

HIV Pre-exposure Prophylaxis (PrEP) Updates

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**UNIVERSITY
OF MALAYA**

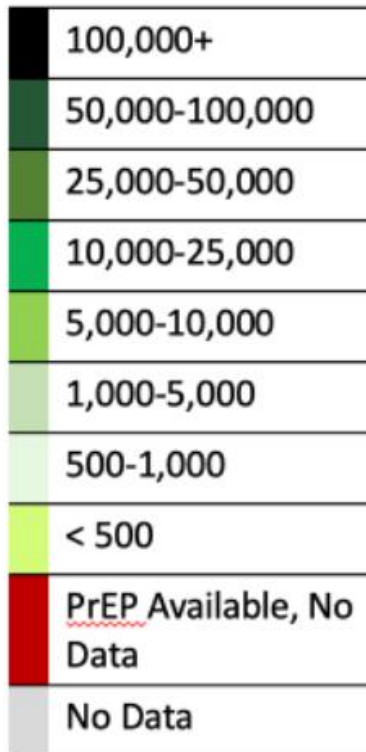
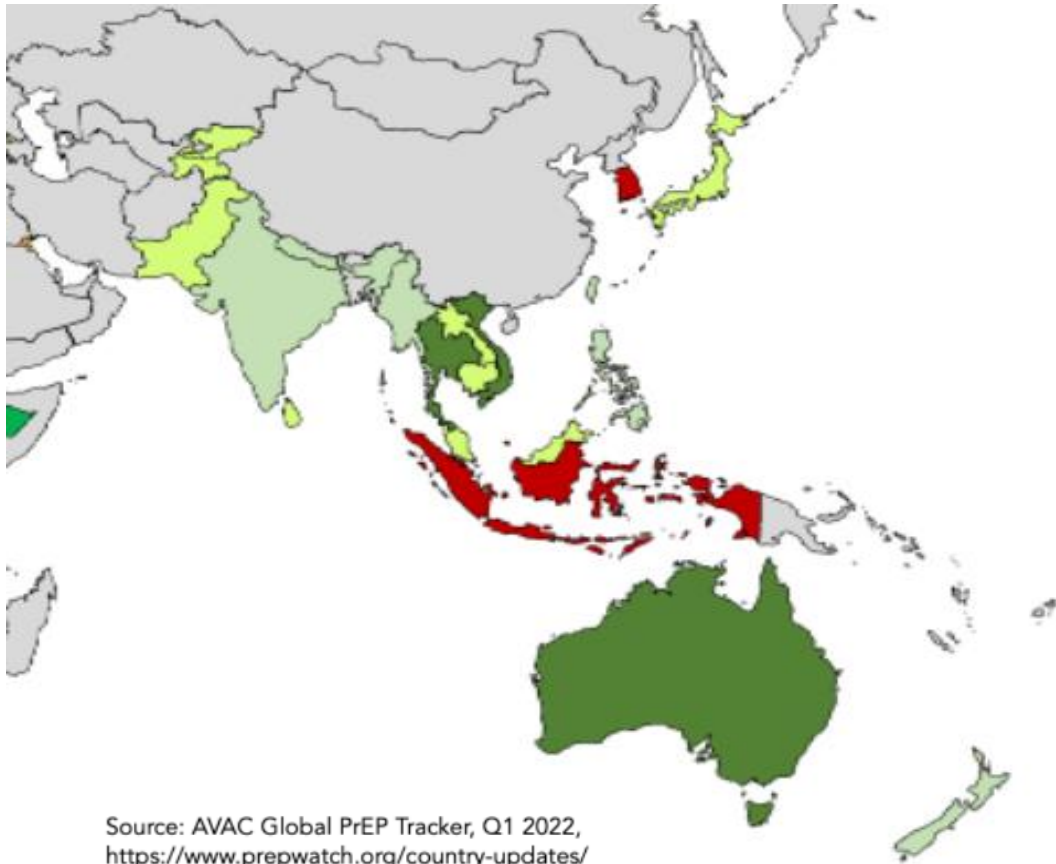


Outline of my talk

- De-medicalization of PrEP
- Starting and stopping PrEP timelines
- On demand PrEP
- HIV ST and PrEP
- Differentiated service delivery approaches
- LA Cabotegravir

** Mainly limiting to WHO Guidelines and oral TDF/FTC PrEP*

PrEP initiation in the Asia-Pacific, March 2022



Country	Cumulative Initiations Across All Products
Australia	49,355
Thailand	41,027
Vietnam	33,938
Nepal	4,410
Taiwan	4,142
Philippines	3,192
Myanmar	1,779
India	1,651

Source: AVAC Global PrEP Tracker, Q1 2022, <https://www.prepwatch.org/country-updates/>

Eligible participants will be given free PrEP for a year!



Interested? Questions?

UMMC - 6016 622 7319 | ummc@ummc.com
The Red Clinic - 6016 243666 | rcz@redclinic.com
CHCC Sentul - 6016 2767300 | hsh@chccsentul.com

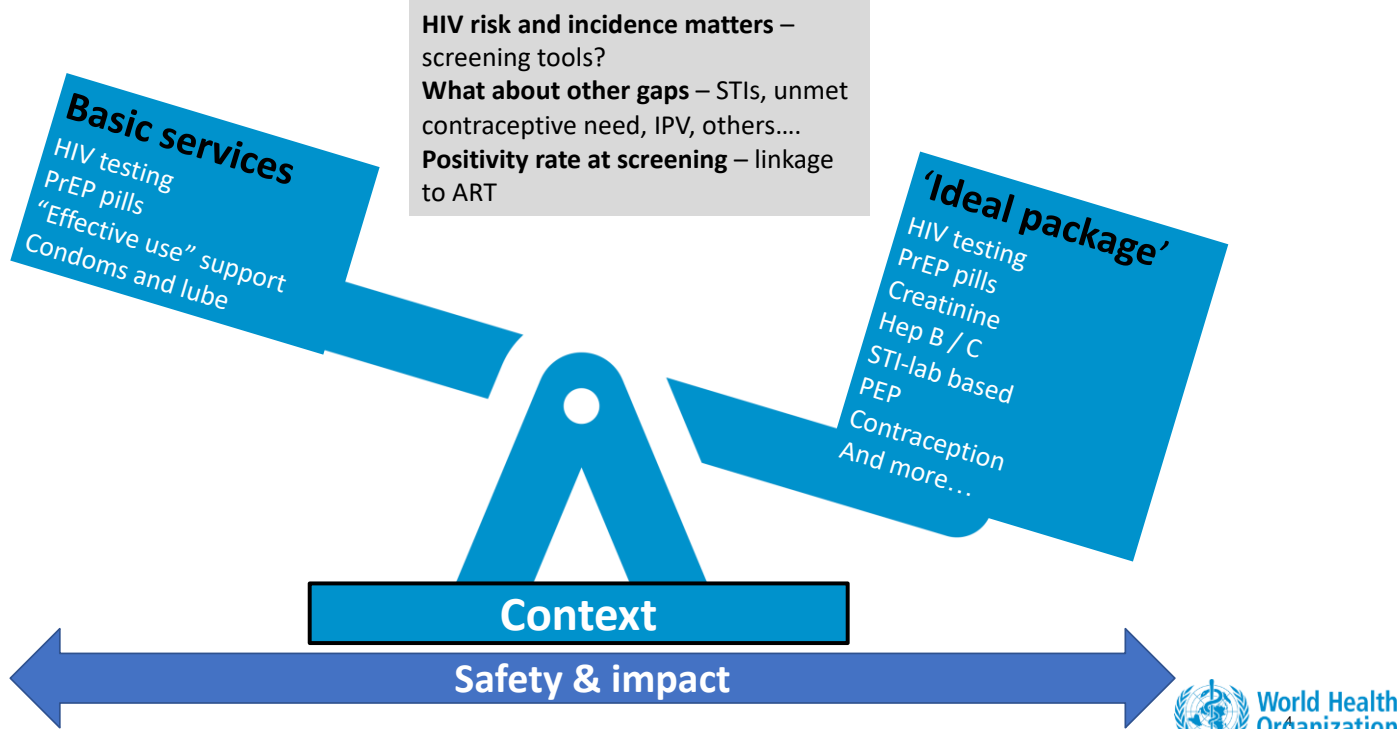
If you think you might know someone who would need this or might be interested to be part of this study, please pass the message around (discreetly!)

