LA: 20 studies, LEN: 2 studies) involving 15 594 participants and spanning Africa, Asia, Europe and the Americas. Evidence included non-randomized comparator studies (n=7) and observational studies without a comparator group (n=15). There was limited information on continued HIV testing among those who discontinued injectable LA-PrEP.



## Implementing lenacapavir in countries



# Global Fund, PEPFAR Announce Coordinated Effort to Reach 2 Million People with Lenacapavir for PrEP to Significantly Reduce Global HIV Infections





17 December 2024

GENEVA | WASHINGTON D.C. – The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and the United States President's Emergency Plan for AIDS Relief (PEPFAR) have joined forces with the Children's Investment Fund Foundation (BMGF) to announce today a coordinated effce equitable access to twice-yearly injectable lenacapavir for Global Fund Secure contingent upon regulatory approval from the U.S. Food apparamaceutical regulators, and a recommendation from the Pledge – A Histor

# equitable access to twice-yearly injectable lenacapavir for contingent upon regulatory approval from the U.S. Food a pharmaceutical regulators, and a recommendation from to Pledge – A Historic Private Sector Commitment from Children's Investment Fund Foundation



02 April 2025

LONDON – The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) today announced the first pledge to its Eighth Replenishment Campaign – and it comes from the private sector. The Children's Investment Fund Foundation (CIFF) has made a groundbreaking US\$150 million commitment, a five-fold increase from its previous contribution. This historic pledge not only underscores CIFF's unwavering commitment to global health, but also sets a powerful precedent for private sector leadership in the fight against HIV/AIDS, tuberculosis (TB) and malaria.





Unitaid launches new funding opportunity to support costeffective and impactful rollout of lenacapavir in sub-Saharan Africa

04 July 2025



# 2025 update to the antiretrovirals in pregnancy research toolkit!

New materials and guidance are available!

**Open Access Living Toolkit!** 





## Thank you!

#### **ACKNOWLEDGMENTS**

- WHO F. Renaud, M. Doherty, M. Vitoria
- HHS PTWG chairs & Secretariat E. Abrams, S. Delany-Moretlwe, S. Lockman, C. Waitt, L. Mofenson, C. Townsend, J. Zech
- HHS PTWG experts on HIV, Hepatitis, and STIs

Special thanks to all the women around the world who inspire our work

For more information, please contact:
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Michelle Rodolph rodolphm@who.int (PrEP)







## **Country Presentation**

Hasina Subedar Senior Technical Advisor, NDOH, South Africa



# Integrating PrEP Into Antenatal and Postnatal Services to Prevent HIV Among Pregnant & Breastfeeding Women

Orapeleng Motlhaoleng Leeuw and Hasina Subedar

National Department of Health - South Africa





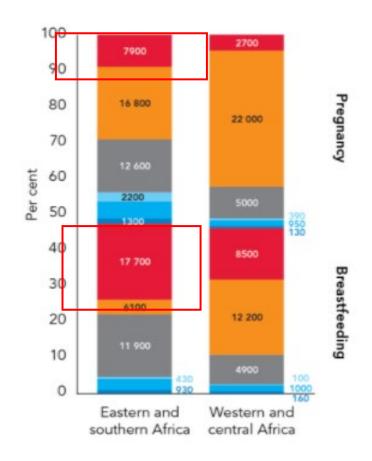




#### Background

- Historically there was observed high rate of new HIV infections among pregnant and breastfeeding women
- 1/3 of HIV infections in infants were attributed to new maternal HIV infections during pregnancy and breastfeeding period
- Antenatal HIV testing and retesting data from 2019 to 2022 revealed high testing rates, highlighting opportunities to identify women at ongoing risk of HIV infection
- There are 76,000 new infant HIV infections projected in the next 10 years
- This formed the basis for expanding PrEP availability and standardizing risk-benefit counseling

Risk factors for HIV vertical transmission



Source: UNAIDS 2019 estimates.

