25 MARCH 2021 | WEBINAR 20

### **Developing Guidelines and Plans for the Delivery of Event-Driven PrEP**

PrEP Learning Network Webinar Series

Thank you to Gaston Djomand from Centers for Disease Control (CDC), Chris Obermeyer from USAID, and Greg Carl from the Institute for HIV Research and Innovation in Thailand who presented during the March PrEP Learning Network webinar. In this webinar, we discussed developing guidelines and plans for the delivery of Event-Driven PrEP (ED-PrEP). In case you missed it, you can access the webinar recording <u>here</u>.

### **Top Questions & Answers**

Below is a highlight of the Q&A for those seeking more information on ED-PrEP. Learn more by listening to the webinar <u>recording</u>, accessing complementary resources including the webinar slides in <u>English</u> and <u>French</u>, signing up for <u>future webinars</u>, or visiting the <u>PrEP Virtual Learning Network</u> <u>page</u>.

# Why is Event-Driven PrEP only for men who have sex with men (MSM) and not all men or women?

Although the recommendation of ED-PrEP for MSM doesn't differentiate between men assuming insertive, receptive and versatile roles, there is insufficient evidence to support the recommendation of ED-PrEP for men who have sex with women. There is some evidence that ED-PrEP may not be suitable for cisgender women due to the pharmacokinetics of Tenofovir and the added time it takes to reach optimal concentration in vaginal tissue. There is also some evidence that ED-PrEP may not be suitable for transgender women who use gender affirming hormone therapy. Unfortunately, there is a lack of research on this topic for these populations, and very little (if any) pharmacological data on penile tissue. It was strongly suggested during the webinar that advocates put ED-PrEP for other populations on the research agenda. It could be a very important tool for people who cannot or will not take daily oral PrEP.



Join us for the next webinar in the series.

Reframing PrEP Continuation: Highlights from the PMM-Jhpiego-USAID Think Thank on Prevention Effective Use of PrEP

27 May 2021 9:00-10:30 EST 16:00-17:30 EAT

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### Does the effectiveness of ED-PrEP depend on whether one is the insertive or the receptive partner?

ED-PrEP is safe and highly effective in reducing risk of HIV acquisition through receptive and/or insertive sex between men.

### Is ED-PrEP also effective in bisexual men?

Evidence suggests that ED-PrEP is effective at preventing HIV during anal sex between men. For men who have sex with men and women, an additional prevention strategy is recommended to prevent acquisition during sex with women as there is insufficient data to suggest its efficacy in preventing HIV acquisition during insertive vaginal sex.

### Are there data on how effective ED-PrEP is among MSM in West Africa or sub-Saharan Africa?

There is no reason to believe it would not be effective among MSM in West Africa or sub-Saharan Africa.

## Can daily oral PrEP be started with double dose (two tablets) for immediate effect like it is recommended for ED-PrEP?

The updated WHO guidance for ED-PrEP states that MSM taking daily or ED-PrEP should start PrEP with two pills, which will be effective within two hours. MSM can also stop taking PrEP (either regimen) by taking a pill each day for two days after last exposure.

### Are baseline blood tests also required for ED-PrEP?

WHO recommends the same lab screening for daily oral PrEP and ED-PrEP. Initiation steps for ED-PrEP are the same as daily oral PrEP. However, chronic Hepatitis B is a contraindication with the ED-PrEP regimen.

# Intimate partner violence (IPV) screening is recommended for daily oral PrEP. Is IPV screening also recommended for ED-PrEP?

Screening for gender-based violence (GBV), including IPV, appropriate referrals and first-line support is recommended for all clients starting PrEP, both daily and ED-PrEP.

# Are there data on side effects related to ED-PrEP? Would it be a good option for those who stop daily PrEP due to side effects?

ED-PrEP users experience side effects that are more mild/less frequent than those on daily. Some <u>data</u> show that there is a bit more nausea for ED-PrEP users, but generally side effects are uncommon. It is also important to note that the <u>ANRS Prévenir</u> showed no difference in HIV breakthrough infections between daily oral PrEP and ED-PrEP.

#### Can other forms of protection such as condoms be used in combination with ED-PrEP?

Condoms should be used whenever possible to prevent against other STIs.

#### Are there studies on condom use among those using ED-PrEP?

An <u>implementation study</u> from Amsterdam showed that people using ED-PrEP (vs. daily oral PrEP) had lower incidence of other bacterial sexually transmitted infections (STIs). This is likely a result of differences in sexual behavior—incidence of STIs with either PrEP regimen is a function of how much condom-less sex takes place.