PREP STUDY FOR MSM

Study procedures, My PrEP Demonstration Project

- Procedure
- Rapid HIV Ag/
- HIV POC VL
- Creatinine
- Rectal CT/NG
- RPR/TPHA
- HBsAg/Ab
- HCV-Ab
- Questionnaire
- Diary (weekly)
- Drug dispensi
- Pill count

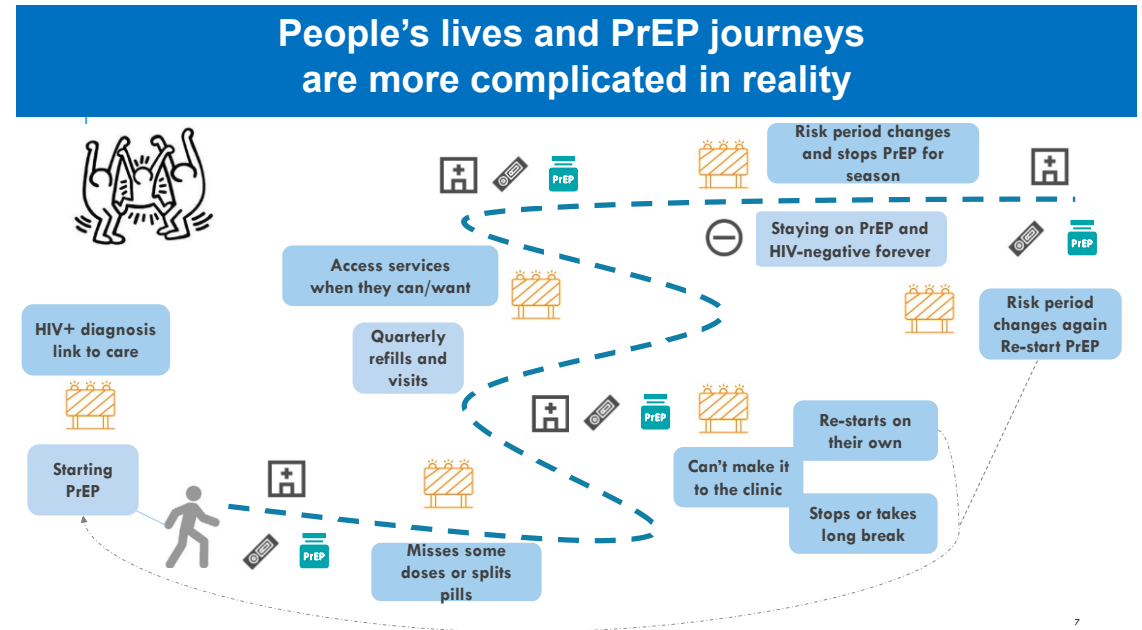
Making PrEP more effective and efficient: balancing costs, efficiency and impact



Demedicalization & Simplifying PrEP service delivery

New PrEP Guidance:

- Kidney function monitoring
- HIV self testing (HIVST) for PrEP
- Viral hepatitis testing
- Starting and stopping PrEP
- Differentiated service delivery approaches



To accelerate PrEP scale-up and overcome barriers, we need differentiated and simplified PrEP services

Need for simplified and differentiated delivery of PrEP

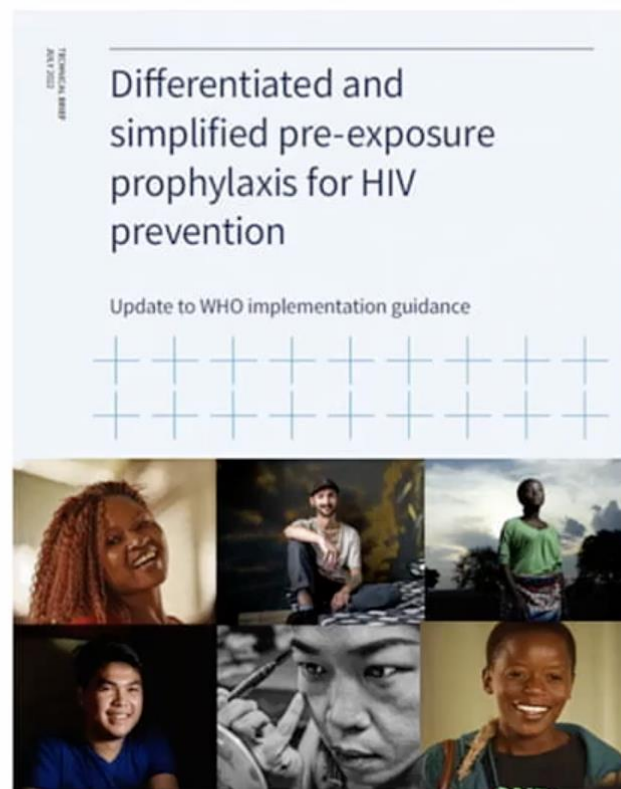
Person- and community centred services

Adapt services to needs and preferences of users

Make services more acceptable and accessible

Improve uptake, persistence, and effective use

Risk of 're-medicalization' of PrEP with CAB-LA



CDC PrEP Clinical Practice Guidelines

PrEP Eligibility (Updated 2021)

Risk based identification

All sexually active adults & adolescents

SO WHAT'S NEW?