Sources: Graybill et al, AIDS, 2020; Joseph Davey et al, AIDS, 2019; Stranix-Chibanda

et al, CID, 2020

Acknowledgement: Clinical Training Slides PrEP-PP 2021

In red: mother infected in pregnancy or breast feeding & infant infected (~1/3 of cases)

# Opportunity for Expanding PrEP for Pregnant Women: Antenatal HIV Testing and Re-Testing Data 2019- 2022

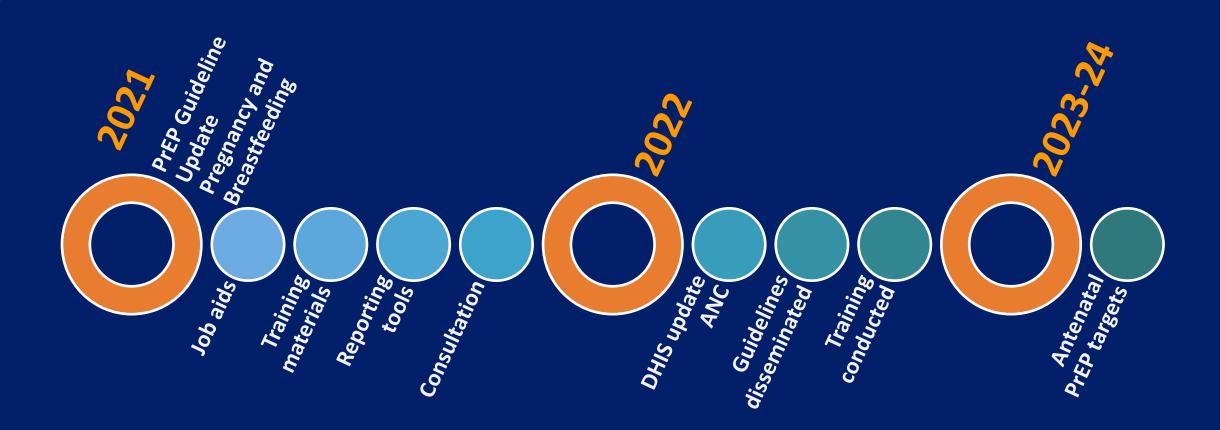
U	Antenatal HIV 1st test	Antenatal client HIV 1st test negative	Antenatal HIV 1st test positive	Antenatal client HIV re- test	Antenatal HIV re-test positive	Antenatal HIV re-test negative
<b>2018</b>	845 125	753 478	91 647	1 186 321	7 187	1 179 134
<b>2019</b>	875 840	794 683	81 157	1 415 890	6 758	1 409 132
<b>2020</b>	889 705	818 098	71 607	1 803 074	6 374	1 796 700
<b>2021</b>	856 232	796 452	59 780	1 983 587	5 820	1 977 767
<b>2</b> 022	811 935	762 907	49 028	2 024 093	5 692	2 018 401

- Antenatal HIV testing and retesting data from 2019 to 2022 revealed high testing rates,
   highlighting opportunities to identify women at ongoing risk of HIV acquisition.
- This formed the basis for expanding PrEP availability and standardizing risk-benefit counseling.





#### **Pathway to PrEP Rollout in South Africa**







# Resources Developed to Support the Introduction of Oral PrEP in Antenatal and Postnatal Services



Implementation guideline, job aids, clinical stationery



Implementation planning tool



Facility based oral PrEP Targets (incl. demand generation, HIV testing)



Monitoring and evaluation DHIS & TIER.Net



Social mobilisation and demand creation resources



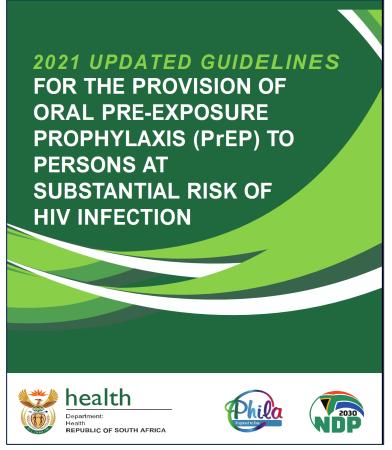
**Training videos (online & offline)** 



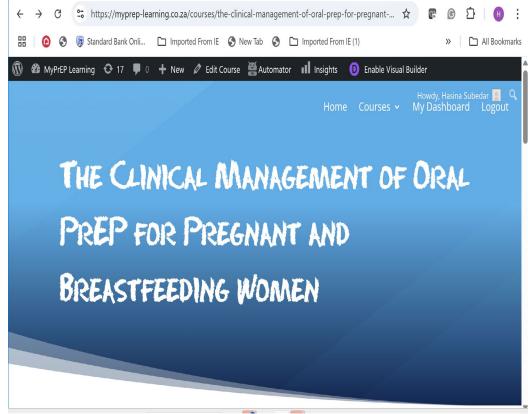


#### Implementation Guidelines and Resources

#### South Africa PrEP Guideline



## Online Training Video Oral PrEP for Pregnant and Breastfeeding Women







# Expanding PrEP Availability for Pregnant and Breastfeeding Women

#### **Approaches in different contexts:**

## Existing PrEP users that became pregnant

- Retention
- Linked to ANC package
- Risk reduction counselling
- Partner testing

