

Updated WHO guidance on pre-exposure prophylaxis (PrEP)

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**Presenting on behalf of the WHO HHS PrEP team:
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WHO RECOMMENDS ORAL PREP FOR HIV PREVENTION

- ✓ Recommended by WHO for all individuals at substantial risk of HIV since 2015
- ✓ High quality evidence from clinical trials, open-label extension studies and real-world implementation for oral PrEP:
 - ✓ Highly effective when used as directed (effectiveness correlated with adherence)
 - ✓ Safe with few side effects
- ✓ Not protective against other STIs or pregnancy
- ✓ Large-scale uptake, as part of combination prevention, has been associated with population-level decreases in new HIV diagnoses



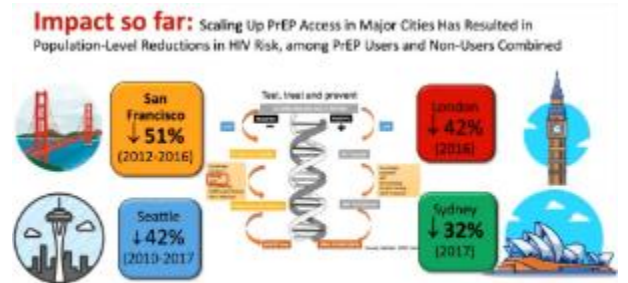
Anderson et al. *Sci Transl Med.* 2012 Sep 12; 4(151): 151ra125.

Grulich et al. *Lancet HIV.* 2018 Nov;5(11):e629-e637.

Eastcourt et al. *AIDS.* 2021 Mar 15;35(4):665-673.

Smith et al. *Clin Infect Dis.* 2020 Dec 15; 71(12): 3144-3151.

Zimmerman et al *Arch Sex Behav.* 2021 Feb 22. doi: 10.1007/s10508-020-01833-5

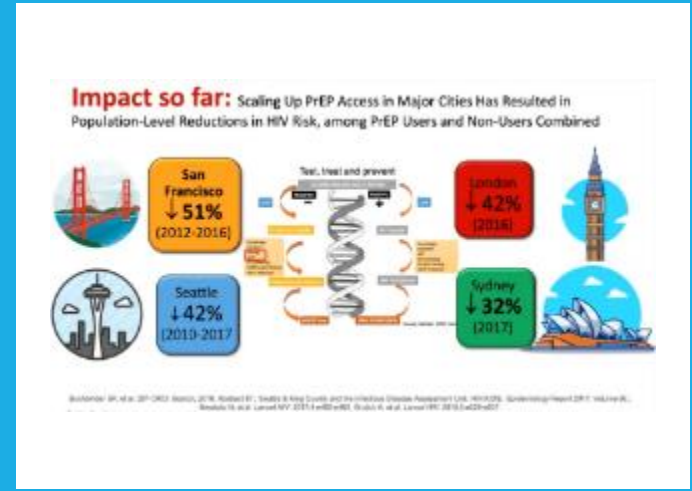


WHO RECOMMENDS ORAL PREP FOR HIV PREVENTION

- ✓ PrEP is empowering and has psychological benefits including reduced shame and fear
- ✓ PrEP is an additional prevention option; filling a prevention gap
- ✓ PrEP is an important HIV prevention tool, featuring in the political declaration 2021 and Global AIDS strategy, and is integral to the global 95% target for comprehensive prevention for 2025

