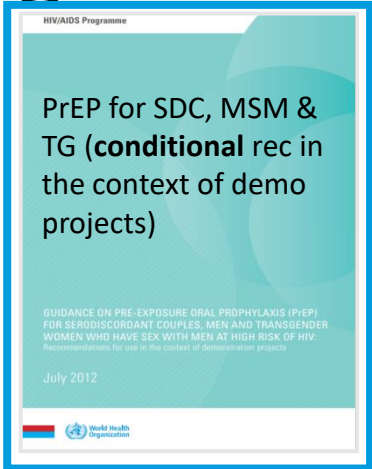


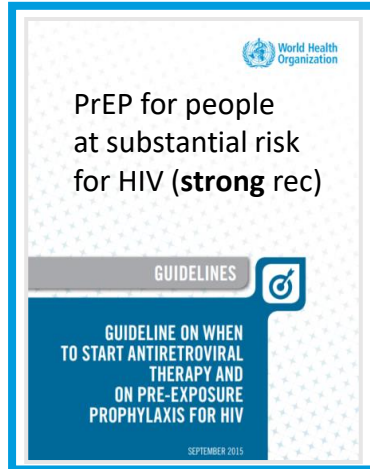
Upcoming guidelines on long-acting formulations and delivery methods for HIV prevention

- Michelle Rodolph, 5th May 2022

WHO PrEP recommendations and guidance

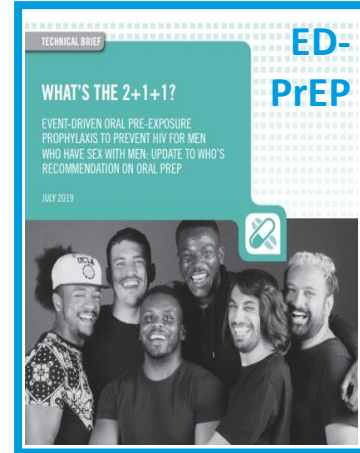


2012



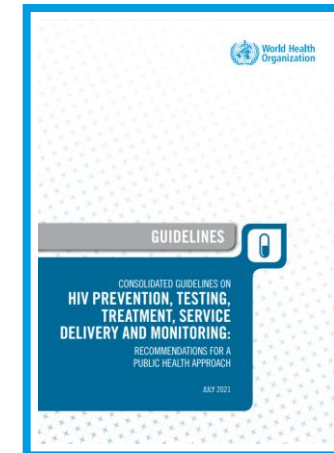
2014

2015/16



2017

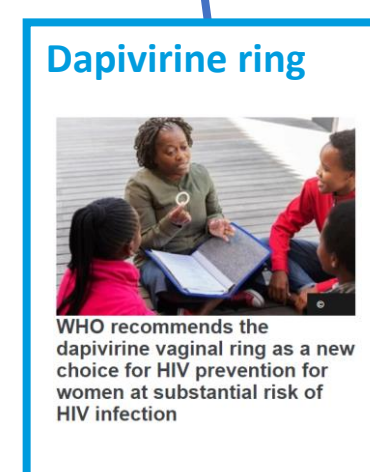
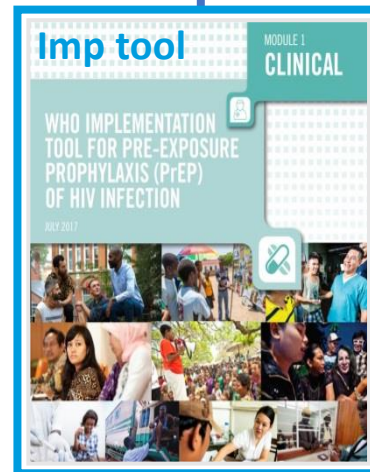
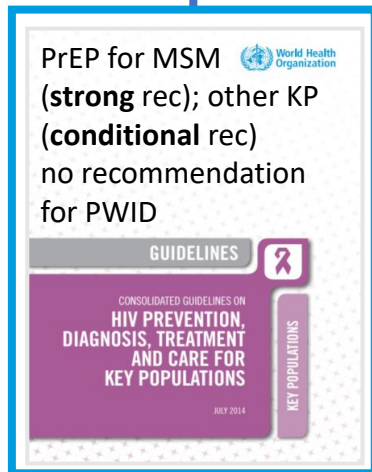
2019



2021

Revised PrEP implementation guidance, including for simplified PrEP service delivery