HIV risk (Anal or vaginal sex) in the past 6 months

- HIV positive partner (not virally suppressed)
- Bacterial STI in the past 6 months
- History of inconsistent or no condom use

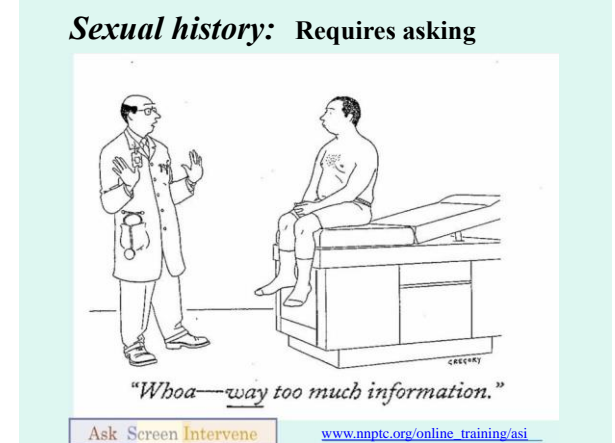
- **Universal PrEP Education:**
Recommendation to inform all sexually active adults and adolescents about PrEP

- Offer Prep To Anyone Asking For PrEP

Asking for PrEP = Anticipated risk of acquiring HIV

Sexual History Taking: Language matters

- Taking “risk” out of the equation
- Use positive “gain-framing” messages focusing on empowerment & health promotion
- Open ended questions about sexual behaviours



Sexual Health Based

“PrEP is a tool that can be used to reduce anxiety about HIV and take control of your sexual health.”

VS

Risk Based

“PrEP is for people at high risk for HIV who want to decrease their risk of becoming infected

Kidney function in tenofovir disoproxil fumarate-based oral pre-exposure prophylaxis users: a systematic review and meta-analysis of published literature and a multi-country meta-analysis of individual participant data

Robin Schaefer, Pedro Henrique Amparo da Costa Leite*, Ronaldo Silva, Quarraisha Abdool Karim, Christopher Akolo, Carlos F Cáceres, Inês Dourado, Kimberly Green, Anita Hettema, Elske Hoornenborg, Smarajit Jana†, Bernhard Kerschberger, Hally Mahler, Sindy Matse, Hamish McManus, Jean-Michel Molina, Sushena Reza-Paul, Iskandar Azwa, Maryam Shahmanesh, Doug Taylor, Hamid Vega-Ramirez, Valdiléa G Veloso, Rachel Baggaley, Shona Dalal*

- 11 RCTs, 13523 participants
- PrEP use was associated with increased risk of grade 1 and higher kidney adverse events (pooled OR 1.49, 95% CI 1.22–1.81) and grade 2 and higher events (OR 1.75, 0.68–4.49)
- 349 (2.43%)/14368 PrEP users with longitudinal analyses had a Creatinine clearance (CrCl) decline to < 60 mL/min with higher risks associated with increasing age and baseline Cr Cl of 60–89.99 mL/min (aHR) 8.49, 95% CI 6.44–11.20) and less than 60 mL/min (aHR 20.83, 12.83–33.82).

Conclusion: Kidney function screening and monitoring should focus on **older individuals, those with baseline Cr Cl of < 90 mL/min** and those **with kidney-related comorbidities**. Less frequent or optional screening among younger individuals without kidney-related comorbidities may reduce barriers to PrEP implementation and use.

Kidney function monitoring for oral PrEP

Impaired kidney function, indicated by a creatinine clearance of <60ml/min, is a contraindication for using oral PrEP containing TDF.

Population		Initiation	Follow-up
Kidney-related comorbidities	Age		
No	<30	Optional	Optional (until age 30 or kidney-related comorbidities develop) If baseline done and CrCl <90ml/min, conduct follow-up ever 6-12months
No	30-49	Conduct once within 1-3 months after oral PrEP initiation	If CrCl ≥90ml/min, optional (until age 50 or kidney-related comorbidities develop) If CrCl <90ml/min, screening every 6-12 months
Yes	Any age	Conduct once within 1-3 months after oral PrEP initiation	Screening every 6-12 months
No	50+		

CDC 2021 PrEP Guidelines: Key Monitoring Updates

- **Revised HIV testing:**

- Assess HIV status at follow-up visits during and recently after PrEP:
HIV-1 RNA assay recommended
- Every **3 months** with oral PrEP, every **2 months** with LA CAB

- **Revised renal function monitoring:**

- Every 12 months with oral PrEP if aged <50 yr and eCrCl \geq 90 mL/min at PrEP initiation
- Every 6 months with oral PrEP if age \geq 50 yr or eCrCl <90 mL/min at PrEP initiation
- No renal monitoring with LA CAB

- **Lipid monitoring every 12 mo with oral FTC/TAF**

HIV testing for Oral PrEP

HIV testing is required prior to starting or restarting PrEP and should be conducted regularly (e.g., every 3 months) during PrEP use.



- Use WHO **serial testing strategies, within a validated testing algorithm**, using WHO prequalified assays.
- Individuals may be tested at POC following the **national testing algorithm**, usually a combination of 3rd generation RDTs
- **More expensive and complex testing strategies may hinder access and are unlikely to provide any greater benefit in settings where NAT or 4th generation assays are not routinely used for HIV diagnosis**
- If the initial HIV test -ve and no history or signs/symptoms of an acute viral syndrome, **offer same day initiation**
- Once initiated on PrEP, HIV testing is suggested every 3 months and whenever restarting PrEP after a gap in use.
- Additional HIV testing 1 month after starting or restarting PrEP may also be beneficial

Argument for not using HIV RNA tests for HIV testing whilst on oral PrEP...for now

Table: Summary of Relevant Findings from HPTN 083*		
	CAB% arm	TDF/FTC& arm
Number of Incident HIV Infections	12	39
Number with Delayed Detection	7 (58.2%)	7 (17.9%)
Median Delay in Diagnosis in Days (range)	98 (35-185)	31 (7-68)
Earlier Detection with Viral Load Testing	5/7 (71.4%)	6/7 (85.7%)
Emergence of Important Class Resistance	4/12 (33%)	4/39 (10.3%)