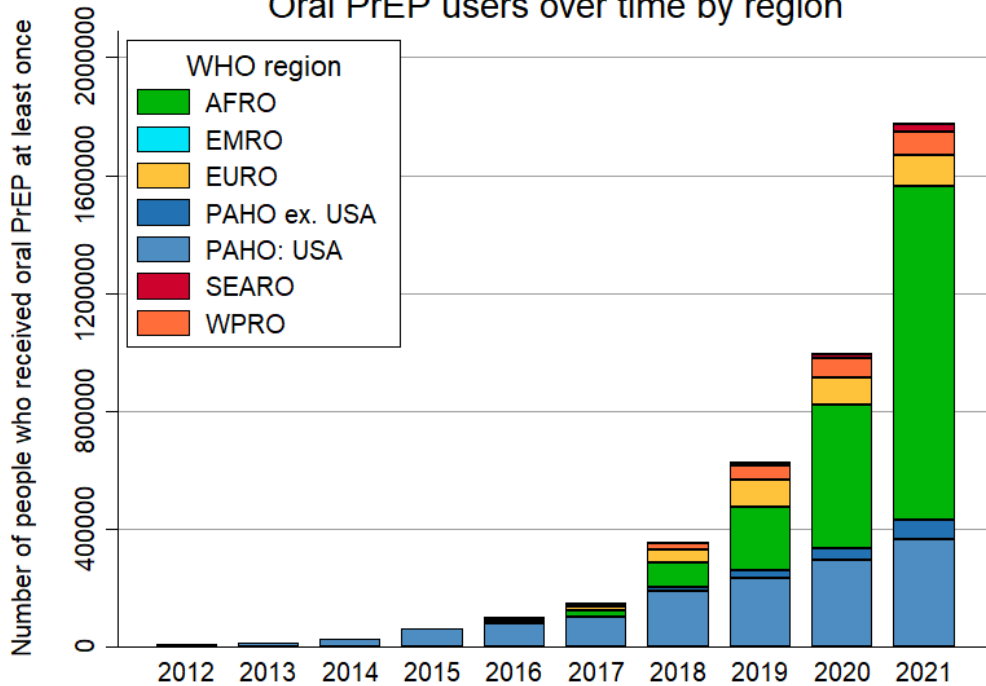


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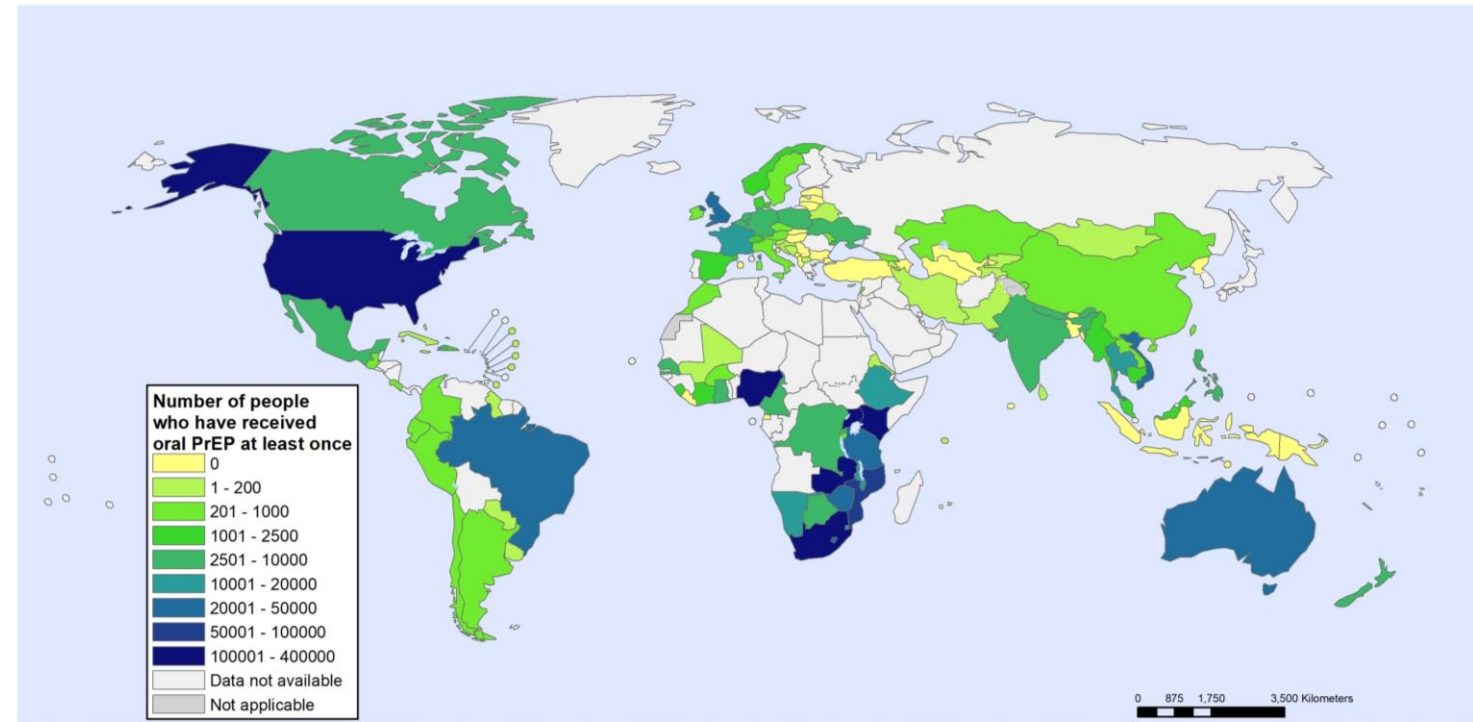
Number of people who received oral PrEP at least once in a year