## Pregnant HIV negative women at high risk

- HTS
- Risk reduction counselling
- Information PrEP
- Baseline testing
- Initiation
- Adherence support
- Partner testing

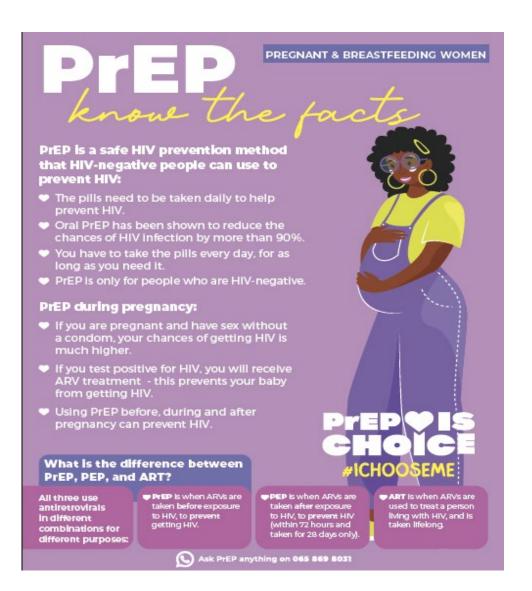
#### Retaining women on PrEP post delivery period

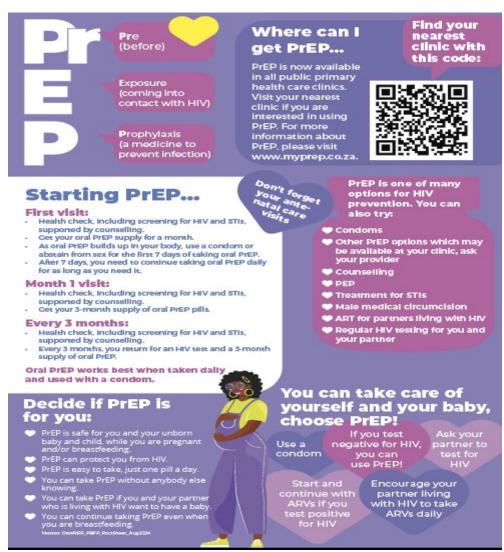
- Adherence support
- Partner testing





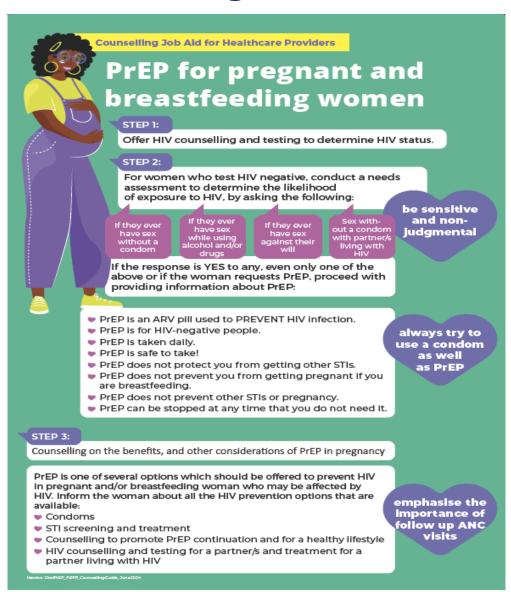
#### PrEP Fact Sheet Used to Create Awareness and Demand for PrEP