*: HPTN 083 – The HIV Prevention Trials Network 083 study

=: CAB – cabotegravir

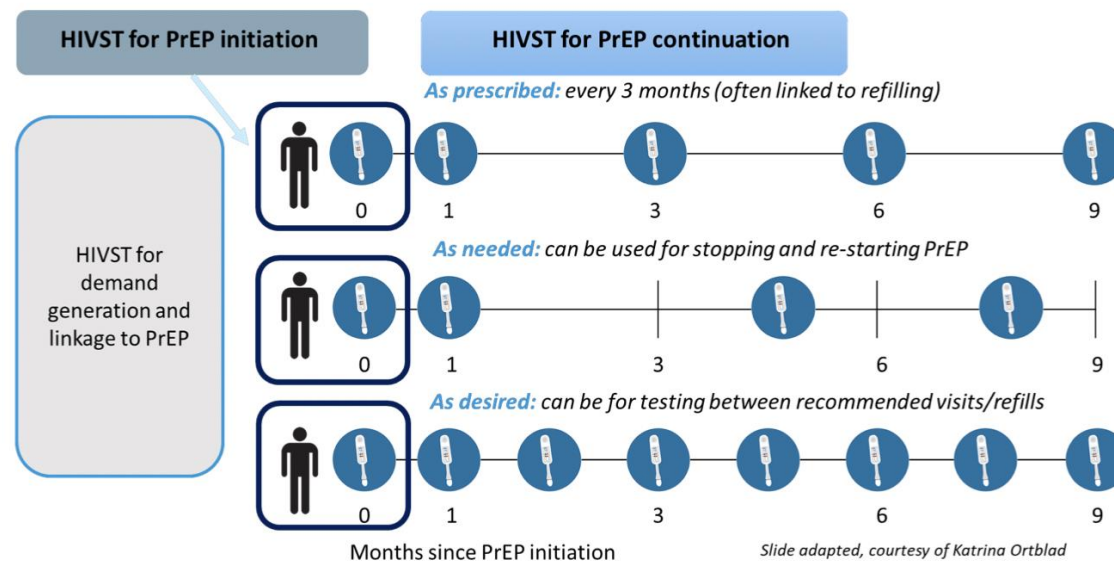
&: TDF/FTC – tenofovir disoproxil fumarate and emtricitabine

- HIV RNA tests are more expensive with longer turn around times than Ag/Ab tests
- No access to CAB currently
- Delayed detection was less common for incident infections occurring on TDF/FTC vs CAB arm
- When delays occurred they were also shorter in duration for people on oral TDF based PrEP (median 31 vs 98 days)
- Resistance that may be seen in oral PrEP failures (M184V and/or K65R) do not have a major impact on 1st line regimens containing DTG or BIC. (NADIA, VISEND, S2D2)
- INSTI resistance emerging on CAB (including Q148R/K and R263K) is associated with DTG and BIC failure and would therefore likely impact 1st line INSTI based HIV regimens
- Benefit is clearer for people on CAB but marginal for people on oral TDF/FTC

HIV Self Testing (HIVST) for oral PrEP

HIV testing is required prior to starting or restarting PrEP and should be conducted regularly (e.g., every 3 months) during PrEP use.

- HIVST: additional testing choice, can **complement existing HIV testing strategies** for oral PrEP and DVR, and may:
 - **reduce clinic visits**
 - be preferred for **convenience, privacy, and self-managed care**
 - ? increase **PrEP use and persistence**
 - ? **HIV testing frequency**
- Programmes can consider HIVST for oral PrEP and DVR users when starting, re-starting, and/or continuing PrEP
 - **Clear and concise messaging**
- Where HIVST-supported PrEP delivery models reduce clinic visits, important that **comprehensive services** to address the diverse needs of PrEP users still provided
- **Operational research** on HIVST-supported PrEP delivery, e.g. optimizing delivery, understanding impact, and costs.



HIV Self Testing---> reaching the 1st 95 in Indonesia

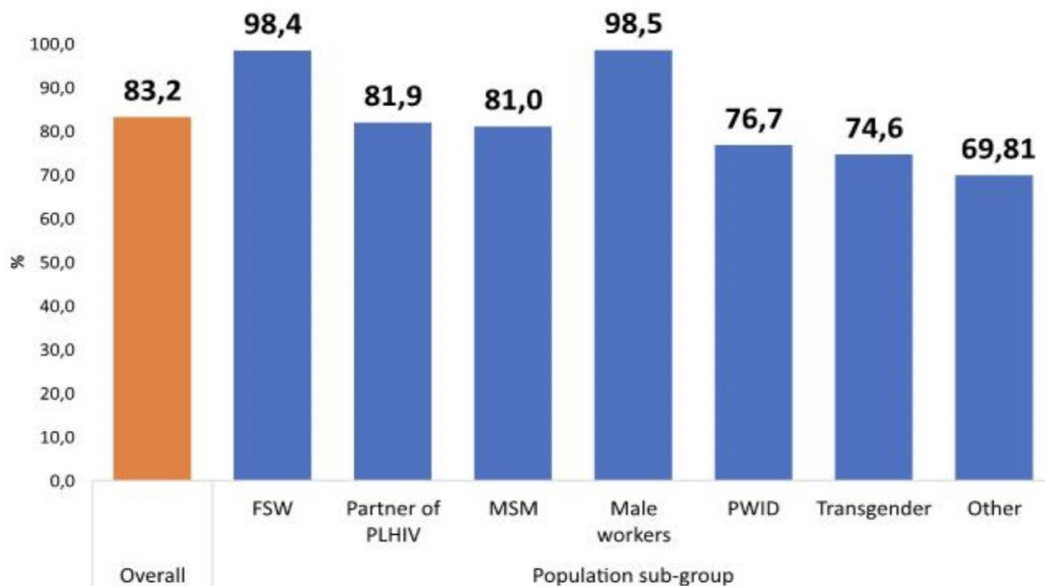
Only 49% of PLHIV in Indonesia know their status (MOH 2022)

National roll out of CBS through HIV ST among key populations (n= 36, 616)

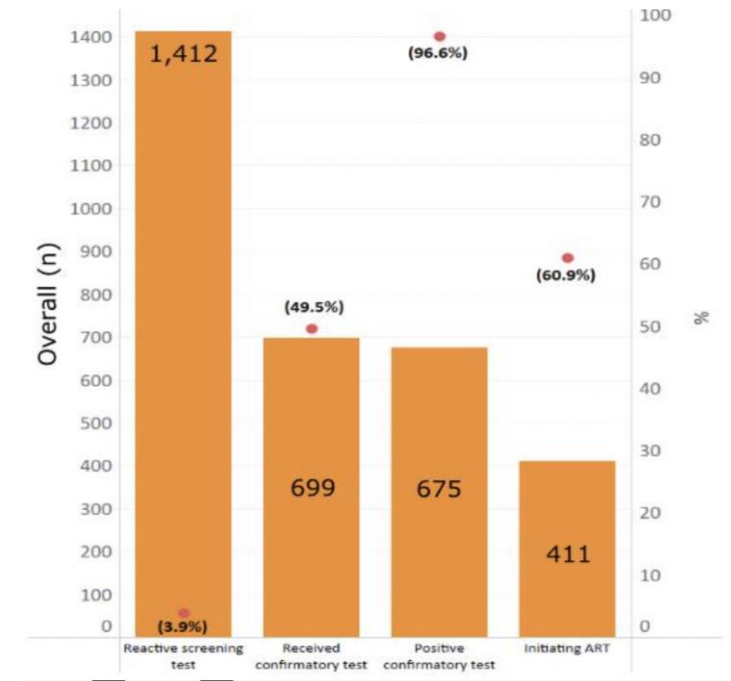
75% of distribution of ST kits occurred from hotspots

83% were 1st time testers (3.9% positivity rate)

Most unwilling to pay



Percentage of 1st time testers by key population



Cascade of HIV CBS to ART initiation



PrEP and viral hepatitis

In many settings, populations at risk of HIV are also at high risk of hepatitis B and C infection.