Oral PrEP users over time by region



~1.8 million PrEP users in 2021 despite COVID-19 disruptions

Number of oral PrEP users in each WHO member state in 2021



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: WHO; GAM
Map Production: HQ UCN/HHS/TPP
World Health Organization



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WHO PrEP recommendations and guidance

HIV/AIDS Programme

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

2012

World Health Organization

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

GUIDELINES

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

SEPTEMBER 2015

2015/16

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

2019

World Health Organization

Updates on oral PrEP + dapivirine vaginal ring

GUIDELINES

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

AUG 2021

2021

Differentiated and simplified pre-exposure prophylaxis for HIV prevention

Update to WHO implementation guidance

TECHNICAL BRIEF

2022

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

AUG 2017

2019

DPV-VR

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

2021

CAB-LA

GUIDELINES ON LONG-ACTING INJECTABLE CABOTEGRAVIR FOR HIV PREVENTION

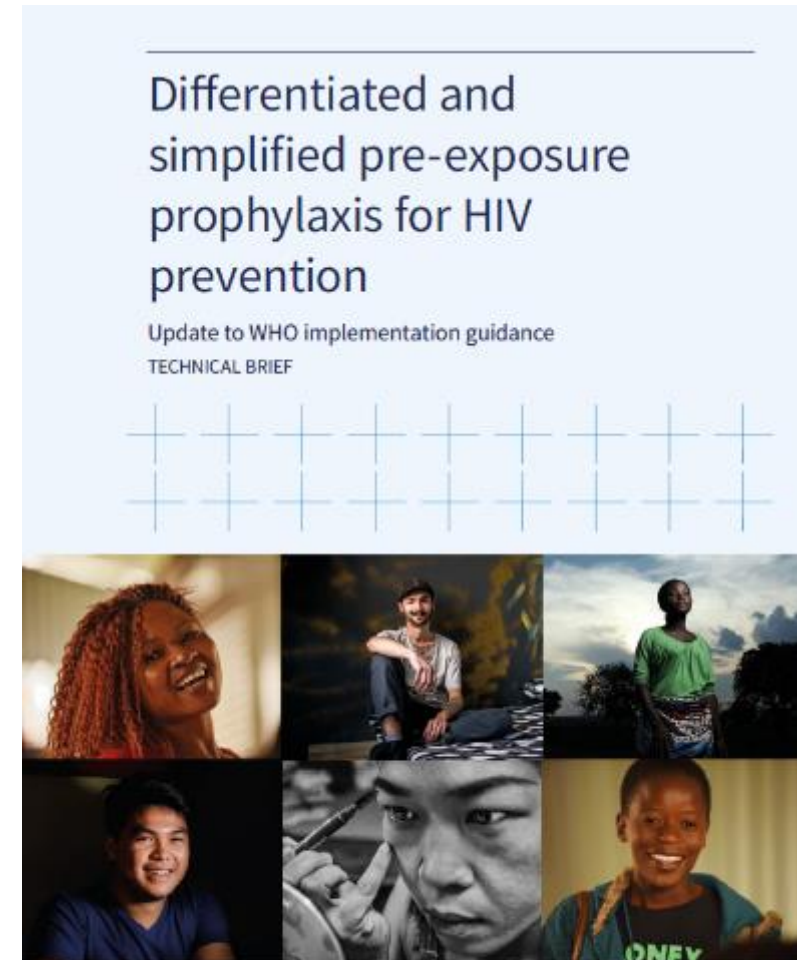
2022

Upcoming: Updates to PrEP impl. tool

2023

Accelerate PrEP scale-up through differentiated and simplified PrEP services

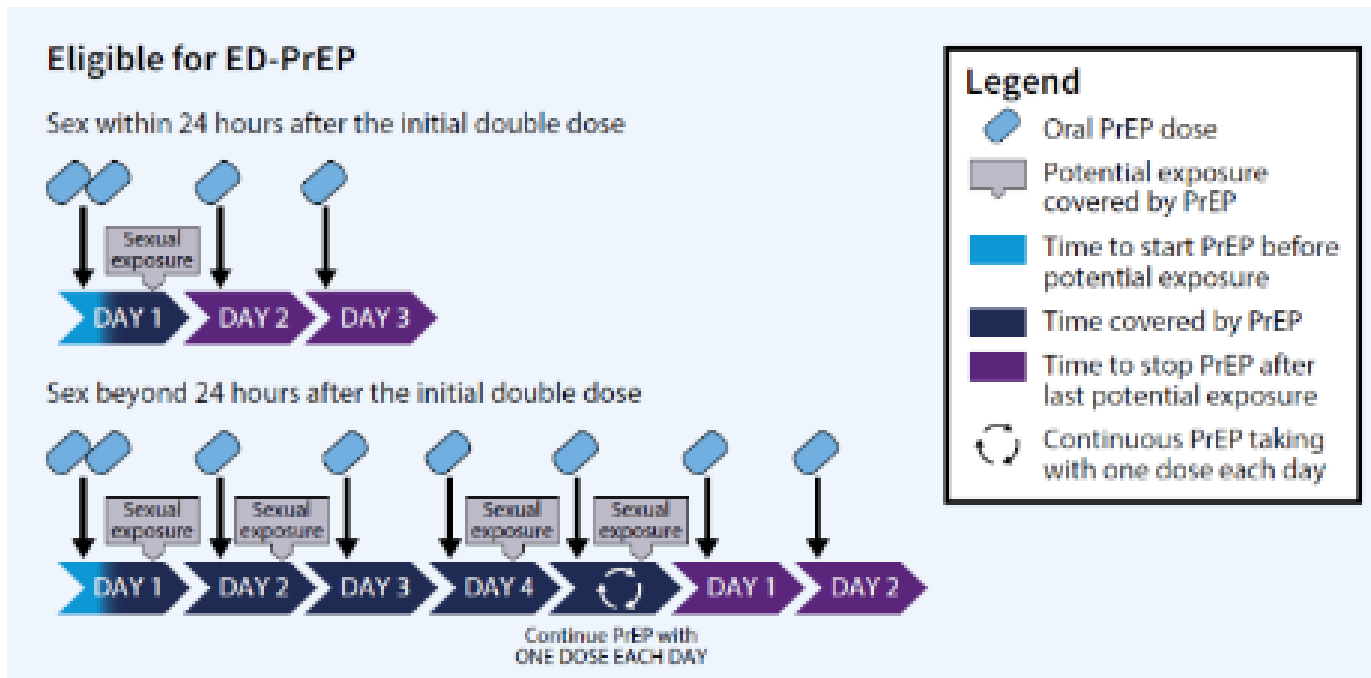
- Technical brief includes guidance on:
 - Starting, stopping and ED-PrEP
 - Kidney function monitoring
 - Viral hepatitis
 - HIV self-testing
 - Differentiated service delivery models
- The focus of the technical brief is **oral PrEP**
 - Guidance on CAB-LA (and DVR) as relevant



