



# WHO RECOMMENDATIONS ON PREP FOR PREGNANT AND BREASTFEEDING WOMEN

Dr Thato Chidarikire: HIV PREVENTION

WHO-SA

**HIVE Launch Meeting**

December 4-6, 2024 | Johannesburg, South Africa

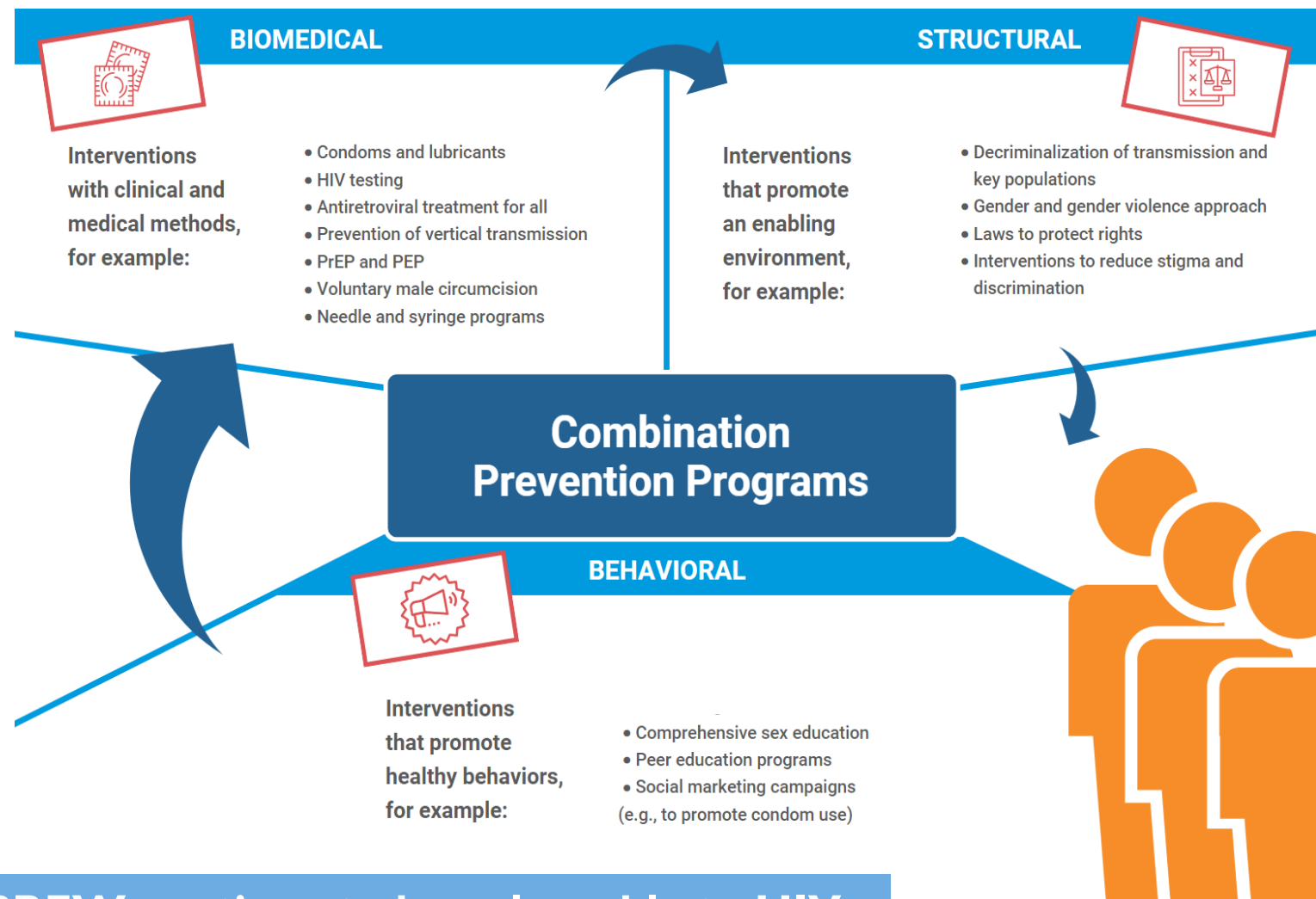


**HIV**  
Impact Network for  
Vertical Transmission  
Elimination