PrEP services provide a unique opportunity to screen for hepatitis B and hepatitis C infection and address multiple public health issues.

Hepatitis B

Testing oral PrEP users for **hepatitis B surface antigen (HBsAg) once**, at or within 3 months of PrEP initiation, is strongly suggested where feasible.

TDF-based daily or event-driven oral PrEP and the dapivirine vaginal ring can be safely offered to persons with HBV infection.

Rapid point-of-care tests are available for HBsAg, and WHO has prequalified several rapid diagnostic tests.

Consider people with detectable HBsAg for treatment.

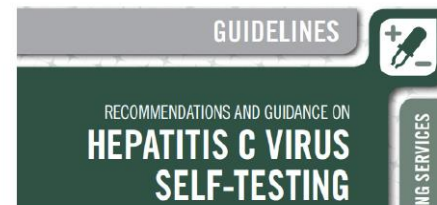
People at risk of acquiring hepatitis B with non-reactive HBsAg test may be considered for hepatitis B vaccination.

Hepatitis C

HCV antibody testing is strongly encouraged at or within the first three months of PrEP initiation and every 12 months thereafter where PrEP services are provided to populations at high risk of HCV infection.

TDF-based daily or event-driven oral PrEP and the dapivirine vaginal ring can be safely offered to persons with HCV infection.

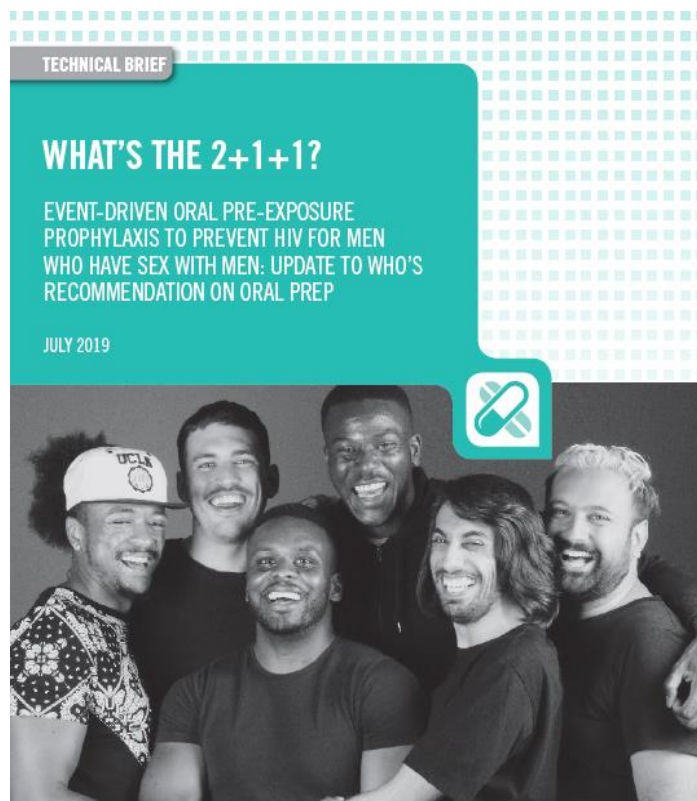
Individuals with reactive serology test results should be referred for further assessment and treatment for hepatitis C infection.



WHO has recently released guidelines on hepatitis C self-testing

Availability of or access to HBV and HCV testing should not be a barrier to PrEP initiation or use. PrEP can be initiated before HBV and HCV test results are available. HBV or HCV testing are not a requirement for PrEP use.

Event Driven (ED) PrEP



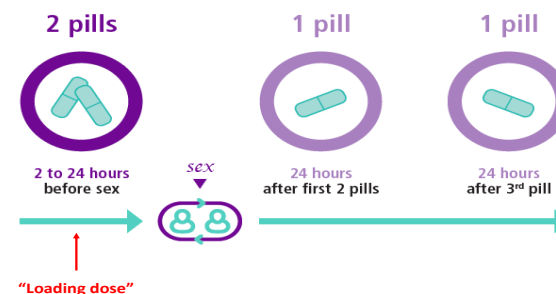
TECHNICAL BRIEF

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

What's the 2+1+1? Dosing regimen for MSM



When to consider ED-PrEP?

For whom is ED-PrEP appropriate?	For whom is ED-PrEP NOT appropriate?
<p>MSM*:</p> <ul style="list-style-type: none"> • who would find ED-PrEP more effective and convenient • who has infrequent sex (for example, sex less than 2 times per week on average) • who is able to plan for sex at least 2 hours in advance, or who can delay sex for at least 2 hours 	<ul style="list-style-type: none"> • cisgender women or transgender women who have vaginal sex • men having anal sex with women • people with hepatitis B infection.

* There is evidence on the efficacy and safety of ED-PrEP only for men who have sex with men (receptive and/or insertive anal sex).



Event Driven(ED)-PrEP Eligibility & Safely Starting and Stopping Oral PrEP

Previous Eligibility for ED PrEP only applied to cisgender MSM

Start with 2 doses 2-24h* before sexual exposure and **stop** after 2 days post-exposure

Eligibility: Assigned male at birth not taking feminizing gender-affirming hormones (GAH, e.g. estradiol) with sexual exposure, including

- Cisgender men
- Transgender women not taking GAH
- Non-binary individuals assigned male at birth not taking GAH

The starting and stopping approach is the same whether the intention is to use daily or ED-PrEP

Rationale: ED-PrEP effective for cisgender men regardless of sexual positioning. Risks associated with cisgender men having sex with men should be no lower than for cisgender men having sex with individuals from other populations. Risks assumed similar for individuals assigned male at birth not taking gender-affirming hormones.

* 2-dose start ideally closer to 24h to potential exposure

Start daily oral PrEP 7 consecutive days before exposure and **stop** after 7 days post-exposure

Eligibility: Individuals not eligible for ED-PrEP, including:

- Assigned female at birth, including
 - Cisgender women
 - Transgender men
 - Non-binary individuals assigned female at birth
- Assigned male at birth taking feminizing GAH
 - Transgender women taking GAH
 - Non-binary individuals assigned male at birth taking GAH
- Individuals with exposure through injecting practices

Rationale: Modelling of pharmacokinetics with TDF and FTC support a shorter stopping regimen of up to 7-10 days. Compliance with previous 28-day post exposure guidance is likely low and may be barrier for PrEP initiation and re-initiation.