Starting, using and stopping TDF-based oral PrEP: ED-PrEP dosing

| Population | Starting oral PrEP | Using oral PrEP | Stopping oral PrEP |
|---|---|-----------------------|---|
| <p>Cisgender men¹ with sexual exposure, irrespective of the gender of the partner (i.e. including gay, bisexual and heterosexual men)</p> <p>Transgender women and other trans and gender diverse people assigned male at birth who:</p> <ul style="list-style-type: none"> • have sexual exposure AND • not taking exogenous estradiol-based hormones | <p>Double dose 2–24* hours before sexual exposure</p> <p>* ideally closer to 24 hours</p> | <p>1 dose per day</p> | <p>1 dose per day until 2 days after day last potential sexual exposure</p> |

Starting, using and stopping TDF-based oral PrEP: ED-PrEP dosing



Individuals eligible for event driven (ED-PrEP) dosing start and stop PrEP using the same approach, whether they intend to use PrEP:

- every day (daily)
- for one event (ED-PrEP) or
- multiple events (ED-PrEP)

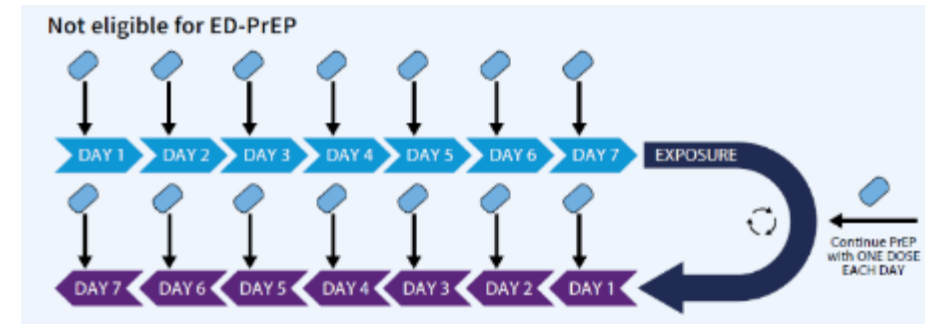
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| <p>Key points</p> <ul style="list-style-type: none"> • Expanded eligibility for ED-PrEP to prevent sexual acquisition of HIV : no longer just for MSM • HBV infection no longer a contraindication for oral ED-PrEP dosing | | | |

← Broader eligibility

Starting, using and stopping oral PrEP: daily dosing

| Population | Starting oral PrEP | Using oral PrEP | Stopping oral PrEP |
|--|---|-----------------|---|
| Cisgender women and trans and gender diverse people assigned female at birth (including transgender men) | 1 dose daily for 7 days before exposure | 1 dose per day | 1 dose per day for 7 days after last potential exposure |
| Cisgender men and trans and gender diverse people assigned male at birth (incl. transgender women) taking exogenous estradiol-based hormones | Simplified starting and stopping | | |
| People using oral PrEP to prevent HIV acquisition from injecting practices including men who inject drugs | | | |

