

Upcoming guidelines on long-acting formulations and delivery methods for HIV prevention

- Michelle Rodolph, 5th May 2022

WHO PrEP recommendations and guidance

PrEP for SDC, MSM & TG (**conditional** rec in the context of demo projects)

GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP) FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV. Recommendations for use in the context of demonstration projects.

July 2012

PrEP for people at substantial risk for HIV (**strong** rec)

GUIDELINES

GUIDELINE ON WHEN TO START ANTIRETROVIRAL THERAPY AND ON PRE-EXPOSURE PROPHYLAXIS FOR HIV

SEPTEMBER 2015

TECHNICAL BRIEF

ED-PrEP

WHAT'S THE 2+1+1?

EVENT-DRIVEN ORAL PRE-EXPOSURE PROPHYLAXIS TO PREVENT HIV FOR MEN WHO HAVE SEX WITH MEN: UPDATE TO WHO'S RECOMMENDATION ON ORAL PrEP

JULY 2019

World Health Organization

GUIDELINES

CONSOLIDATED GUIDELINES ON HIV PREVENTION, TESTING, TREATMENT, SERVICE DELIVERY AND MONITORING: RECOMMENDATIONS FOR A PUBLIC HEALTH APPROACH

JULY 2021

Revised PrEP implementation guidance, including for simplified PrEP service delivery



PrEP for MSM (**strong** rec); other KP (**conditional** rec) no recommendation for PWID

GUIDELINES

CONSOLIDATED GUIDELINES ON HIV PREVENTION, DIAGNOSIS, TREATMENT AND CARE FOR KEY POPULATIONS

JULY 2014

KEY POPULATIONS

Imp tool

MODULE 1: CLINICAL

WHO IMPLEMENTATION TOOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) OF HIV INFECTION

JULY 2017

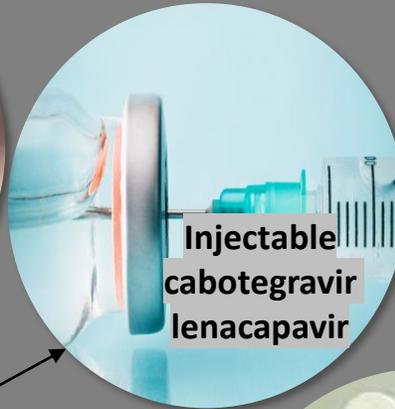
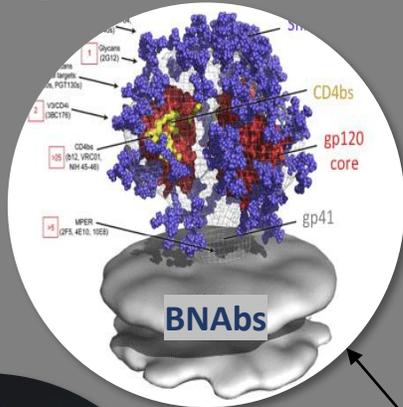
Dapivirine ring

WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection

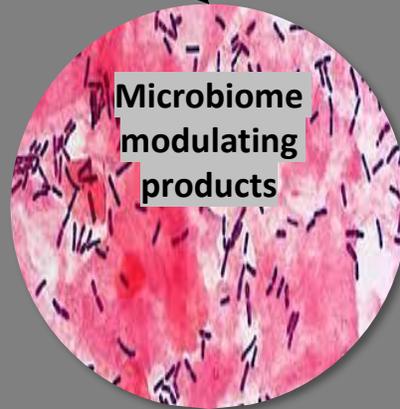
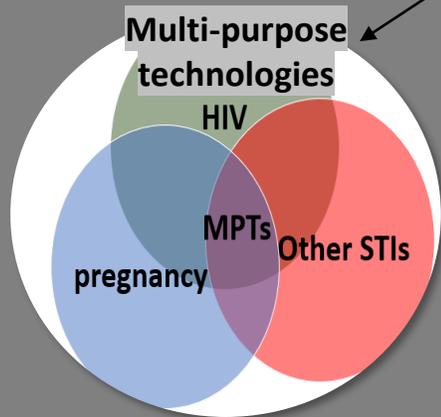
WHO considers recommendation on CAB-LA

