



WHO RECOMMENDATIONS ON PREP FOR PREGNANT AND BREASTFEEDING WOMEN

Dr Thato Chidarikire: HIV PREVENTION

WHO-SA

HIVE Launch Meeting

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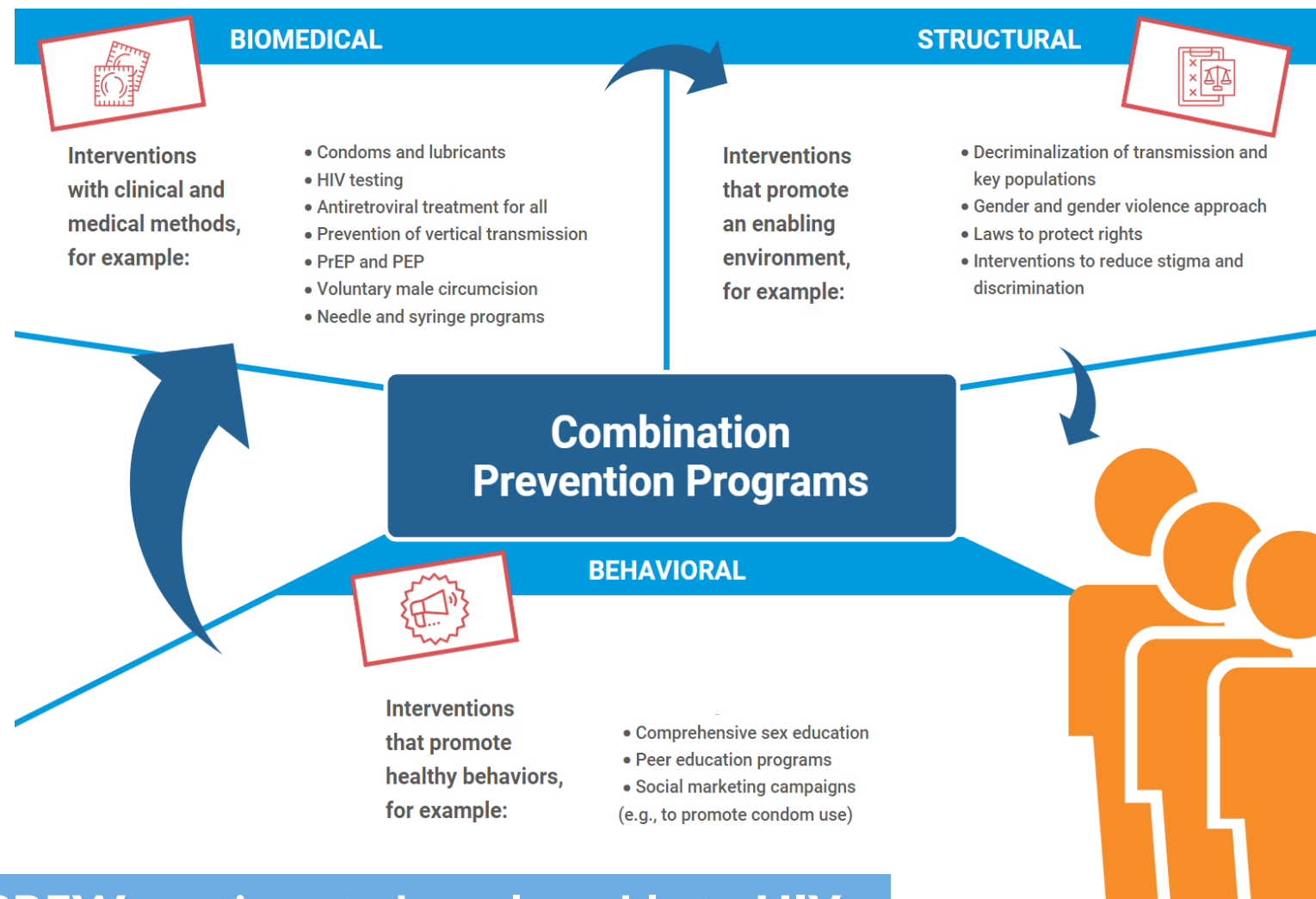