#### **Counselling Job Aid for Health Care Providers**









## Counselling Steps for All Pregnant and Breastfeeding Individuals

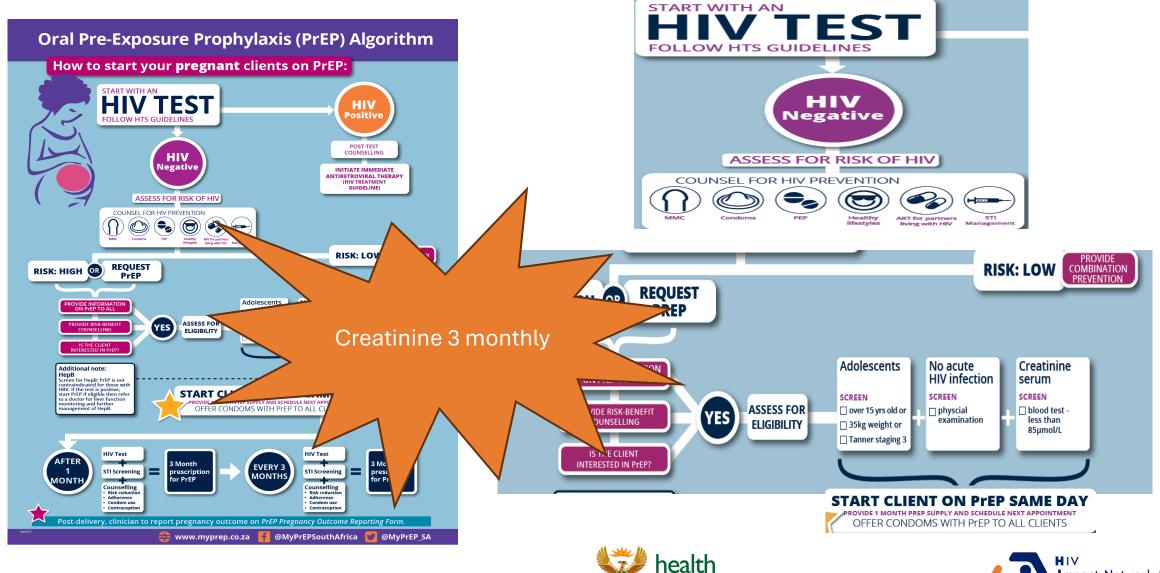
- Identify pregnant and breastfeeding women who are HIV negative and at risk of acquiring HIV during the first antenatal visit and subsequent visits
- Inform all pregnant and breastfeeding women of the HIV prevention methods available to them and about each of these methods, including PrEP
- Support the woman to choose an HIV prevention method/s that best suits her
- Refer all women choosing PrEP as a preferred option to a healthcare professional for further assessment and initiation

#### **PrEP Eligibility Criteria**

- HIV negative by routine rapid antibody test
- Absence of symptoms of acute HIV infection
- Willing and able to take PrEP as prescribed
- No contraindication to TDF or FTC
- Adolescents > 35 kg in weight; if <15
  years in age, adolescents should be
  Tanner stage 3 (sexual
  maturity rating) or greater</li>



## Implementation Guidance: Clinical Algorithm for PrEP Initiation



Department:

REPUBLIC OF SOUTH AFRICA



# Reporting of PrEP in Pregnancy: Opportunities for Safety Surveillance

#### **Routine Reporting**

 New data element collected on DHIS from 1 April 2023

ANC clients started on PrEP

#### Pregnancy Outcome Report

 Routine reporting of the outcome of the pregnancy of a woman initiated and managed on PrEP during pregnancy

Collation and analysis of pregnancy outcome reporting data are required

#### **Seroconversion Report**

All clients on PrEP that seroconvert

Collation and analysis of seroconversion data are required



# Monitoring and Evaluation Tool: Pregnancy Outcome Reporting

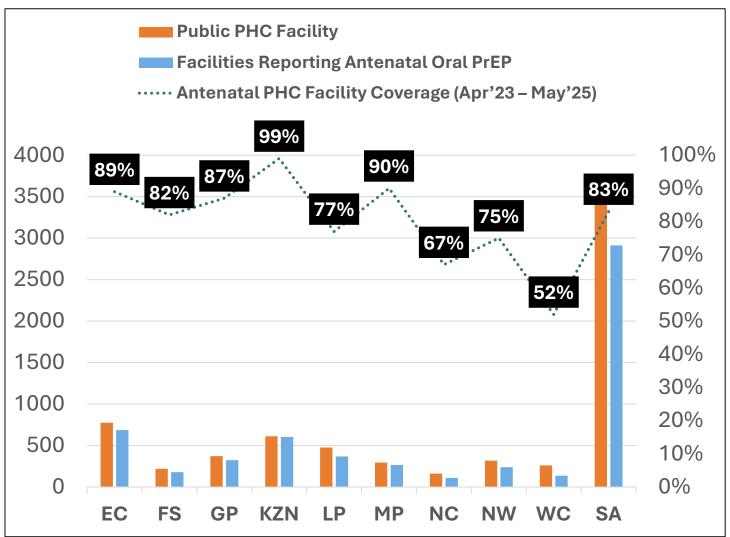
health  Sugar Training  HEEP VALUE OF		PrEP Pregnancy Outcome Reporting Form										
First name						Folder #						
Surname						#						
ID Number	dd / mm / yy	dd / mm / yy Gender:				M /	Address					
Instructions: Please use the below to capture the pregnacy outcomes of mothers exposed to PrEP drugs at any time during their pregnancy. The available fields must be completed as much as possible with the relevant information available at the time of reporting. Please complete and affix a copy of the PrEP clinical form and/or laboratory results that are necessary.												
PrEP drugs exposure before/during pregnancy												
PrEP start date dd /		mm / yy	Time of Pri		Before pregnar		Date of positive urine test	dd / mm / yy				
PrEP stop o	date dd / r	nm / yy		on	During pregnancy		Date of delivery	dd / mm / yy				
Drug nam	Drug name (s): Dose: Daily Monthly OtherSpecify:											
				Pregnand	y outcome							
Did the clie complications pregnancy?	nt experience any during	Y Yes. Specify:  N No										
2. Did the clie	nt give birth to (a)	Y Yes. Date of delivery dd / mm / yy										
live infant(s)?	, , , , , , , , , , , , , , , , , , ,	No. Specify reason:										
3. Was the inf birth?	ant normal at	Y Yes  No. Specify abnormality and reason:										
<ol> <li>Additional of pregnancy/del</li> </ol>												
					information							
Infant number	Infant sex	Infant length (cm)	nfant weight (g)	APGAR score			Comment					
1	F M											
2	F M											
3	F M											
(with focus	medical history s on relevant prior cal/obsteric history)											