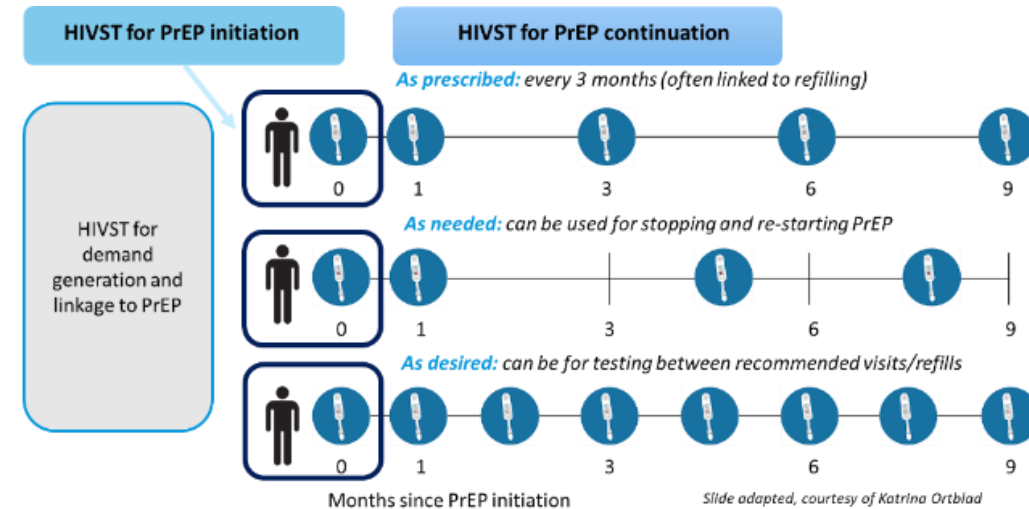


Key points

- If not eligible for ED-PrEP: Start daily oral PrEP with 7 doses and stop with 7 doses

Other key messages: PrEP is part of a service

- PrEP as part of a service should be flexible to the needs and preferences of the clients:
 - **Regular HIV testing** is required before and during use
 - HIVST can be used to complement existing testing strategies
 - HIVST may be preferred for convenience, privacy, and self-managed care
 - HIVST may reduce clinic visit
 - **Kidney function** testing MAY be required (within 1-3 months of initiation) depending on age and co-morbidities
 - **Testing for hepatitis B and C viruses** is encouraged within 1-3 months of initiation but not required
 - Regular **testing for STIs** is highly encouraged



Differentiated service delivery supports scale-up, access, acceptability

Differentiated PrEP services:

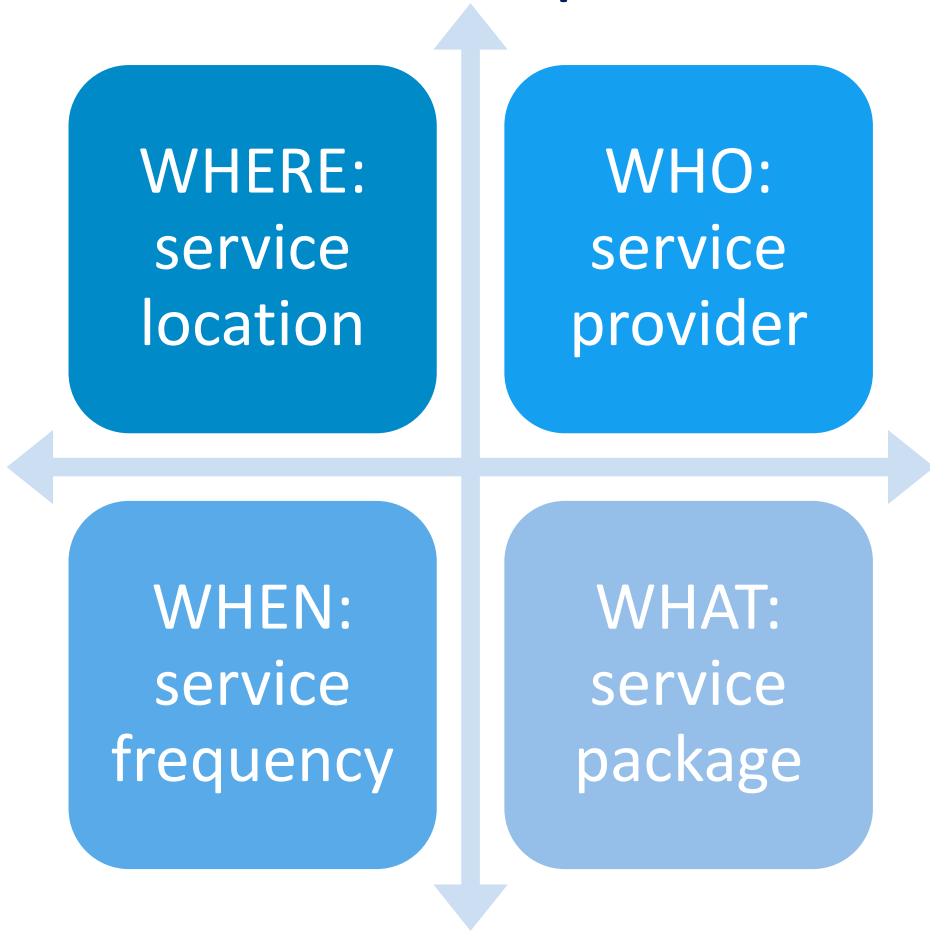
- Person- and community centred (i.e. adapted to end user needs & preferences)
- Support making services more accessible and acceptable
- May improve uptake, persistence, effective use