# PREP: KEY PART OF COMBINATION HIV PREVENTION

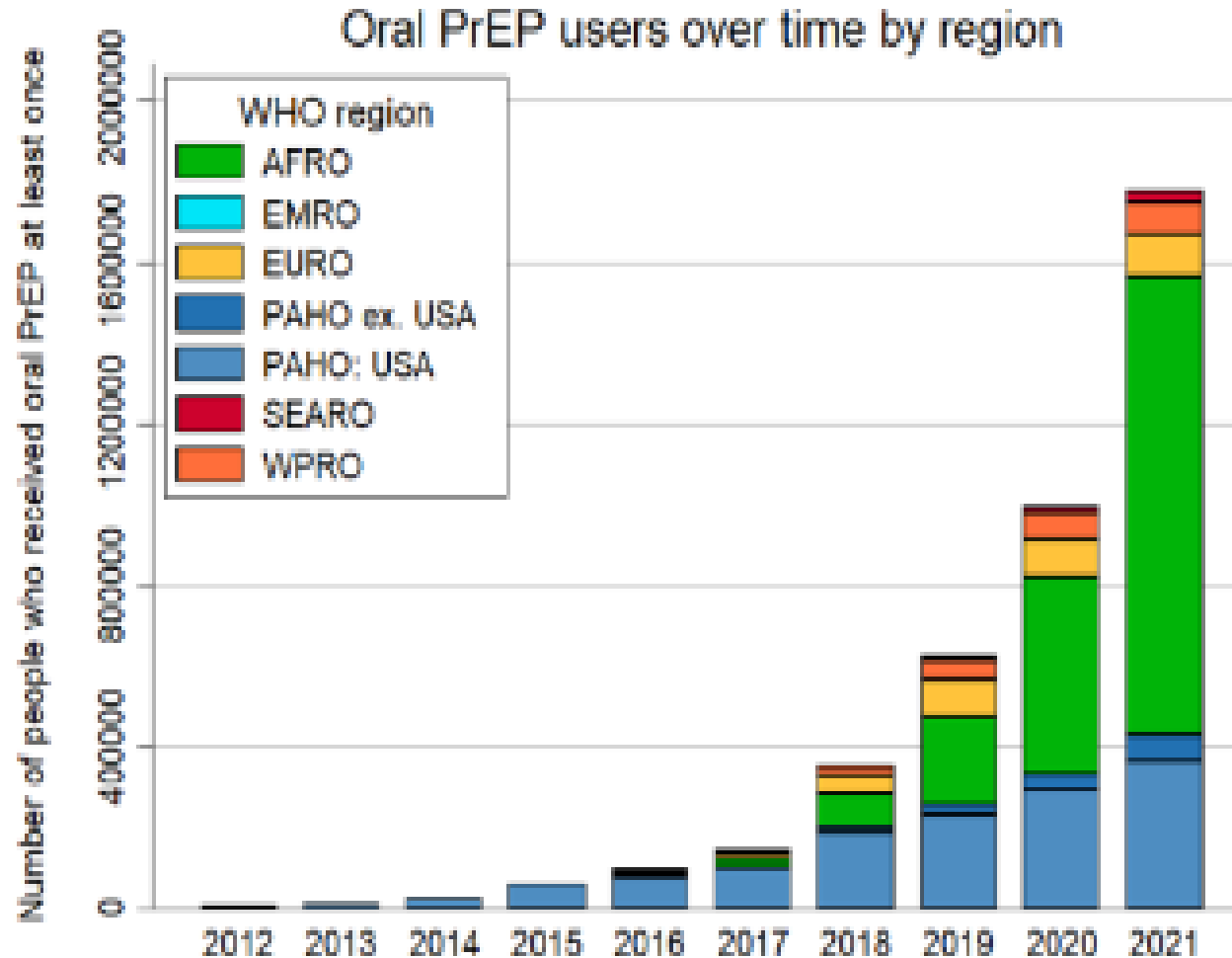
- Pre-exposure prophylaxis (PrEP) is an effective ARV-based HIV prevention option. It is started prior to a potential exposure
- PrEP is not life-long and can be started/ stopped/ restarted
- PrEP does NOT protect against other STIs OR pregnancy
- Empowering tool with psychological benefits