ANRS Prévenir Study: Daily versus On-demand PrEP in high risk MSM

- Multicenter, open-label, prospective cohort study mainly in MSM (98.5%) from Paris

Beginning of Study
May 3, 2017

Current Analysis
Sep 20, 2020

HIV-negative adults at high risk of HIV infection with inconsistent condom use; eGFR \geq 50 mL/min; HBsAg negative in on-demand arm (N = 3059)*

Daily FTC/TDF PrEP [†] (n = 1544)
On-Demand FTC/TDF PrEP [†] (2-1-1: 2 doses before sex, 1 dose QD for 2 days after sex) (n = 1515)

*Participants enrolled in **arm of their choice** with ability to switch. [†]Plus condoms, gels, risk reduction and adherence counseling, questionnaire on sexual behavior. Follow-up every 3 mos with STI and/or HIV testing, plasma creatinine measurement.

- Primary endpoint: \geq 15% reduction in new HIV diagnoses among MSM in Paris vs rate reported by National Surveillance network in 2016
- Secondary endpoints: HIV incidence, PrEP adherence, sexual behaviour, safety

ANRS Prévenir: HIV Incidence and PrEP Adherence

- Overall HIV incidence: **1.1/1000 PY** (95% CI: 0.04-0.23)
 - 3 cases in each arm**, Mean follow-up: 22.1 months (5633 PYFU)
 - Overall HIV infections averted: n=361**, based on 6.6/100 PY incidence reported for placebo arm in ANRS IPERGAY study
 - Higher rates of drug related adverse events in the on demand group

Outcome	Daily PrEP (2583.25 PYFU)	On-Demand PrEP (2553.68 PYFU)	IRR (95% CI)
HIV incidence/100 PY (95% CI)	0.12 (0.02-0.34)	0.12 (0.02-0.34)	0.99 (0.13-7.38)

Prophylaxis at Last Sexual Encounter, n (%)*	Daily PrEP (8769 Acts)	On-Demand PrEP (8507 Acts)	Total (17,277 Acts)
PrEP use	8049 (95.7)	6680 (81.6)	14729 (88.8)
▪ Correct*	7877 (97.9)	6480 (97.0)	14357 (97.5)
▪ Suboptimal	172 (2.1)	200 (3.0)	372 (2.5)
No PrEP	358 (4.3)	1505 (18.4)	1864 (11.2)
Condom use	1474 (16.8)	1666 (19.6)	3141 (18.2)

*Per protocol, or at least 1 pill before and after sexual encounter, within 24 hrs.

Differentiated PrEP Service Delivery

Building blocks of differentiated service delivery

- Differentiated PrEP services:
 - Person- and community-centred
 - Adapts services to needs and preferences
 - May make PrEP services more acceptable and accessible
 - Support uptake, persistence, effective use.
- Common framework for differentiated PrEP service delivery: four building blocks of “where” (service location), “who” (service provider), “when” (service frequency), and “what” (service package).
 - Building blocks can differ between PrEP initiation, continuation, and reinitiation, and between PrEP products.

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

Key Considerations

WHERE

- Community involvement
- Government support and policy
- Logistics systems
- Adequate infrastructure
- Clinical oversight and referral pathways
- Data systems
- Person-centred and integrated services

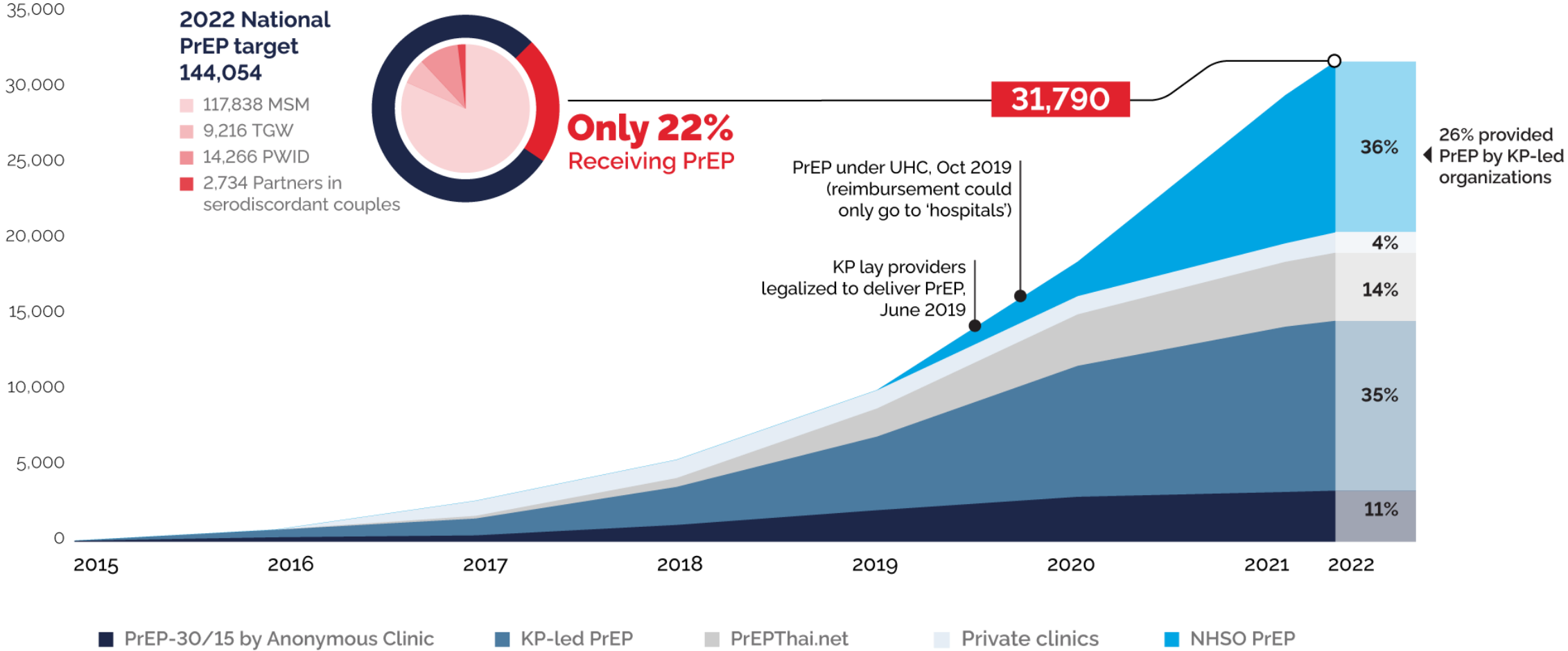
WHO

- **Task sharing** to make the best use of available human resources e.g. physicians, nurses, pharmacists, clinical officers, and trained and supervised peer and community health workers
- Acceptability of provider types to the PrEP user
- Registration and regulation of provider types to provide PrEP - may vary by PrEP product type (e.g. DVR and oral PrEP vs CAB-LA)
- Training and accreditation, quality assurance, protocols, and linkage to facilities, remuneration

WHEN and WHAT

- Dynamic use of PrEP
- Client centered: follow-up and dispensing tailored to needs of PrEP clients
- Integrated service package that is responsive to the needs and wants of a client (N.B. some clients may only want PrEP)
- Integration and co-delivery with STIs, family planning / contraceptive services etc.