Following the biomedical prevention technologies pipeline

TDF/FTC



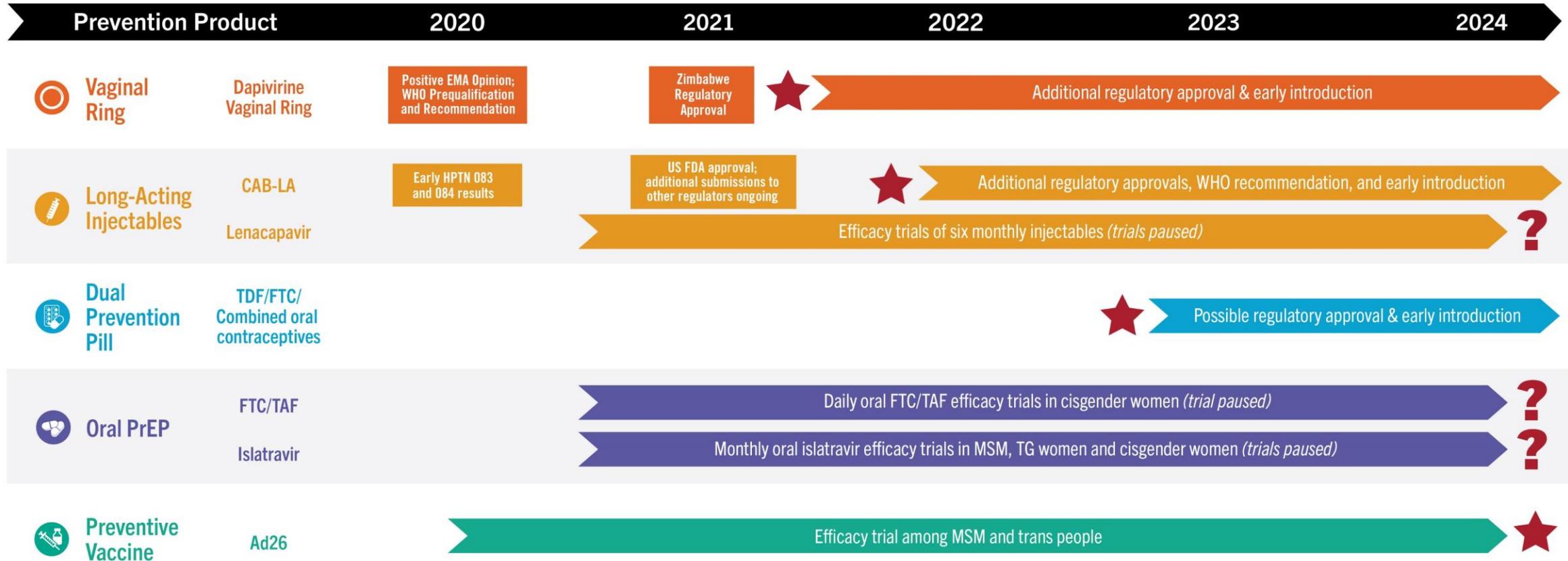
Potential future prevention technologies



Years Ahead in HIV Prevention Research

Time to Market

★ Earliest time to market
? Efficacy trials paused



January 2022

Oral PrEP highly efficacious but coverage low, impact outside MSM in HIC uncertain.... New products could overcome current issues



1. New products - offer choice and may ↑demand

2. Overcome barriers to current biomedical prevention choices

- Acceptability
- Adherence/effective use
- Continuation
- Renal and other safety issues safety – & additional monitoring required

JOINT UNITED
NATIONS STATEMENT
ON ENDING DISCRIMINATION
IN HEALTH CARE SETTINGS

But structural issues and S&D in the health sector will remain key barriers to any new product's success