DSD building blocks provide a framework for: initiation, follow-up, re-initiation and switching between PrEP products

What do MEN NEED and VALUE from a service?

| Building block | PrEP initiation, initial follow-up (0–3 months), and re-initiation | | | PrEP continuation (3+ months) | |
|---|--|---|---|--|---|
| | Initiation | Initial follow-up (0–3 months) (if required) | Re-initiation after discontinuation | PrEP refill | Follow-up |
| Where: Service location (e.g., primary health care facility, community setting, virtual setting) | Locations for PrEP assessment and initiation | Locations for initial follow-up | Locations for PrEP re-initiation | Locations where PrEP refills can be collected | Locations where follow-up services will be provided |
| Who: Service provider (e.g., physician, nurse, pharmacist, peer) | Service provider/s authorized to assess for and initiate PrEP | Service providers who can carry out initial follow-up visit/s | Service provider/s authorized to re-initiate PrEP | Service provider/s who can dispense PrEP refills | Service provider/s who conduct follow-up |
| When: Service frequency (e.g., monthly, every 3 months) | Timing of PrEP assessment and initiation | Timing of initial follow-up | Timing of PrEP re-initiation | Frequency of PrEP refill visits (length of supply) | Frequency of follow-up services |
| What: Service package (including HIV testing, clinical monitoring, PrEP prescription and dispensing, and comprehensive services) | Service package for PrEP assessment and initiation | Service package at initial follow-up | Service package for PrEP re-initiation | Service package with PrEP refill | Service package with follow-up |

Differentiated services for PrEP for men: what are the options?



Offering choice in PrEP products may increase demand, uptake and effective use of HIV prevention

New recommendation

Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (*conditional recommendation; moderate certainty of evidence*).



28 July 2022 | News release

WHO recommends long-acting cabotegravir for HIV prevention

Schmidt HMA et al. *Journal of the International AIDS Society* 2022; **25**:e25962
<https://onlinelibrary.wiley.com/doi/10.1002/jia2.25962> | <https://doi.org/10.1002/jia2.25962>



VIEWPOINT

Long-acting injectable cabotegravir: implementation science needed to advance this additional HIV prevention choice

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Offering choice in PrEP products may increase demand, uptake and effective use of HIV prevention

New recommendation

Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (*conditional recommendation; moderate certainty of evidence*).

- Highly efficacious (HPTN083 included MSM)
- Has a good safety profile
- Delivered as an intramuscular gluteal injection every 2 months (first 2 injections delivered 1 month apart)
- Often acceptable to communities and may be preferred to oral PrEP by some people: choice is critical
- Priority to support CAB-LA as an additional option for PrEP **alongside** oral PrEP (and DVR) and other prevention
- Implementation science urgently needed to fill evidence gaps