HIV
Impact Network for
Vertical Transmission
Elimination



PREP: KEY PART OF COMBINATION HIV PREVENTION

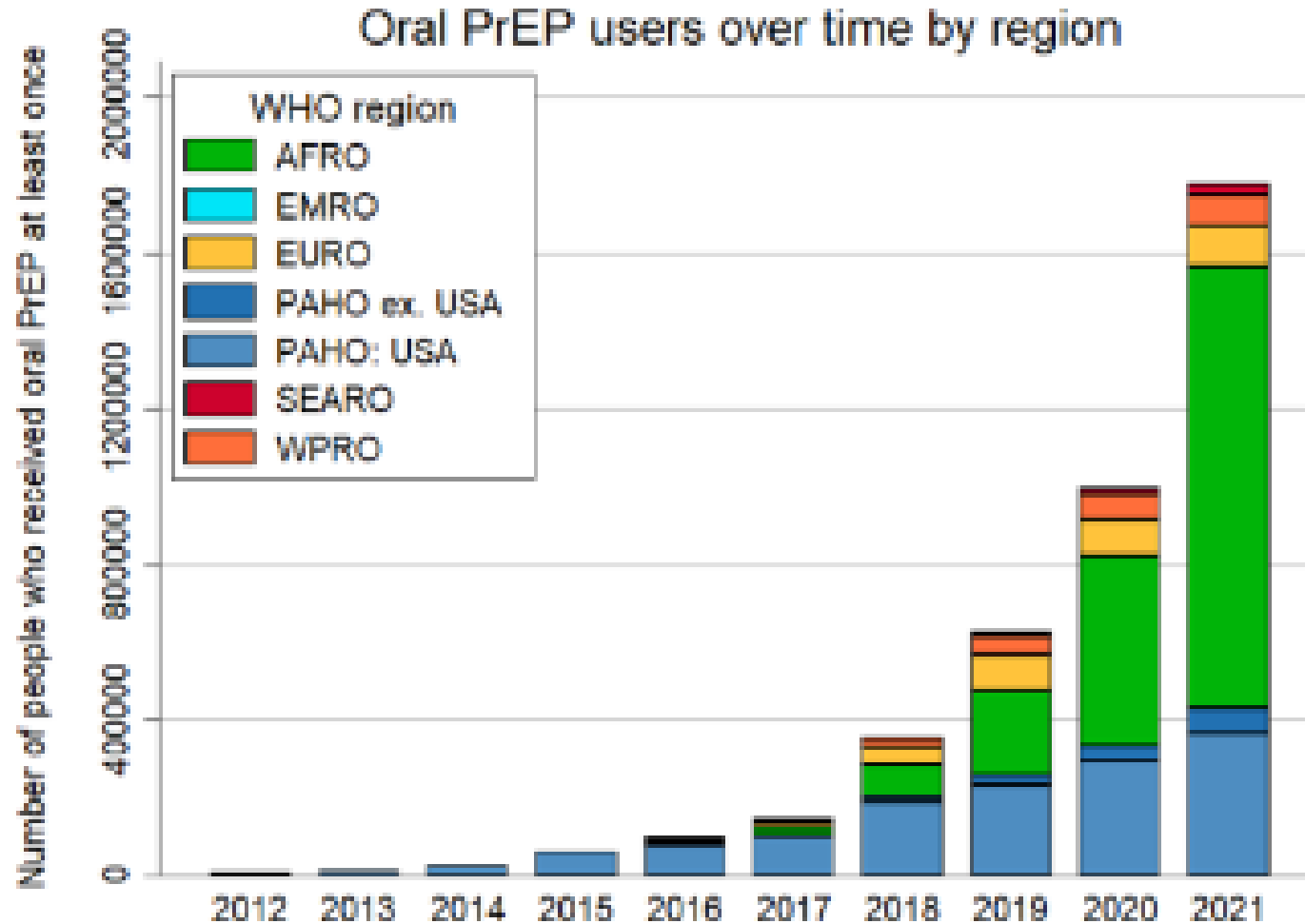
- Pre-exposure prophylaxis (PrEP) is an effective ARV-based HIV prevention option. It is started prior to a potential exposure
- PrEP is not life-long and can be started/ stopped/ restarted
- PrEP does NOT protect against other STIs OR pregnancy
- Empowering tool with psychological benefits