Benefits, concerns and issues

	pros	cons	issues
Oral PrEP 	<p>>90% protection against HIV acceptable</p> <p>≈900K PrEP initiations – but a long way to go ... 2020 UN goal 3M</p> <p>Schaefer R. Adoption of guidelines on and use of oral PrEP Lancet HIV., 2021</p>	<p>Adherence issues with daily use (or ED for MSM)</p> <p>Safety (minor issue)</p> <p>DR (probably minor)</p> <p>Cost (big price reductions with generics - but still costly)</p>	<p>Simplifying PrEP to reduce costs & increase access</p> <ul style="list-style-type: none"> • Community & pharmacy delivery • ↓ Cr monitoring • HIVST <p>C19 delivery lessons</p>
DVR 	<p>? Efficacy ≈ 50-?70%</p> <ul style="list-style-type: none"> • No safety issues • HIV testing straightforward • Other lab motioning not needed • DR not an issue <p>1M ring</p> <p>Opportunities for community self-care approaches</p> <p>Discrete women-controlled</p>	<p>?acceptability</p> <ul style="list-style-type: none"> • A 'new' untried modality in LMIC • No 'real world' implementation 	<p>Cost - ?3/12 product</p> <p>Dual product with hormonal contraceptive</p> <p>Where to implement</p> <ul style="list-style-type: none"> • Community & pharmacy delivery <p>Training of providers (inc peer support)</p> <ul style="list-style-type: none"> • ?messaging around efficacy
CAB-LA 	<p>Efficacious (?>F cf M)</p> <p>2M IM</p> <p>Acceptable (likely)</p>	<p>IM injection (limits potential for self-care)</p> <p>No 'real world' implementation</p>	<p>Cost - unknown</p> <p>HIV testing complexities</p> <p>DR with 1st line Rx,</p> <p>Safety during Pregnancy and BF</p>

*Dapivirine vaginal ring: **new** recommendation*

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.

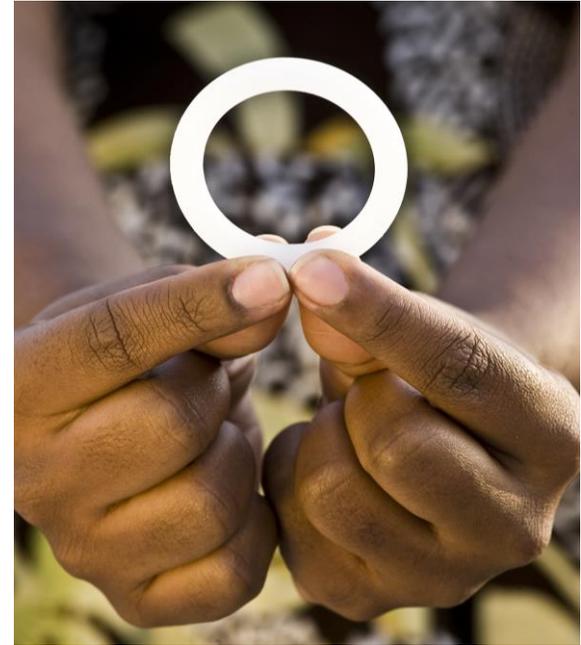
(conditional recommendation; moderate-certainty of evidence)

- Current evidence suggests that oral daily PrEP, when taken as prescribed, has greater efficacy for HIV prevention than the dapivirine vaginal ring.
- Oral PrEP should be offered at sites where the dapivirine ring is provided to enable women to make a choice.