The tool is used to capture outcome for women who initiated and continued PrEP during pregnancy





# Implementation Progress: Public Primary Health Care Facilities Reporting Oral PrEP in Antenatal Services

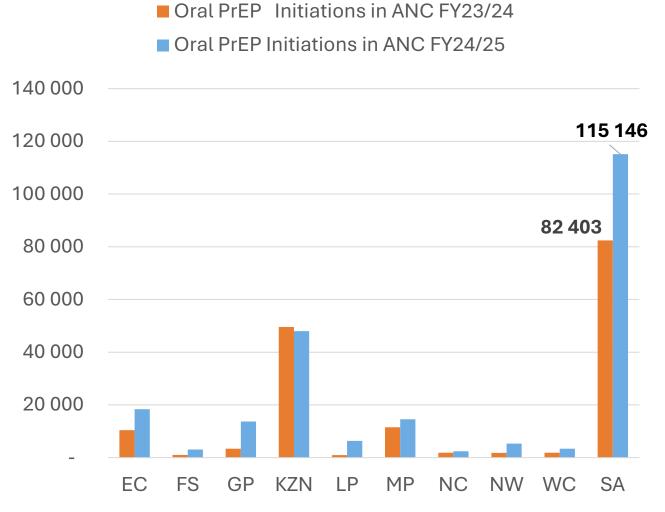


- 83% of all PHC facilities in South Africa reported offering oral PrEP within antenatal services during the reporting period.
- While national averages are strong, interprovincial disparities suggest a need for targeted efforts to improve PrEP integration and reporting in underperforming provinces.





#### Implementation Progress: Uptake of Oral PrEP Initiation in Antenatal Services



- Nationally, oral PrEP initiations in ANC rose from 82,403 (FY23/24) to 115,146 (FY24/25 YTD).
- This is a ~40% increase, signaling successful scale-up and integration of PrEP into antenatal care
- While national figures are promising, wide variation persists between provinces, requiring targeted support in provinces with low uptake
- Sustain momentum in high-performing provinces.
- Scale tailored demand creation, provider mentorship, and consistent supply in underperforming provinces.
- Deepen the integration of PrEP into ANC workflow to ensure early and continued offer of PrEP services.





#### Challenges and Lessons Learned

Despite progress, challenges remain. Some of the key challenges include:

Inconsistent risk perception among pregnant women and healthcare providers.

Stigma associated with taking PrEP during pregnancy, often mistaken for HIV treatment.

Provider hesitancy due to limited experience or confidence in counseling on PrEP during pregnancy.

Limited post-initiation support, which affects continuity during the postpartum period.





#### **Conclusions and Lessons Learned**

South Africa's experience demonstrates that pregnant and breastfeeding women will take up PrEP when services are accessible, counselling is affirming, and follow-up is supportive.

