West Africa PrEP Learning Network Session #2 *Adapting WHO Guidance for National PrEP Policy and Programming: Guideline Development*

WHO | LVCT Health | PZAT | FHI 360 | Afton Bloom

AUGUST 2020

CHOICE Collaboration for HIV Prevention Options to Control the Epidemic

USAID FROM THE AMERICAN PEOPLE

PEPFAR

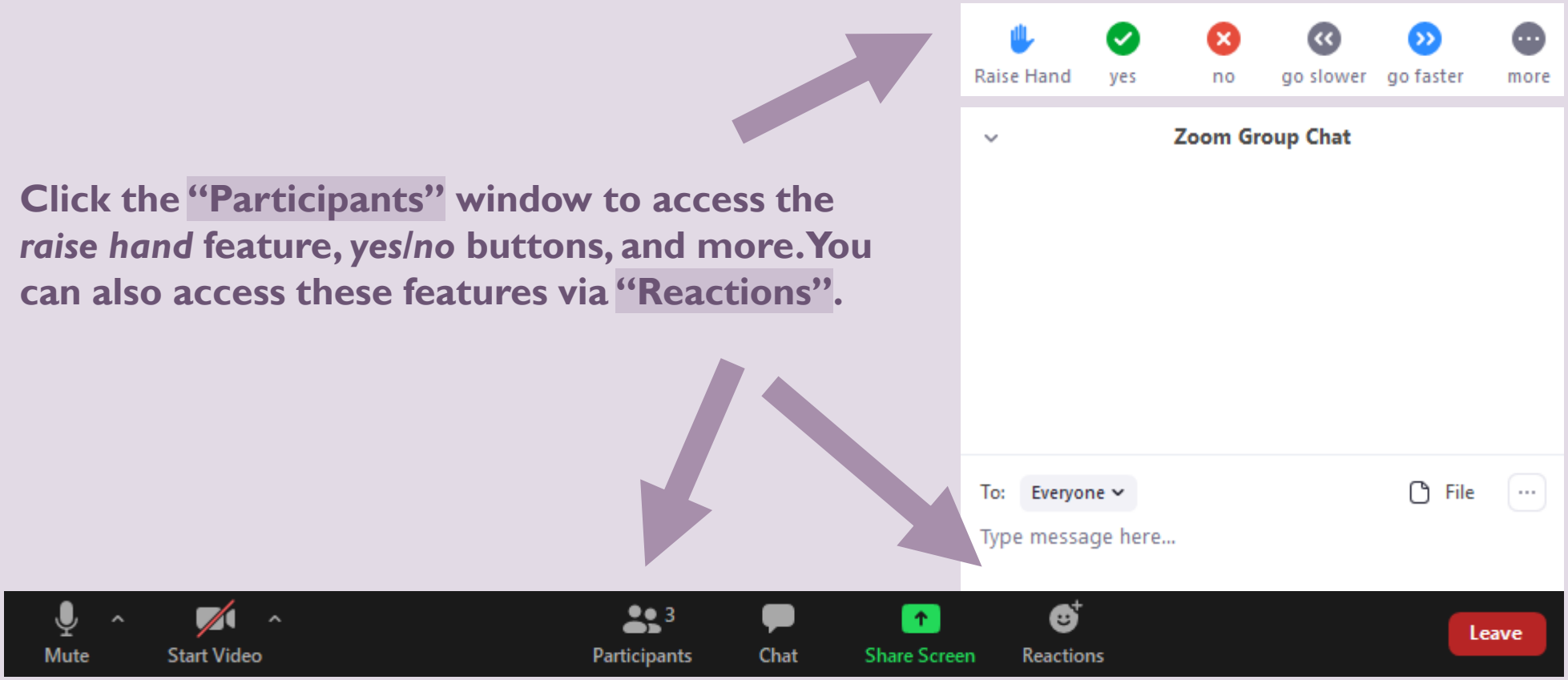
EpiC Meeting Targets and Maintaining Epidemic Control

RISE Reaching Impact, Saturation, and Epidemic Control

Please introduce yourself in the chat box!

Click on "More" to access *thumbs up* and *thumbs down*.

Click the "Participants" window to access the *raise hand* feature, *yes/no* buttons, and more. You can also access these features via "Reactions".