**PBFW continue to be vulnerable to HIV infection in specific contexts, particularly for high-burden settings where women remain at high risk of HIV acquisition.**

Adapted from PAHO

# Rapid PrEP SCALE-UP is needed to end the epidemic by 2030



**Sources:** Global AIDS Monitoring for 2023, WHO PrEP reporting and personal communications (unpublished)

**Note:** here "PrEP user" refers someone who is known to have used PrEP at least once within the previous 12 months

# Offering choice in prevention and PrEP products can increase uptake, effective use, satisfaction and protection

- The advantages, disadvantages and other features of each product should be clearly explained to allow a genuine choice
- Prevention and PrEP choice is dynamic
- WHO does not support one PrEP product over any other

**The best PrEP product is the one someone *wants* to use and will use well**



**2021 WHO Recommendation**



**2015**



**2022**

# ORAL PREP IN PBFW

The PROMISE study (Promoting Maternal and Infant Survival Everywhere) was a landmark clinical trial that investigated the safety and efficacy of antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP) in pregnant and breastfeeding women.

## Findings:

1. **\*PrEP efficacy:\*** PrEP was found to be highly effective in preventing HIV acquisition in pregnant and breastfeeding women.
2. **\*ART efficacy:\*** ART was highly effective in preventing MTCT of HIV.
3. **\*Safety:\*** Both PrEP and ART were found to be safe for pregnant and breastfeeding women.
4. **\*Adherence:\*** Adherence to PrEP and ART was high, with over 90% of participants reporting good adherence.

## Objective:

1. **\*To evaluate the safety and efficacy of ART and PrEP in preventing mother-to-child transmission (MTCT) of HIV and reducing HIV acquisition in pregnant and breastfeeding women.**
2. **\*Design:\*** A randomized, open-label, multicenter trial conducted in 14 countries.
3. **\*Participants:\*** Over 4,000 pregnant women living with HIV or at high risk of acquiring HIV.
4. **\*Interventions:\*** Participants received either ART, PrEP (tenofovir/emtricitabine), or a combination of both.

# ORAL PREP

## Implications:

1. **\*PrEP as an additional prevention option:\*** The study demonstrated that PrEP can be a valuable addition to existing HIV prevention strategies for pregnant and breastfeeding women.

2. **\*ART as a cornerstone of PMTCT:\*** The study reinforced the importance of ART as a cornerstone of prevention of mother-to-child transmission (PMTCT) programs.

3. **\*Integration of PrEP and ART into maternal and child health services:\*** The study highlighted the need for integration of PrEP and ART into maternal and child health services to improve HIV prevention and treatment outcomes.

# DAPIVIRINE RING IN PBFW

Safety studies of DVR use during pregnancy have shown a favorable safety profile among pregnant women and their infants; there is no evidence of negative impact on pregnancy or infant outcomes.

## DVR safety data during pre-conception and early pregnancy

- While MTN-020/ASPIRE did not enroll pregnant individuals, almost 90 incident pregnancies occurred among participants using the DVR, offering insight on pre-conception and early pregnancy exposure safety data.
- Among participants, there was no impact on fertility rates and no association with preterm birth, pregnancy loss, congenital anomalies, or poor infant growth.

# DAPIVIRINE RING IN PBFW

## DVR safety data during pregnancy

- MTN-042/DELIVER was the first major study among pregnant individuals in three gestational age cohorts. Participants were randomized to use the DVR or oral PrEP through delivery.
- Data showed the DVR had no association with preterm birth or stillbirth or maternal or infant SAEs. There were also no HIV seroconversions and pregnancy complications were uncommon, similar to the background rates observed in study communities.

## DVR safety data during breastfeeding

- MTN-043/B-PROTECTED enrolled approx. 200 exclusive breastfeeding mother-infant pairs. Participants were randomized to use DVR or oral PrEP with product used for 12 weeks.
- Key findings showed a good safety profile in both mothers and infants, with no SAEs related to the DVR in either group and very little dapivirine present in milk, with even less passed to infants.