### What are the recommended follow-up steps to ensure compliance on the part of the client?

It is recommended that the number of visits, procedures, and lab work are the same for ED and daily oral PrEP clients. Effective counseling to ED-PrEP users may increase effective use.

#### How can we monitor effective use among ED-PrEP users?

Clients should be able to openly speak with providers and counselors about their challenges with effectively using oral PrEP when using either regimen. Providers should enable clients to switch between ED-PrEP and daily oral PrEP as needed or requested.









### How are MSM who use ED-PrEP reported in PrEP\_Curr? Will MSM still be counted in PrEP\_Curr?

The definition for PrEP\_Curr is any client who took PrEP during the reporting period regardless of duration. PrEP\_Curr reporting is based upon refills regardless of actual use, so there is no difference for MSM who are on ED-PrEP.

### What is the shelf life of PrEP drugs? Do you inform PrEP clients of when their ARVs expire?

The shelf life of a product refers to the period between the time it is manufactured to the time of expiration assuming it is in the original packaging and within certain environmental conditions. The shelf life of the drugs used for oral PrEP may vary by product and manufacturer. Once drugs for oral PrEP reach a country, they typically have at least 12-24 months of shelf life remaining. It is important that those managing drug supplies for oral PrEP monitor expiration dates for efficient stock management and that those dispensing oral PrEP ensure PrEP users are aware of expiration dates on the drugs they are receiving. This is particularly important for ED-PrEP users who may use a single bottle over multiple months.

### How can ED-PrEP be planned for and operationalized for a broad MSM program?

Due to it being a relatively new recommended approach, ED-PrEP has not yet been taken up by many key population (KP) programs, especially as many national programs are only now starting to roll out daily PrEP. We anticipate seeing this change soon within PEPFAR-supported KP programs given new Country Operational Plan (COP) global guidance that ED-PrEP be considered as an option for MSM. We anticipate implementation will require a version of what has been required to approve daily PrEP programs. This includes careful consultation with ministry of health/National AIDS Control Council stakeholders, PEPFAR/Global Fund, WHO/UNAIDS, civil society, etc. to update national PrEP guidelines, reinforce provider training, disseminate social and behavioral change and demand creation materials, and assure necessary commodities at clinical and community distribution sites. See the resources below, such as the ED-PrEP Guidelines Template, to help support these consultations and policy/guideline updates.

### **Additional Resources**

For more information on Event-Driven PrEP, please see the following resources:

- <u>ED-PrEP Learning Session Slides</u>: Check out the slides from the presentation which include examples from various countries in English and French and research on ED-PrEP.
- <u>WHO 2+1+1 Technical Brief</u>: A technical update released in 2019 that updated the WHO recommendation on oral PrEP to include an option for ED-PrEP.
- <u>ED-PrEP Guidelines Template</u>: Click here for an English-language template for ED-PrEP, developed by CHOICE in partnership with USAID. French-language template guidelines can be found <u>here</u>.
- <u>WHO/Jhpiego Oral PrEP eLearning Course</u>: This free online course developed by WHO, PAHO and Jhpiego addresses key aspects of clinical training for healthcare providers screening and managing oral PrEP clients, including ED-PrEP.
- <u>Event-based PrEP | Prepster</u>: Check out this fun education platform for more information on PrEP including ED-PrEP.
- <u>Manuscript</u>: Daily and non-daily pre-exposure prophylaxis in African women (HPTN 067/ADAPT Cape Town Trial): a randomised, open-label, phase 2 trial. Lancet HIV, 2018.
- <u>PrEP in the City</u>: This campaign for transgender women aims to increase PrEP uptake in Thailand.

We hope you join us again on <u>27 May 2021</u>! Our next webinar will focus on **Reframing PrEP Continuation: Highlights from the PMM-Jhpiego-USAID Think Thank on Prevention Effective Use of PrEP.** Join us to hear the latest discussions on the how effective PrEP use can be best defined, measured, and promoted. Learnings from diverse stakeholders will be shared, including a report back from the latest in the series of PrEP Effective Use Think Tanks (September 29, 2020) from the PMM-Jhpiego-USAID.

Visit the <u>PrEP Virtual Learning Network</u> for more information on previous or upcoming sessions.