Panelists

- Michelle Rodolph, WHO
- Joseph Murungu, Pangaea Zimbabwe AIDS Trust, Zimbabwe
- Patriciah Jeckonia, LVCT Health, Kenya
- Jules Bagendabanga, FHI 360, Mali

Agenda

Time	Topic
5 min	Introduction to CHOICE and the Learning Network
25 min	WHO guidelines for oral PrEP
55 min	Adapting WHO guidelines to country contexts - Who is PrEP for? - Who is eligible for PrEP? Who is ready for PrEP? - How is PrEP initiation and follow-up conducted?
5 min	Wrap-up

Introduction to CHOICE

CHOICE is an 18-month collaboration funded by USAID in partnership with PEFPAR through two central mechanisms: Meeting Targets and Maintaining Epidemic Control (EpiC) and Reaching Impact, Saturation, and Epidemic Control (RISE).

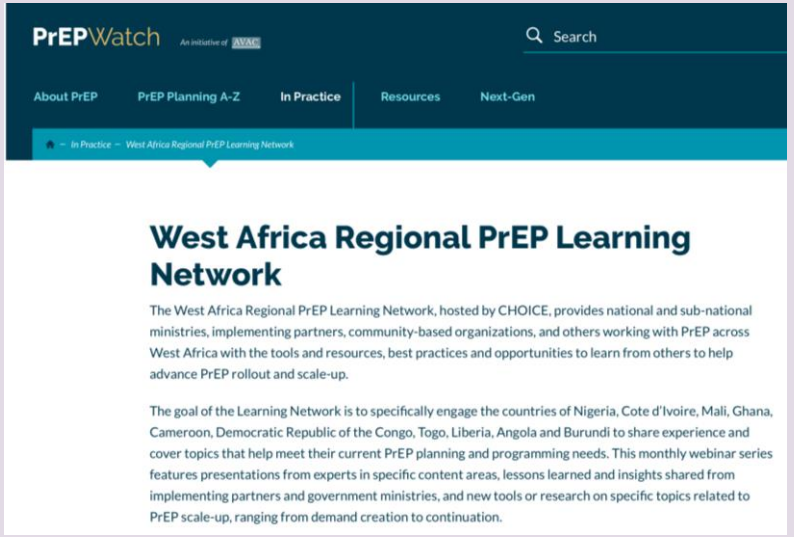
The goal of this collaboration is to address technical gaps and support national scale-up of antiretroviral-based HIV prevention products in PEPFAR countries through catalytic evidence generation, translation and research utilization.

CHOICE is led by FHI 360 and Jhpiego, in partnership with Afton Bloom, Avenir Health, LVCT Health and PZAT

West Africa Regional PrEP Learning Network

To learn more about the Network visit https://www.prepwatch.org/in-practice/west-africa-prep-learning-network/

For questions or thoughts on the Network email WestAfrica@PrEPNetwork.org



Key topics for this webinar series

Oral PrEP Introduction Framework

PLANNING & BUDGETING

National and subnational plans include oral PrEP and guidelines are established to support access to PrEP via priority delivery channels

SUPPLY CHAIN MANAGEMENT

Oral PrEP is regularly available in sufficient quantity to meet projected demand via priority delivery channels

RING DELIVERY PLATFORMS

Oral PrEP is delivered by trained healthcare workers across diverse delivery channels that effectively reach target end users

UPTAKE & EFFECTIVE USE

End users are aware of oral PrEP and have the support, motivation, and ability to seek out, initiate, and effectively use PrEP during periods of HIV risk

MONITORING

Oral PrEP is effectively integrated into national, subnational, program, and facility monitoring systems and ongoing research supports learning