# CAB-LA PREP IN PBFW

Intramuscular injection every 8 weeks  
(with first two, 4 weeks apart)

Phase III trials (HPTN 083 and 084)  
showed high efficacy

Data available from the number of women  
who became pregnant during the studies  
**suggest** that CAB-LA **may be** safe during  
pregnancy and breastfeeding

Antenatal and postnatal care services offer an  
opportunity to offer PrEP services, including  
CAB-LA, for women at substantial risk of HIV  
infection

- **More operational experience** and research  
are still needed to understand the unique  
needs and challenges of this population and  
how to best address them.

- The study reported 367 pregnancies.
- Maternal adverse event rates were 45.7, 47.1, and 37.5 per 100 person-years for those using CAB-LA during pregnancy, before pregnancy, and not using CAB-LA, respectively.
- Infant outcomes were consistent across groups, with adverse events reported in 33%, 38%, and 27% of pregnancies. One congenital anomaly was observed in a participant on CAB-LA, with no maternal deaths.

***Overall, CAB-LA was safe and well-tolerated, with outcomes comparable to the general population, confirming its safety for use before and during pregnancy.***

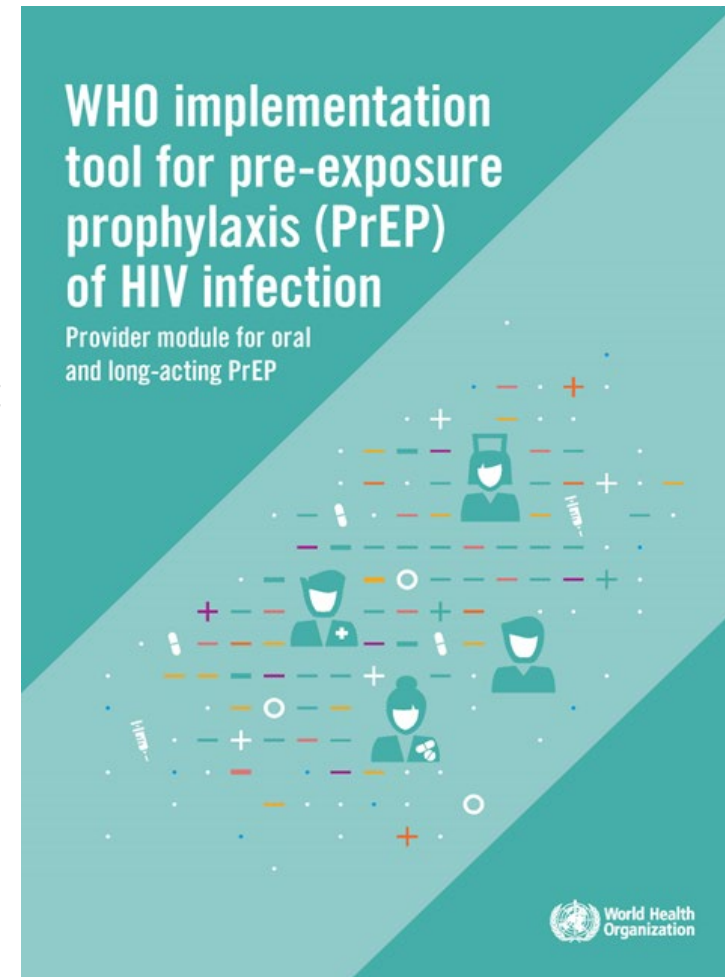
# CAB-LA PREP IN PBFW

More research and safety surveillance in pregnancy are needed to monitor adverse pregnancy and infant outcomes, particularly rare adverse events, through the surveillance of PrEP within larger surveillance programmes or ARV pregnancy registries.