To sustain and scale this progress, we recommend:

- Intentional inclusion of PrEP in maternal health service packages as part of routine care, supports scale up
- Healthcare worker training and mentorship is essential
- Expansion of community-based demand creation and support improves access to women in the postpartum period
- Safety surveillance and longitudinal monitoring helps to generate local evidence and build confidence





#### Resources

#### **Provider tools**

https://myprep.co.za/providers/

#### **Training Videos**

https://myprep.co.za/the-clinical-management-of-oral-prep-for-pregnant-and-breastfeeding-women/





# Thank you.









# Country Presentation Chimika Wilson Phiri HIV Prevention Lead, Ministry of Health, Zambia



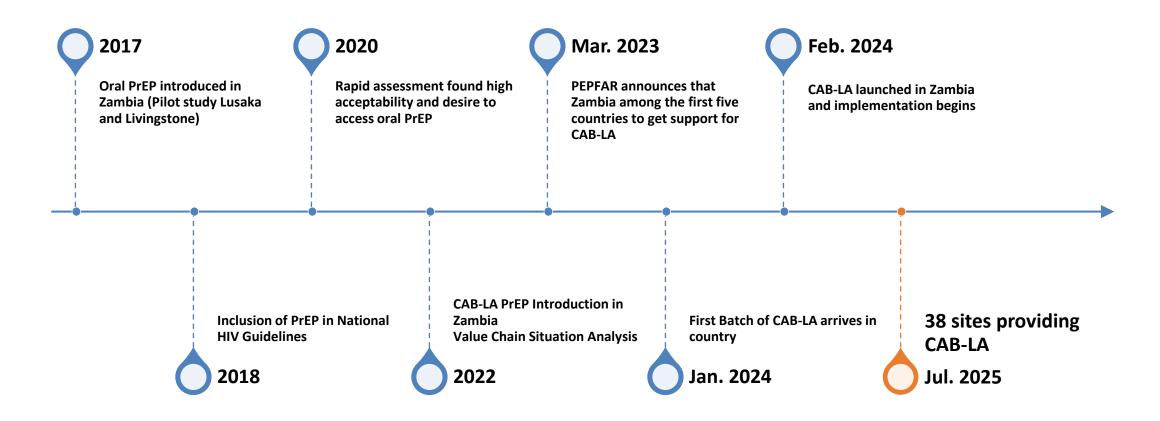
## Preventing Incident HIV Infections Among Pregnant and Breastfeeding Women in Zambia: Tackling Barriers to PrEP Uptake and Continuity