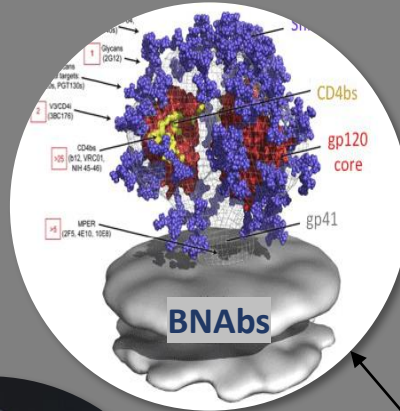
2022



WHO considers recommendation on CAB-LA

Following the biomedical prevention technologies pipeline

TDF/FTC



Dapivirine Vaginal Ring



Injectable
cabotegravir
lenacapavir



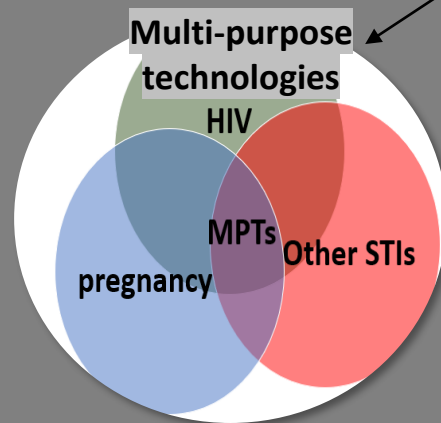
Potential future
prevention
technologies