KP-led PrEP service in Thailand: 80% of current PrEP users



Sources: PrEP Thai.Net, NAP-Web Report, TRCARC and USAID/EpiC Thailand project dating from January 2015 - December 2021

Key population-led health services (KPLHS): filling service gaps for key populations



ACCESSIBILITY

- Located in **hot spots**
- **Flexible service hours** suitable for KP's lifestyle
- **One-stop** service



AVAILABILITY

- **Needs-based** and **client-centered** services, such as hormone monitoring, STI, legal consultation, harm reduction



ACCEPTABILITY

- **Staff are members of KP communities** who truly understand KP's lifestyle
- Services are gender-oriented, and **free from stigma and discrimination**



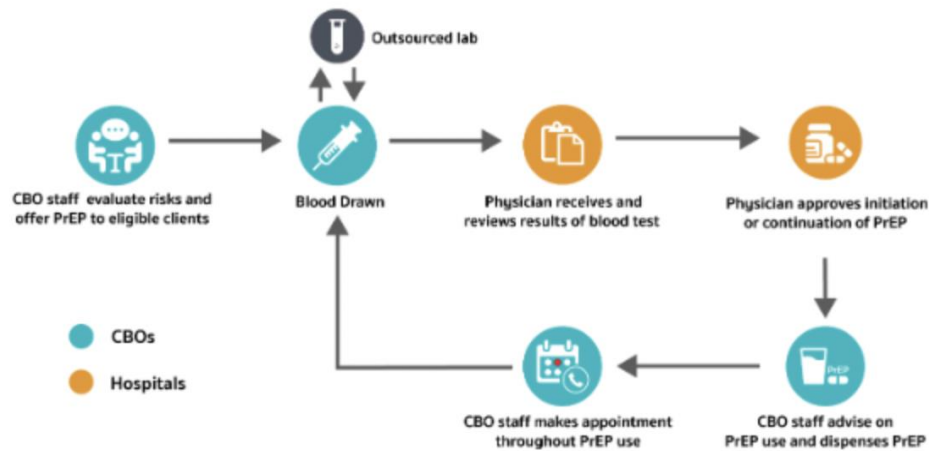
QUALITY

- Staff are **trained and qualified** in accordance with national standards
- Strong **linkages** with and **high acceptance** from public health sectors

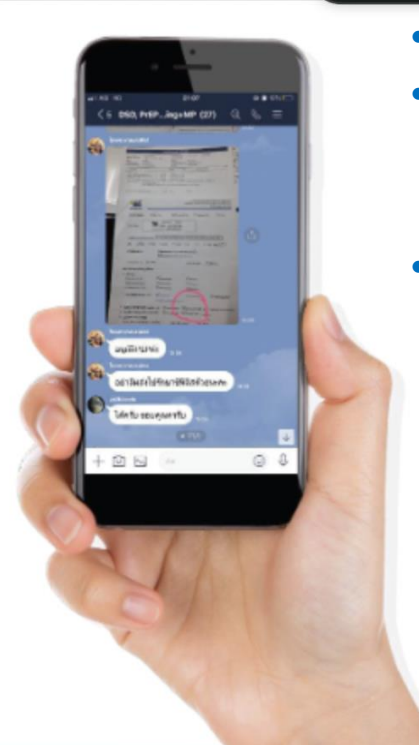


Key population led Same-Day PrEP Service

Same-Day PrEP:
close collaboration between CBOs and hospitals



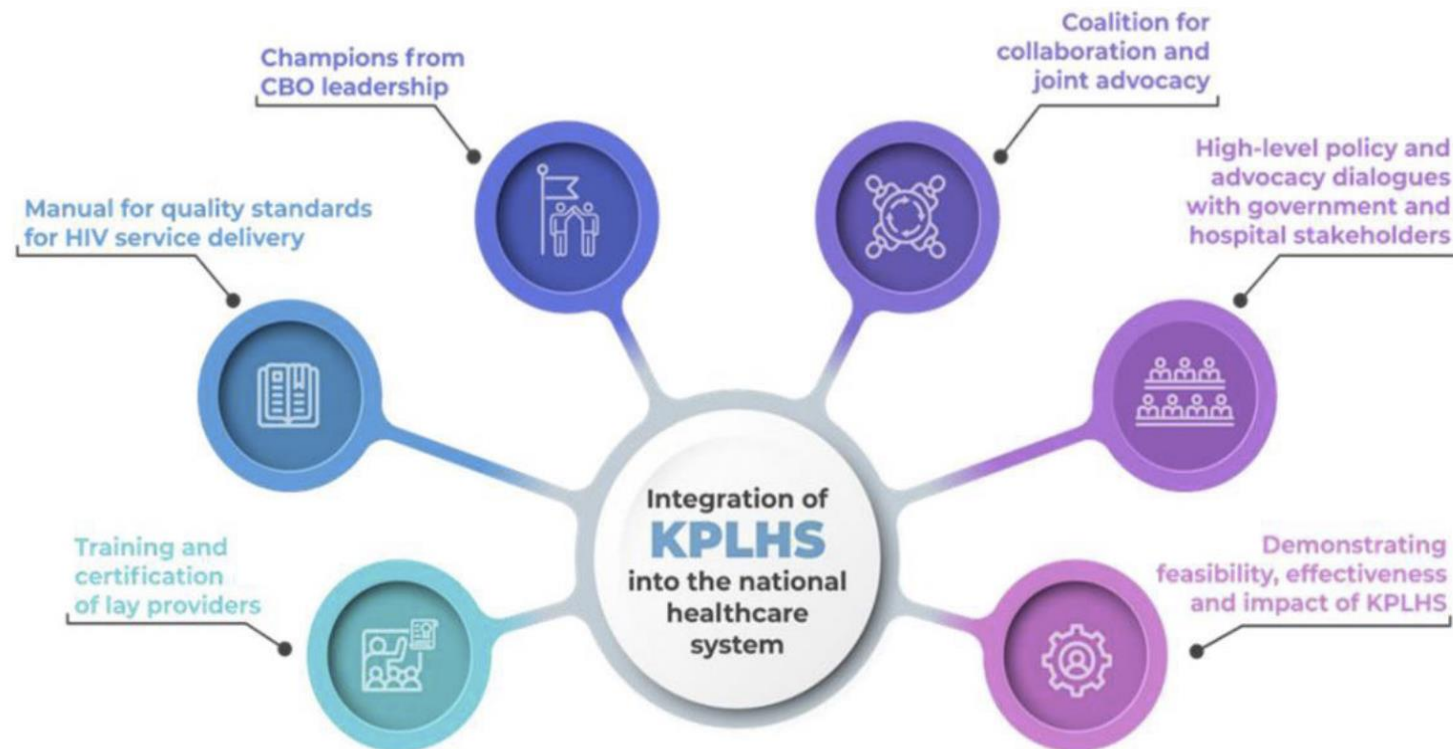
2020 Thailand National Guidelines on HIV/AIDS Treatment and Prevention
Ramautarsing RA, et al. J Int AIDS Soc 2020; 23 Suppl 3: e25540.
Phanuphak N, et al. Sex Health 2018; 15(6): 542-55.