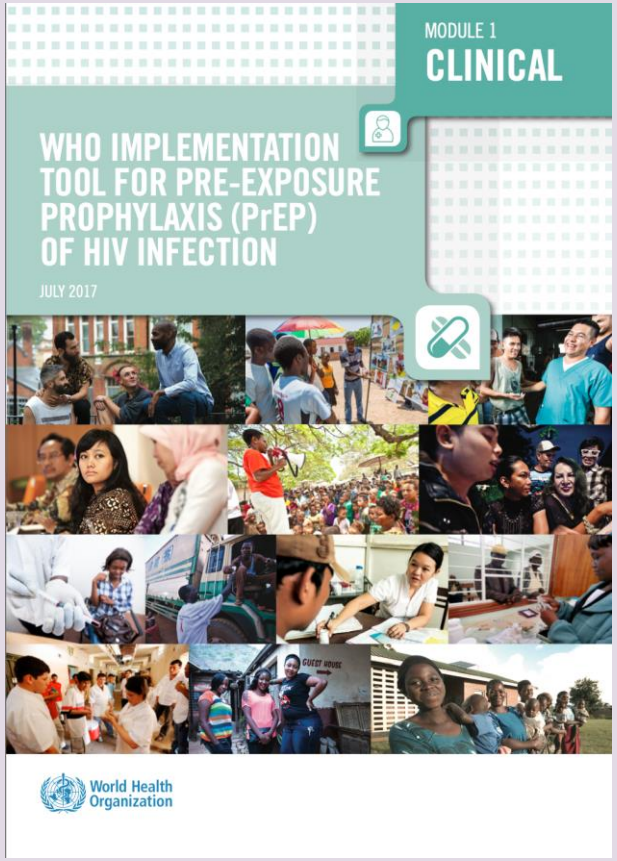
POLL

Does your country have PrEP guidelines in-place?

Introduction
WHO PrEP Guidelines

WHO PrEP Implementation Tool

- The WHO Implementation Tool for PrEP and the Oral PrEP Tool App includes 12 modules to support PrEP delivery
- Today, we will focus on the Clinical module (Module 1), which captures WHO guidance on oral PrEP
- You can find the tool and the app at: https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/



Determining PrEP eligibility & risk

WHO Recommends	Observed Adaptations
SEVEN Eligibility criteria *(ALL 7 to be eligible)*	**Eligibility**
1. HIV negative by same-day rapid test	*1. Prior HIV test result may be accepted*
2. No HIV exposure past 72 hrs/PEP screening	*2. Screening for PEP not done or inconsistent*
3. No acute HIV signs/symptoms	3. Consistently completed
4. CrCl ≥60 ml/min	*4. Often not tested or urinalysis instead*
5. No allergies to PrEP meds	5. Consistently assessed
6. Willing to take PrEP/HIV re-test	*6. Sometimes assumed*
7. At substantial risk *(AT LEAST 1 of 6)* • Request for PrEP • An HIV-positive sex partner not virally suppressed • Use of PEP for sexual exposure • Inconsistent condom use • A sex partner at high risk of HIV infection • Recent history of STIs	*7. Great deal of variability across countries:* • PrEP limited to specific populations • Use of screening instrument to screen people out instead of to include them • List of questions tailored to local policies • Simply requesting PrEP not sufficient to "qualify" as risk in all places

PrEP drug regimens & dosing

WHO Recommends	Observed Adaptations
Three regimens TDF alone, TDF/FTC or TDF/3TC	*Each country makes own choice*
Monthly and multi-month dispensing options	*Variable by country*
Daily PrEP for all women and men who have sex with women: 1 pill daily for 7 consecutive days before sex to start and 1 pill daily for 28 days after last sex to stop	Consistently followed for women and men who have sex with women
Dosing options for MSM - Daily: 2-pill loading/first dose 2-24 hours before sex to start then 1 pill 24 and 48 hours later to stop - Event-driven: 2-pill loading/first dose 2-24 hours before sex to start then 1 pill daily for two days	*Many countries use daily dosing for women and heterosexual men (1 pill for 7 days before sex to start and 1 pill for 28 days after sex to stop).* *Note: Even if event-driven PrEP isn't available, the daily dosing for MSM is still 2 pills 2-24 hours before sex to start and 1 pill daily for 2 days after sex to stop.*