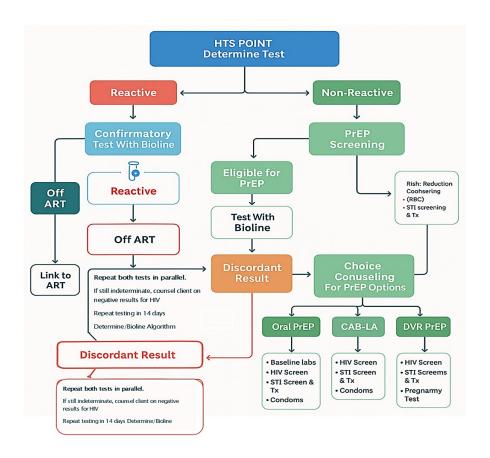
#### Timeline of PrEP Rollout in Zambia





## **PrEP Eligibility Criteria**

#### HIV testing algorithm for PrEP



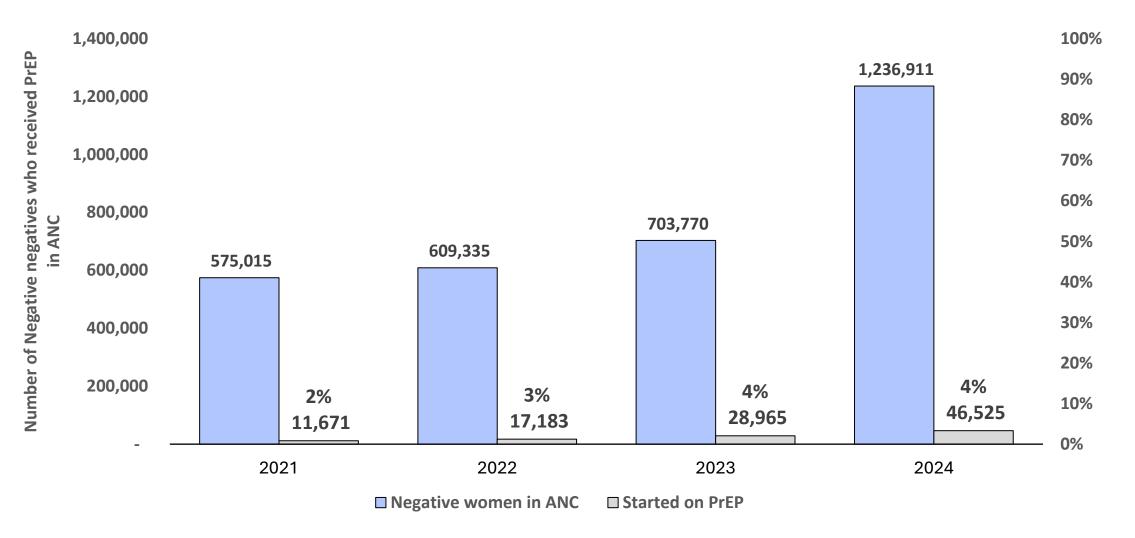
#### **Clients must:**

- Be HIV negative on 2 serological rapid tests
- Not be eligible for PEP
- At risk of HIV infection
- Have no signs and symptoms of AHI
- Make a well-informed decision and be willing to initiate PrEP
- Free from contraindications for use of their chosen PrEP method

Same PrEP eligibility criteria for pregnant and breastfeeding women

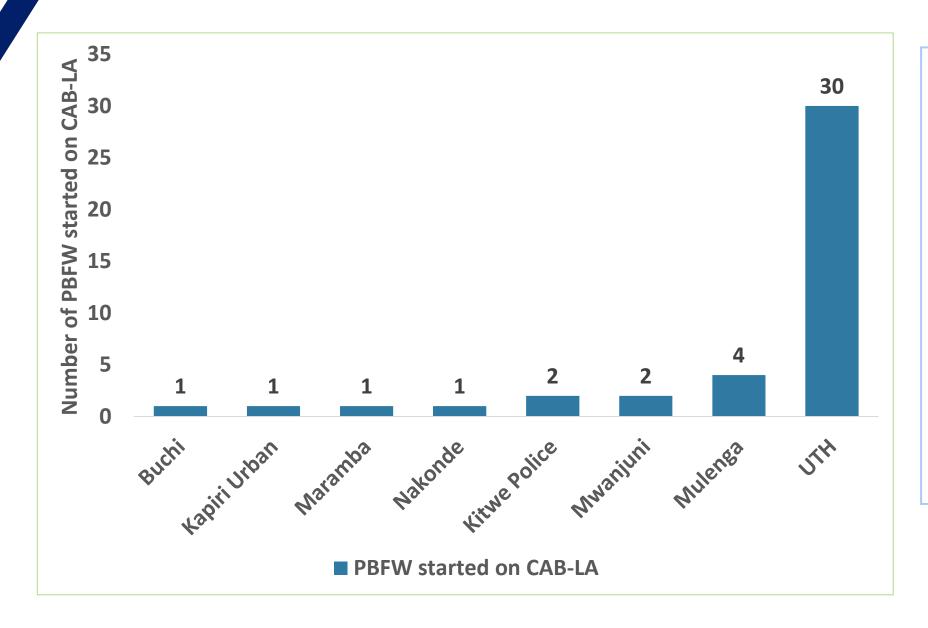


#### Trends in PrEP Uptake for PBFW: 2021-2024





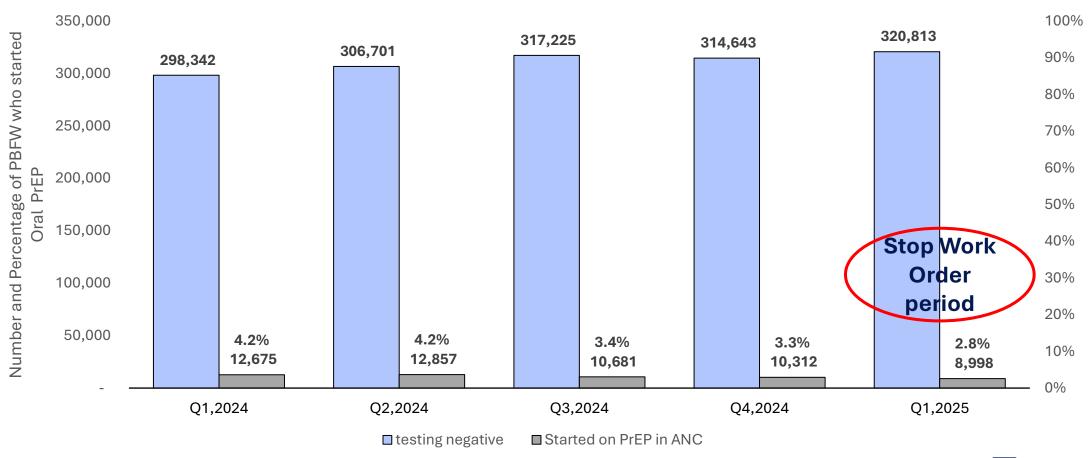
## **CAB-LA Use in PBFW Per Facility**



- Initial guidelines did not permit CAB-LA use among PBFW, however women who got pregnant while on CAB-LA were counselled to continue
- With recent evidence on safety of CAB-LA use in pregnancy there is a gradual uptake at facilities