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Sources: Global AIDS Monitoring for 2023, WHO PrEP reporting and personal communications (unpublished)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 (WHO technical brief: Preventing HIV during pregnancy and breastfeeding in the context of PrEP, 2017)

In 2016, WHO conducted a systematic review to assess available data on the safety of TDF in pregnancy and breastfeeding in HIV-positive and HIV-negative women and their infants. Thirty-three papers published between 2011 and 2016 reported comparative data for the primary analysis. Of these, 26 papers addressed TDF-containing ART in HIV-positive pregnant women; 20 compared TDF-ART with non-TDF-ART, two compared TDF-ART with zidovudine/single-dose nevirapine (AZT/sdNVP), and four compared different TDF-ART durations of use during pregnancy. Five papers reported on TDF use for the treatment of hepatitis B (HBV) among HIV-negative pregnant women, and two papers reported data from PrEP trials on HIV-negative pregnant women.

Evidence from HIV-negative pregnant women taking PrEP data on adverse events reported from two PrEP studies of TDF and TDF/FTC among HIV-negative women are reassuring. While the VOICE study was confounded by poor adherence to PrEP, this was not true for the Partners PrEP study, where adherence was excellent, particularly among women on PrEP around the periconception period. Women randomized to receive PrEP and who became pregnant during the study had to discontinue taking PrEP, per protocol. In both studies, no significant differences in maternal and infant outcomes were reported between women who received PrEP and those who received placebo.

ORAL PREP IN PBFW

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

PrEP can also be considered as an additional prevention choice for HIV-negative pregnant women with a high likelihood of exposure as part of a comprehensive VTP package.

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

PrEP also should be considered as part of a safer conception package for women wanting to become pregnant and who have a high likelihood of exposure to HIV.

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.

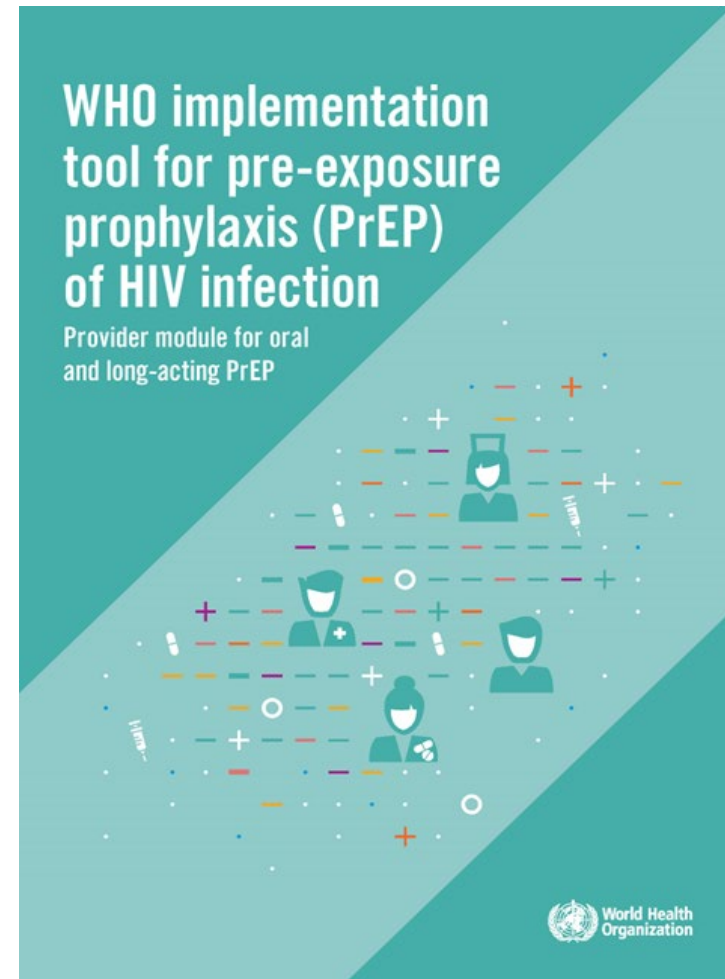
CAB-LA PREP IN PBFW

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.