Elements of initial visits

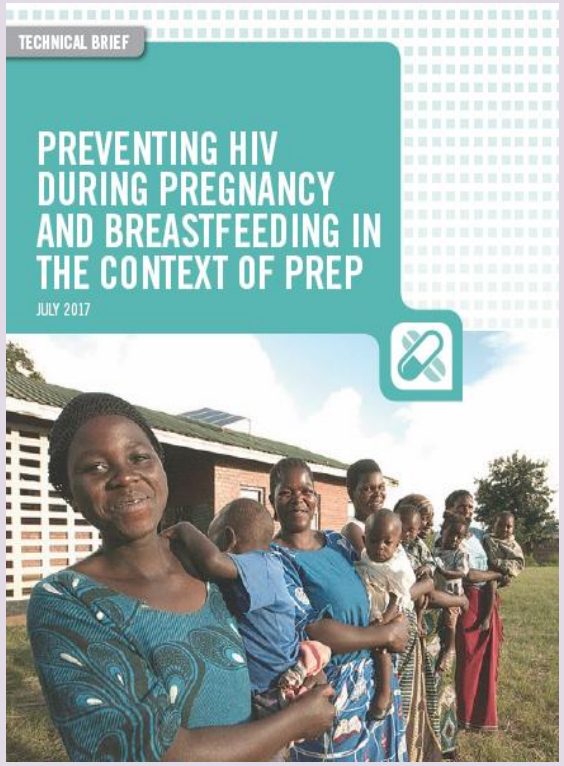
WHO Recommendation	Observed Adaptations
Eligibility Screening, as previously described	*Variability as previously described*
Hep B surface Ag testing with vaccination for negatives	*Largely not done*
Hep C Ab testing for MSM and treatment as indicated	*Largely not done*
Syphilis testing by RPR, if available, and STI screening	*Largely not done unless by syndromic screening*
Pregnancy testing with counseling and referral	*Variable*
Vaccination history with immunizations, as indicated (tetanus, meningitis, HPV, Hep B, Hep A for MSM,	*Inconsistently documented*
Comprehensive counseling: GBV/IPV, SRH (condoms, lubricants, contraception, safer conception) substance abuse and mental health	*Inconsistently documented, though GBV/IPV screening required by PEPFAR*

Elements of follow-up visits

WHO Recommendation	Observed Adaptations
- Re-test for HIV to verify negative HIV status at 1-month post-start and then quarterly thereafter - Re-test for HIV after discontinuation followed by PrEP restart (except MSM on event-driven PrEP who should be re-tested for HIV quarterly, regardless of use pattern if taking as prescribed)	- *Variable re-testing at 1-month post-start* - *Multiple interpretations of how long someone may discontinue and then restart without needing a repeat HIV test*
Assess for side effects and adherence counseling at every visit	Consistently assessed
Re-test serum creatinine/creatinine clearance every 6 months	*Some countries do not do at all, do urinalysis in lieu of serum creatinine, or only re-test individuals at higher risk of renal disease*
Re-screen/-test for STIs every 3 or 6 months, depending upon local policy	*Variable depending upon recommended frequency of STI screening, primarily for key populations*

PrEP for pregnant and breastfeeding women

WHO Recommends	Observed Adaptations
Daily oral PrEP is safe and may be continued in PrEP clients that become pregnant or start breastfeeding	*Most but not all countries consider PrEP to be safe for pregnant and breastfeeding clients*
Pregnant and breastfeeding women are at greater risk than their non-pregnant counterparts and so should be offered PrEP due to this risk factor, especially in high-burden settings	*Most countries, even high burden countries, don't provide integrated PrEP/family planning or PrEP/ANC services (available from the same provider to reach women with PrEP through SRH platforms)*



Overview of national guideline topics

Sample national guideline topics

- **PrEP**
  - Guidance for offer of PrEP
  - PrEP effectiveness
  - Approved drugs for PrEP
  - PrEP minimum package
- **PrEP Initiation**
  - Indicators for PrEP
  - Contraindications for PrEP
  - Initiation visit schedule and readiness
  - PrEP and other PrEP interactions
- **Key counseling messages**
  - Education and counselling
  - Risk reduction counselling
- **Client follow-up**
  - Stopping PrEP
  - Restarting PrEP
- **Management of clients in specific situations**
  - Management of creatinine elevation
  - Management of HIV seroconversion
  - Management of side effects and adverse drug reactions
  - Classification and management of interruption of PrEP
- **Who can deliver PrEP and where**

A guidelines template will be shared with participants after the webinar

CHAT

Any remaining questions on the WHO PrEP guidelines?

Panel Discussion

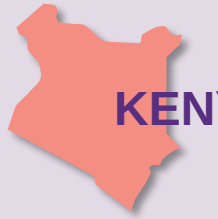
Key topics in guidelines adaptation

? Who is PrEP for?

? Who is eligible or ready for PrEP?

? How is PrEP initiation and follow-up conducted?

Who is PrEP for?



KENYA

- **PrEP is for all people at substantial ongoing risk for HIV**
- **In practice**, focus is on:
  - Key populations,
  - Adolescent girls and young women (AGYW)
  - Serodiscordant couples (SDC)

ZIMBABWE

- **PrEP is for all clients testing HIV negative and at high risk based on the risk assessment**
- **Priority groups** include
  - Female and male sex workers
  - Serodiscordant couples
  - Adolescent girls and young women (AGYW)
  - Pregnant women
  - High-risk men (MSMs, prisoners, long-distance truck drivers)
  - Transgender people

Who is eligible or “ready” for PrEP?