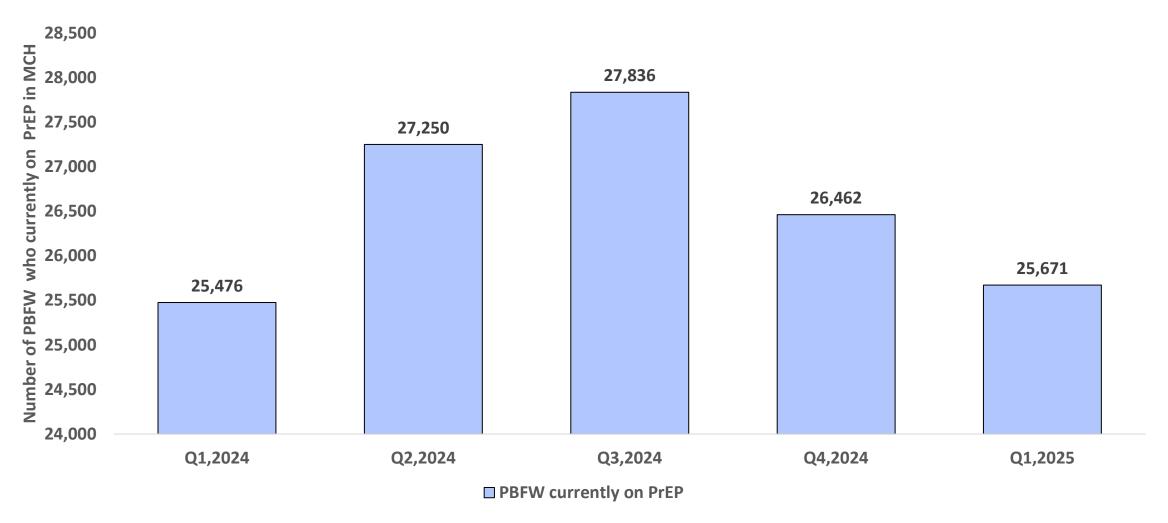


#### PrEP Initiation in PBFW:2024 Q1-2025Q1





#### Trends in PrEP Continuity for PBFW Quarterly





# Innovative Approaches to Increase PrEP Uptake and Continuity

- Integration of PrEP in maternal and child health (MCH) clinics
  - Provision of PrEP in MCH clinics as opposed to the ART clinic
- Increase group and individual counselling on the availability of PrEP in MCH clinics during ANC and postnatal
- Capacity building of providers in MCH settings
- Peer-to-peer approach for demand creation
- Expanding of CAB-LA for PBFW
- Promoting male partner involvement in ANC



#### Challenges and Lessons Learned

- ☐ Low uptake of PrEP among PBFW
  - Lack of autonomy by the PBFW to decide whether to take PrEP
  - Stigma around the use of PrEP is partly contributed to by;
    - Low knowledge of PrEP by the community
    - Centralized access to PrEP in the ART clinic
    - PrEP is still medicalized
  - Age of access to HTS as a barrier
- Multiple data-capturing tools that are not interoperable



# Early Successes and Recommendations for Scale-Up

- Good response to uptake of CAB-LA by pregnant women
- Peer-to-peer approach good strategy for demand creation
- Good collaboration between the government and implementing partners contributed to the successful phase one implementation
- The program plans to scale up CAB-LA to all ten provinces, targeting districts with high maternal incident infections



# Thank you.







## **Q&A/Discussion**

#### **Moderators**



Bernadeta Msongole HIVE Regional Clinical Advisor ICAP Tanzania



Eleen Ekanem HIVE Country Lead PATA, Nigeria

#### **Panelists/Discussants**



Michelle Rodolph
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Hasina Subedar Senior Technical Advisor NDOH- South Africa



Chimika Wilson
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HIV Prevention Lead
Ministry of Health,
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Orapeleng Motlhaoleng-Leeuw Public Health Practitioner NDOH-South Africa



Stella Kassone Technical Director NACOPHA, Tanzania





## **Closing Remarks**

Franklin Emerenini
Deputy Director (HIVE),
ICAP at Columbia University



# Slides & recordings from this session will be available on the HIV Vertical Transmission Elimination Network (HIVE) website

hiveimpactnetwork.com







# Thank you.