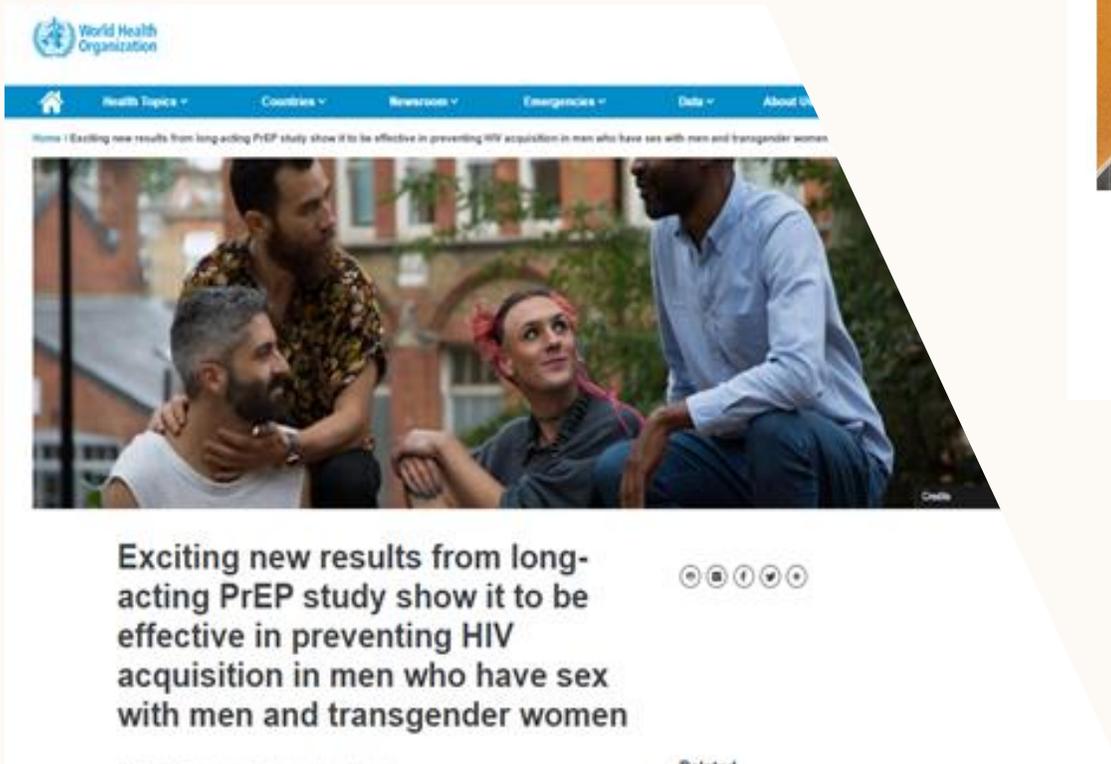


Implementation considerations / Research gaps

- Address the provision of the dapivirine ring as part of **comprehensive services**
- Ensure women are offered full information in order to make an **informed choice** about the benefits and potential risks when considering to use the ring
- Additional **adherence support** and **demand creation**
- **Adolescent girls and young women** may need more support during initiation and for continuation
- Acceptability among women from **key population groups**
- **Training and support for providers** to understand and be able to offer this new product
- Further information on
 - **safety** in pregnancy and breastfeeding
 - **cost-effectiveness**



Long acting injectable cabotegravir



World Health Organization

Home / Exciting new results from long-acting PrEP study show it to be effective in preventing HIV acquisition in men who have sex with men and transgender women



Exciting new results from long-acting PrEP study show it to be effective in preventing HIV acquisition in men who have sex with men and transgender women

9 November 2020 | Departmental news | Reading time: 5 min (1444 words)

Related



World Health Organization

Home / Trial results reveal that long-acting injectable cabotegravir as PrEP is highly effective in preventing HIV acquisition in women



Trial results reveal that long-acting injectable cabotegravir as PrEP is highly effective in preventing HIV acquisition in women