KENYA

Kenya adapted the WHO guidelines Creatinine is recommended but should not delay initiation of PrEP

In practice

- Supervision and continuous support are needed to ensure providers adhere to guidelines
- With pressure on targets, providers often don’t ask clients about their willingness to take PrEP, resulting in high rates of drop-off
- In public facilities, screening for renal disease is often not available and as a result the required annual serum creatinine and creatinine clearance often not done

ZIMBABWE

Zimbabwe adapted the WHO guidelines for PrEP eligibility to include people who are HIV negative and at high-risk of HIV based on risk assessment

In practice

- While the guidelines note same-day HIV tests are preferred, most facilities will accept a test result within the previous 3 months
- If the client has experienced exposure in the past 72 hours, PEP is initiated
- Eligibility includes a commitment to adherence and follow-up
- Other counseling elements include ensuring a basic understanding of PrEP, commitment to adherence, plan for pill storage, and a discussion of disclosure

How is risk assessed?

KENYA

- **Risk assessment** includes questions about sexual behavior (e.g., condomless sex, number of sexual partners, sex under influence of drugs, sex with partners of unknown HIV status or not attained viral suppression, history of GBV, STIs)

- **Challenges:**
  - Documentation of risk and risk review is not consistent across visits

ZIMBABWE

- **Risk assessment** includes questions about sexual activity (e.g., number of partners, condom use, serodiscordancy, partner status including viral load in the six months prior to the assessment)

- **Challenges:**
  - Not every client that tests negative is screened as the assessment process is deemed to be a separate step/additional work
  - Poor documentation of screening process and outcomes
  - Integration with post-test counselling process done in some sites is more efficient

How is PrEP initiation & follow-up conducted?

KENYA

- There is a follow-up visit 1 month after initiation and then every 3 months after that
- Visits alternate between being counsellor-led and clinician-led
- Services at initial follow-up visit include safety monitoring and risk reduction counselling, HBV vaccination if available and HBsAg Neg
- 3-month visits include HTS, risk review, adherence counselling, and review for continuation or discontinuation
- Creatinine clearance is conducted annually
- For clients discontinuing PrEP, they must continue taking PrEP for 28 days from last exposure

ZIMBABWE

- There is a follow-up visit 1 month after initiation and then every 3 months after that
- HIV testing is done at initiation and at each visit
- At each follow-up visit, clients are supposed to be assessed for risk, side effects, and adherence and receive counseling
- ”PrEP centers” offer testing services and PrEP refills
- For clients discontinuing PrEP, they are encouraged to attend an exit visit and should adhere to PrEP for 28 days after exposure and then continue to use combination HIV prevention, including condoms

Guideline development in West Africa

Guidelines for West African countries should consider the following:

- Balance a focus on high-risk **populations** (e.g., MSM, FSW, serodiscordant couples) in implementation with broader guidelines that are not too restrictive and that can accommodate changes in policy and programming over time
- Recognize and integrate **existing global research** in addition to local pilots, particularly around the low risk of creating drug resistance via PrEP use
- Make **laboratory testing** beyond regular HIV tests (e.g., creatinine clearance, Hepatitis B) suggested but not mandatory for PrEP initiation to enable PrEP delivery in low-resource settings
- Include other forms of **follow-up** and monitoring, including regular monitoring for side effects

CHAT

Any remaining questions on national PrEP guidelines?

Wrap-up

Upcoming sessions: Register today!

Aug 19

Sep 16

Up next:

Developing PrEP Implementation Plans

Please add any questions you have on PrEP Implementation Plans to the chat or email them to us at WestAfrica@PrEPNetwork.org

Register for the next session today at https://www.prepwatch.org/in-practice/west-africa-prep-learning-network/

Upcoming Sessions

- October 21: **PrEP Delivery Models**
- November 18: **PrEP Demand Creation**
- December: **PrEP Costing & Target Setting**

Visit PrEPWatch for additional resources

- Webinars will be **recorded** and loaded onto PrEPWatch for you to access at a later date
- Registration for **upcoming webinars** can also be found on PrEPWatch

https://www.prepwatch.org/in-practice/west-africa-prep-learning-network/

Thank you!