Other oral:
F/TAF
Islatravir



Multi-purpose
technologies



Microbiome
modulating
products



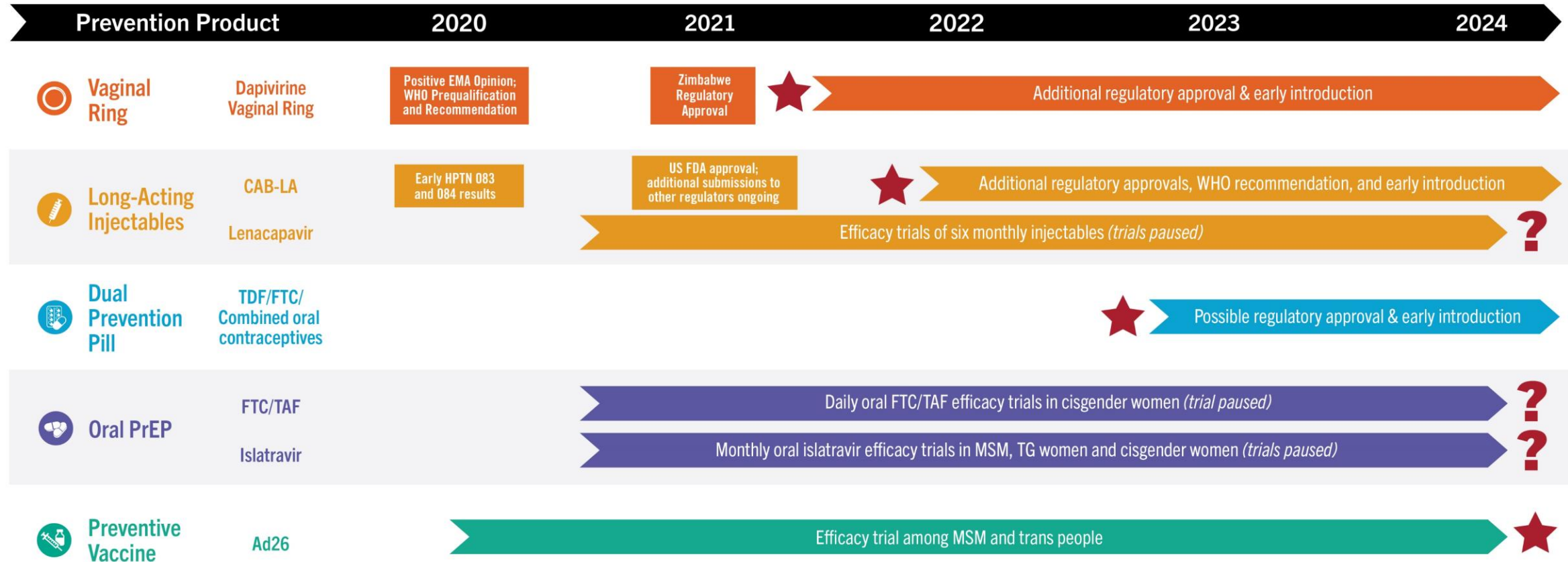
TAF, Islatravir
implant



Years Ahead in HIV Prevention Research

Time to Market

★ Earliest time to market
? Efficacy trials paused

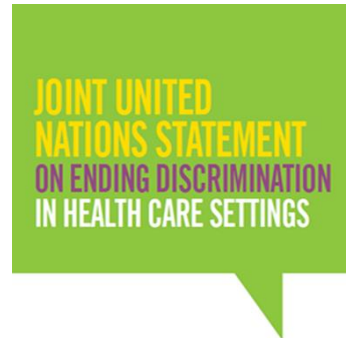


January 2022

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



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



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



Health Topics | Countries | Newsroom | Emergencies | Data | About Us

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

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

Related

General implementation issues

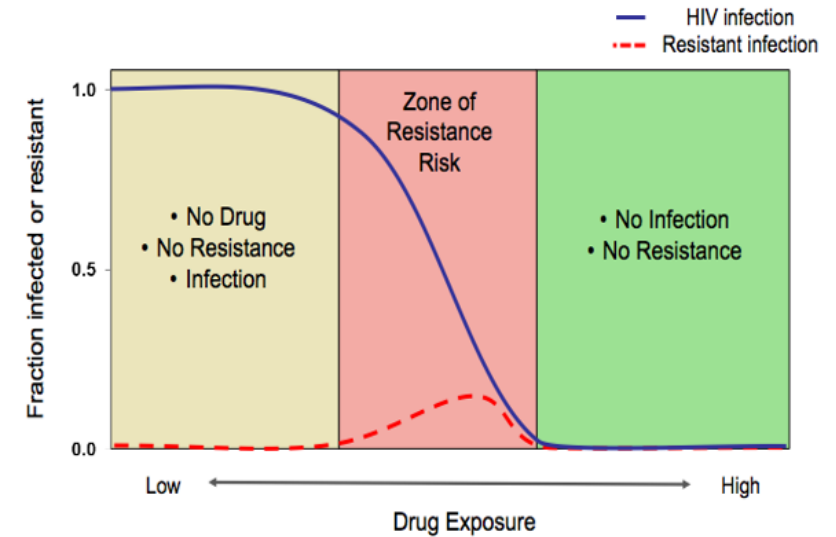
Populations and approaches

- 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

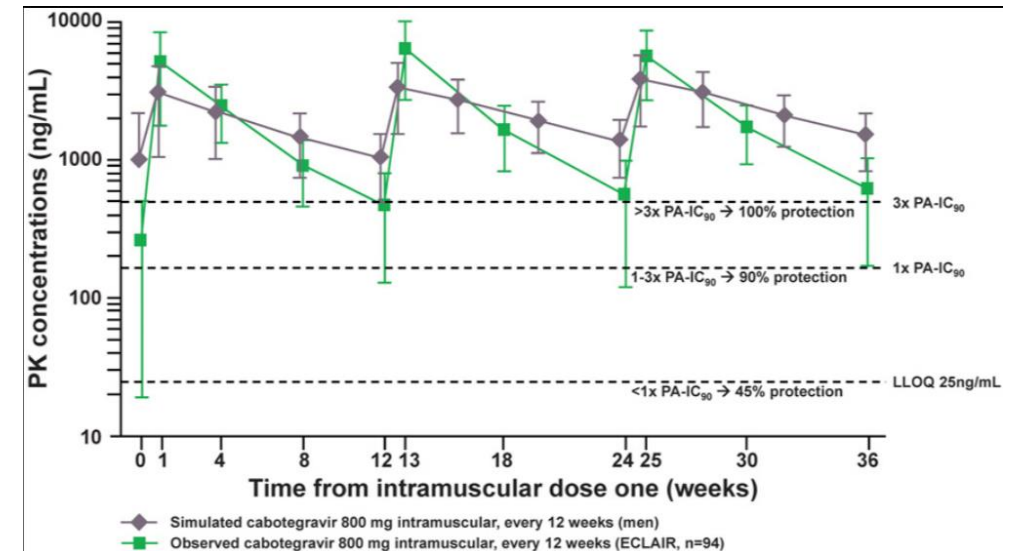
Need to plan an implementation science agenda

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