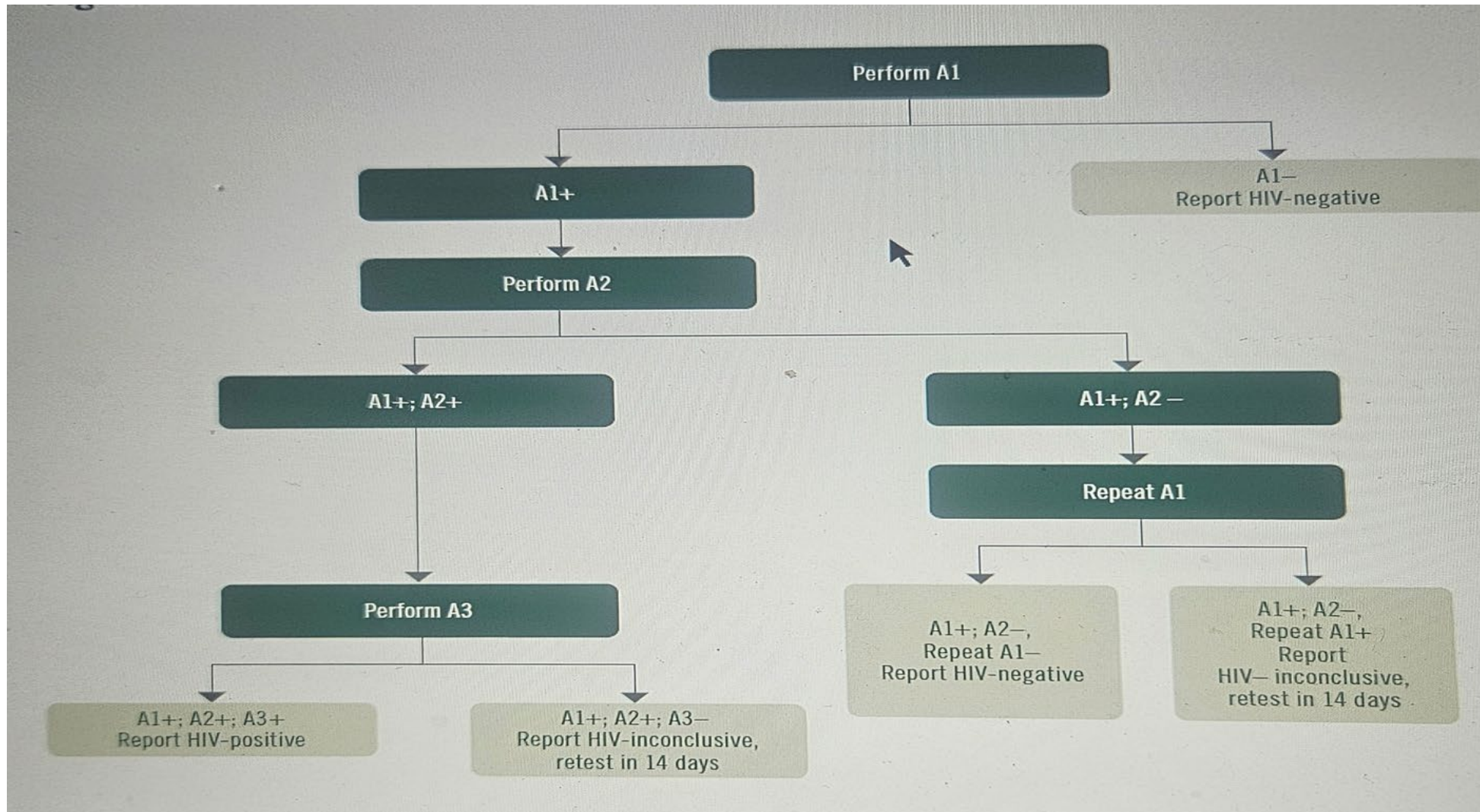
Contraceptive services and links to antenatal care should be available through CAB-LA services.

# TAKE AWAY MESSAGES

- **All PrEP products are effective when used as directed**
  - Effective use is key (using PrEP according to the dosing regimen during periods of potential HIV exposure)
  - Use additional HIV prevention options until you're protected by PrEP
- **PrEP is generally safe and well-tolerated**
  - Generally safe during pregnancy and breastfeeding
  - No significant differences in pregnancy-related adverse events or infant outcomes compared to those not using
  - Side effects are usually mild
- **Few interactions with other medications and contraindications**
  - Follow-up is important to support effective use and provide other services, including for STIs and viral hepatitis
- **HIV testing is required for starting and using PrEP**
- **DSD options and choice for PrEP are needed to support scale-up**
- **PrEP is one part of comprehensive combination HIV prevention and does not replace other services including condoms, harm reduction, PEP etc.**



# WHO 3-TEST ALGORITHM



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# Thank You!