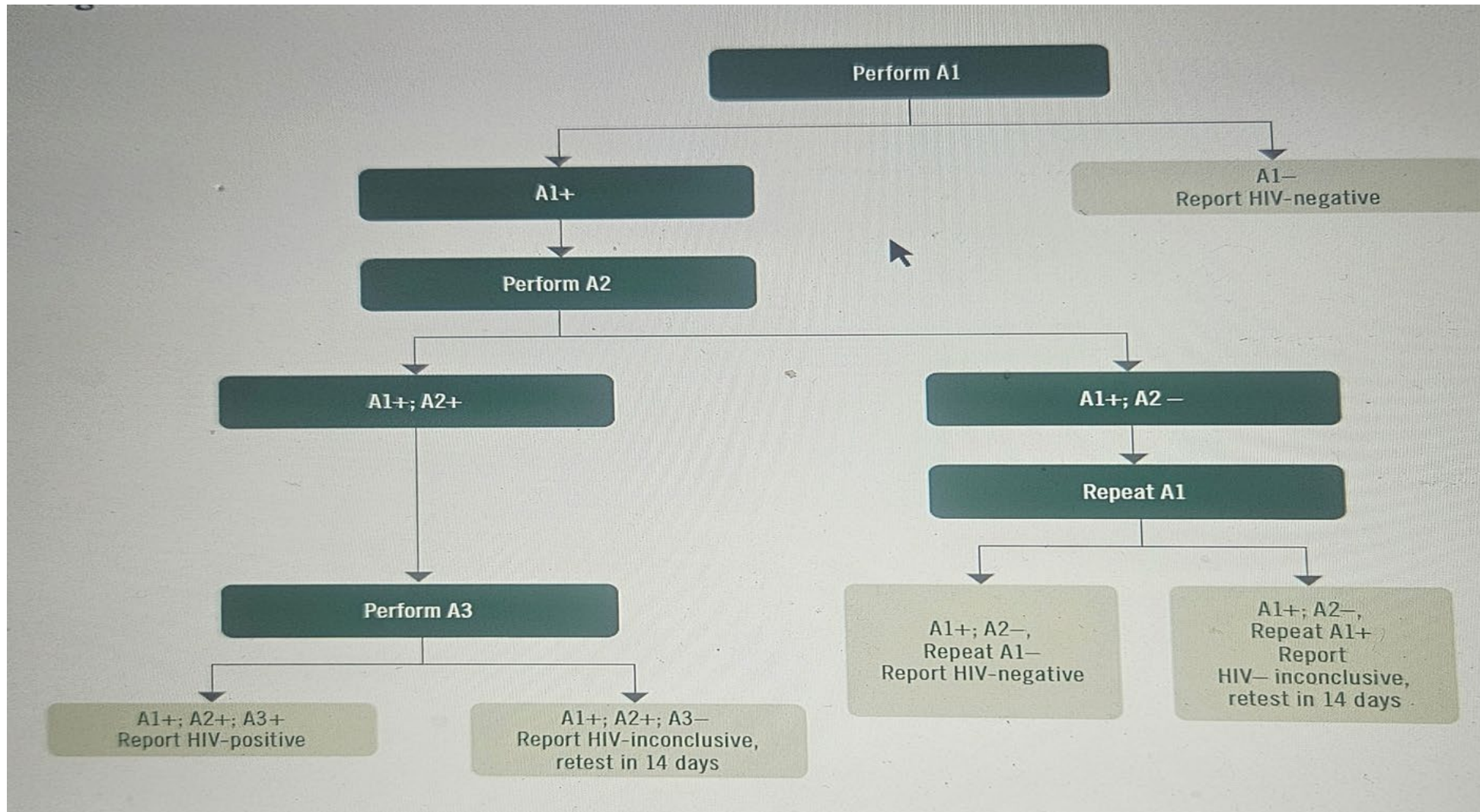
Contraceptive services and links to antenatal care should be available through CAB-LA services.

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!