Consider when providing PrEP to men

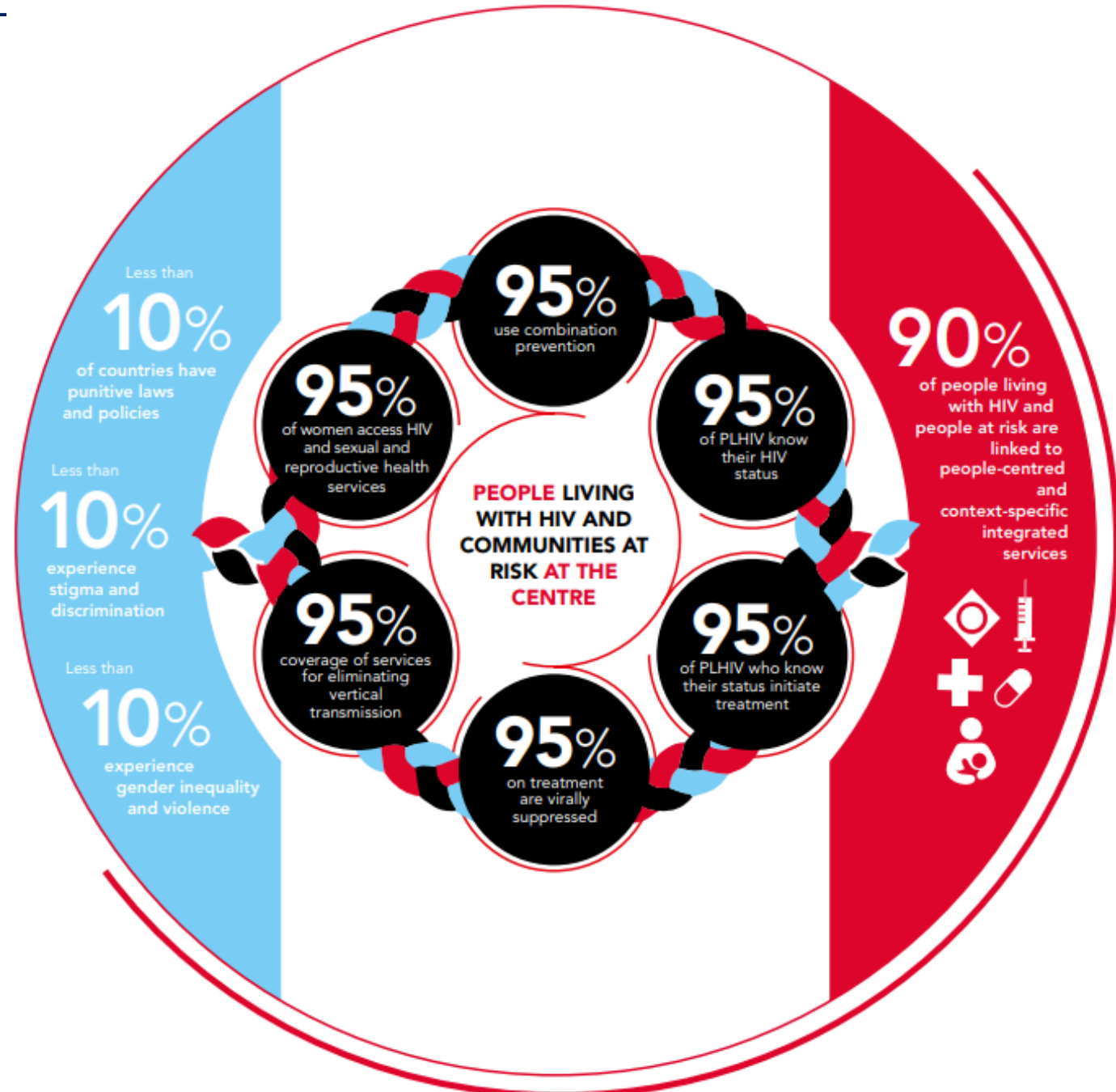
Differentiated and simplified services for PrEP and **product choice** contribute to **scale-up, uptake and persistence** and **effective use**

Addressing **stigma, discrimination, and criminalization** is critical to create enabling environment

Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations



<https://www.who.int/publications/i/item/9789240052390>



Thank you!

Thanks to the **WHO HHS Testing, Prevention, and Populations** team for contributions to this presentation.

Contact the PrEP team for questions or comments:

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- **Robin Schaefer:** schaefer@who.int
- **Heather-Marie Schmidt:** schmidth@unaids.org
- **Maeve Britto de Mello** demellmae@who.int **For STIs**

WHO's global work on PrEP:

<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>

WHO Global PrEP Network webinars:

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



Find the new Technical Brief here:

<https://www.who.int/publications/i/item/9789240053694>

Other new and upcoming WHO PrEP & PEP guidance

- **Guidelines on long-acting injectable cabotegravir (CAB-LA): out now!**
- **Updates to the WHO PrEP Implementation Tool**
 - Clinical module 2023
- WHO is looking into ways to **expand community access to PEP**

Thanks to everyone who contributed to the Technical brief (too many to list – please check the acknowledgement of the document!)