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Related

General implementation issues

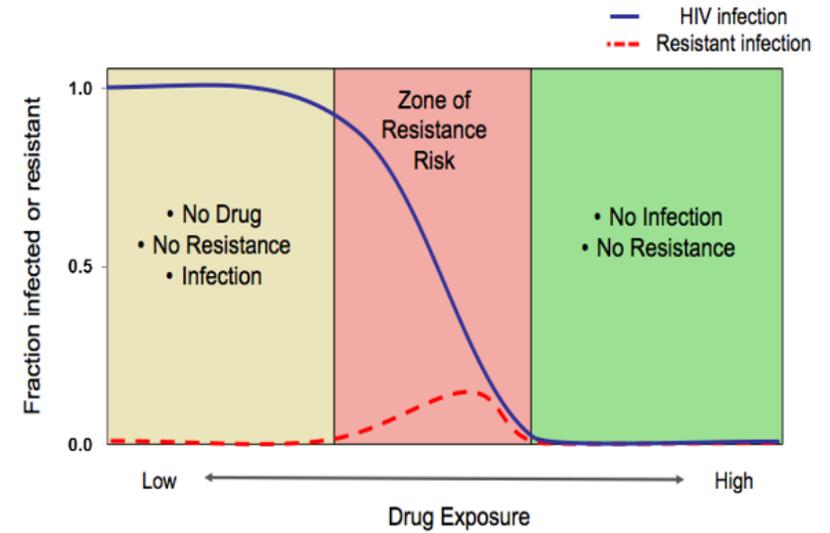
Populations and approaches

- How to deliver for specific focus populations
 - **Key Populations:** more experience needed delivering CAB to key populations groups, esp sex workers and people who use/inject drugs
 - **Transgender women:** Alternative muscle injection sites for people with buttock implants/fillers
- Models of delivery
 - Within current PrEP programmes?
 - Within key populations services?
 - Within SRH services (ANC, PNC, FP, STI)
 - KP services
 - others?
- Alongside other prevention – options and choices

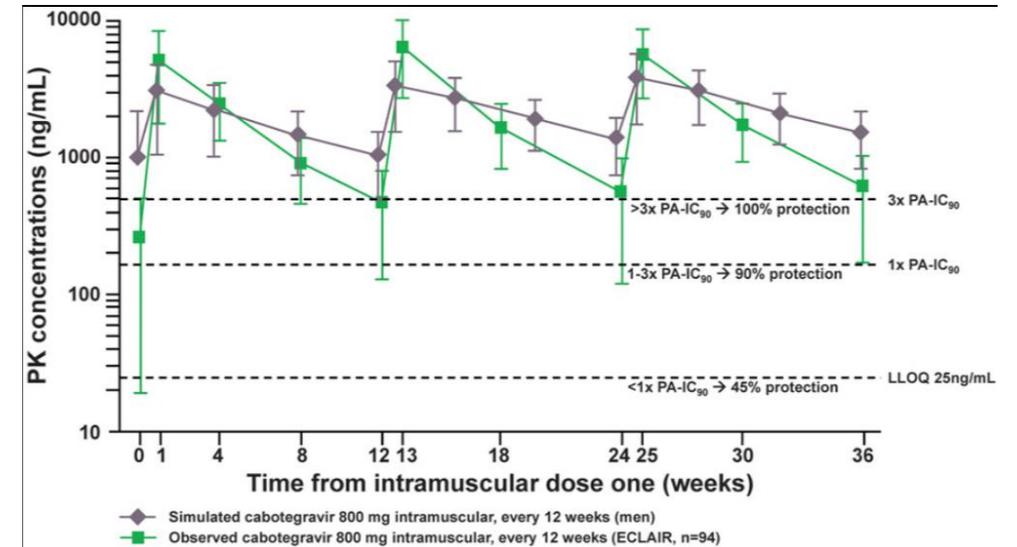
Need to plan an implementation science agenda

Specific implementation issues

- Oral lead in – ‘direct to inject’ can we do without lead in
- Covering the tail to avoid potential seroconversions and DR
 - Covering the tail with TDF/FTC
 - How long
 - Other options
- Restarting after missed appointments
 - What is the wiggle room?



Markowitz et al, Lancet HIV 2017;4:e331-40



Specific implementation issues

HIV testing

- Challenge - initiation in acute phase
- Delayed diagnosis for seroconversion detection in tail seroconverters

Will NATT be the only option?



Public health approach to quality HIV testing in the context of antiretroviral drugs

Meeting report

12-13 December 2017 | Centre for the AIDS Programme of Research in South Africa, Durban, South Africa

Thank you

I thank my colleagues at WHO Heather-Marie Schmidt, Robin Schaefer and Rachel Baggaley.



**World Health
Organization**

<https://www.who.int/groups/global-prep-network>

<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/overview>

Please contact me for questions or further information: rodolphm@who.int