- Key population lay providers-led
- PrEP is dispensed by KP on doctor's standing order (prescribed remotely)
- Doctor reviews results remotely & clients are informed of results after PrEP initiation

LAY PROVIDER CERTIFICATION TO DELIVER KP-LED HIV SERVICES IN THAILAND

- **2018:** NHSO indirect reimbursement via hospitals for HIV testing & PrEP
- **2019:** lay providers legalized to perform finger prick blood collection and STI sample collection, PoC lab testing for HIV and STIs and report results, dispense PrEP/PEP and oral STI treatment as prescribed by a physician
- **2021:** Direct reimbursement for certified lay providers and CBOs





Long-acting injectable cabotegravir for HIV prevention

Launch of new WHO Guidelines

Dr Rachel Baggaley
WHO, Geneva

29th July 2022



Launch of WHO guidelines on LA CAB at AIDS 2022, Montreal

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)

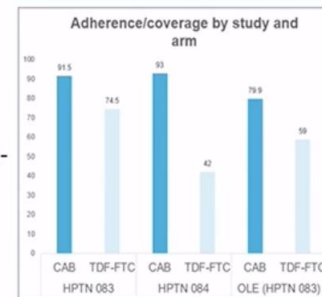
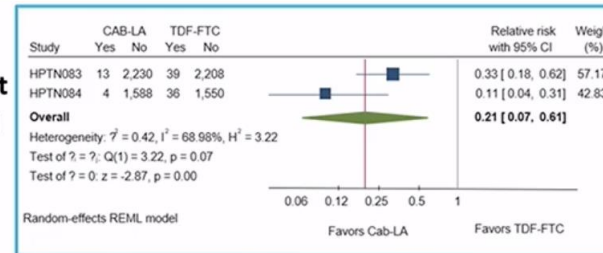
CAB-LA is highly effective

Data from 2 large, multi-site RCTs across diverse populations suggest CAB-LA is a highly effective and safe biomedical HIV prevention tool

- CAB-LA reduces HIV incidence (RR: 0.21, 95% CI: 0.07-0.61) - corresponding to a 79% relative risk reduction
- Note: Relative HIV risk reduction ranged from 66% in HPTN 083 to 88% in HPTN 084

High adherence to CAB-LA

- High adherence to CAB-LA across efficacy studies
 - Lower adherence to TDF-FTC
- Initial results from HPTN 083 OLE found decreased adherence to both CAB-LA and TDF-FTC in the first year following unblinding



Combined effect size across HPTN 083 and HPTN 084

HPTN 083 & 084: LA IM CAB every 2M vs Daily Oral FTC/TDF for PrEP

- International, randomized, double-blind phase 2b/3 (083) and phase 3 (084) trials
- LA IM CAB met criteria for **superiority** vs daily oral FTC/TDF in both trials

HPTN 083

- N = 4566 MSM and TGW
- **12 incident infections on LA CAB**
 - **4 with on-time injections**
 - Additional 3 identified after initial analysis (**7 reported with on-time injections to date**)
- Rare INSTI resistance
- HR for CAB vs FTC/TDF: **0.34 (95% CI: 0.18-0.62)**

HPTN 084

- N = 3224 cisgender women
- 4 incident infections on LA CAB
 - **1 with on-time injections**
 - 1 later determined to be infected at baseline
- No INSTI resistance detected
- HR for CAB vs FTC/TDF: **0.12 (95% CI: 0.05-0.31)**



VIEWPOINT | Open Access |

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

Heather-Marie Ann Schmidt, Michelle Rodolph , Robin Schaefer, Rachel Baggaley, Meg Doherty

First published: 28 July 2022 | <https://doi.org/10.1002/jia2.25963>

- Current experience with CAB-LA provision is largely limited to clinical trial settings
- Evidence is lacking about effective models for providing CAB-LA in real-world settings, esp for populations not included in the trials, including sex workers, PWIDs and transgender men & others living in diverse settings and geographies
- Need for further studies to support additional safety data of CAB-LA in some populations
 - interaction bet CAB-LA and gender-affirming hormone use among trans & gender diverse populations
 - use of alternative injection sites in those unable to receive IM gluteal injections e.g. buttock implants
 - acceptability, feasibility, safety and training needs for individuals to self-administer injections
 - Safety in pregnancy and breast feeding
- Differentiated service delivery models – patient centred services, needs and preferences of communities
- Optimal HIV testing strategies - NAAT vs HIV 3rd generation test
- Starting, stopping and switching bet PrEP options

Long-acting PrEP

ORAL

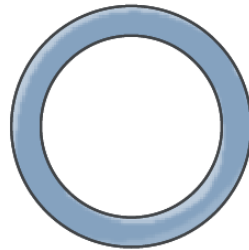


Oral islatravir (MSD)

Nucleoside Reverse
Transcriptase
Translocation Inhibitor

1-monthly

INTRAVAGINAL RING (IVR)

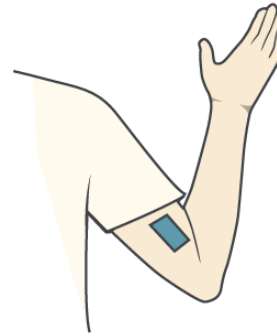


Dapivirine intravaginal ring (IPM)

Non-nucleoside Reverse
Transcriptase Inhibitor

1-monthly

IMPLANT

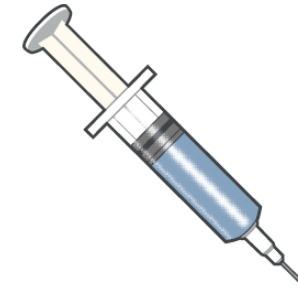


Islatravir implant (MSD)

Nucleoside Reverse
Transcriptase
Translocation Inhibitor

1-yearly

INJECTABLE



Cabotegravir IM injection (ViiV)

Integrase Strand
Transfer Inhibitor

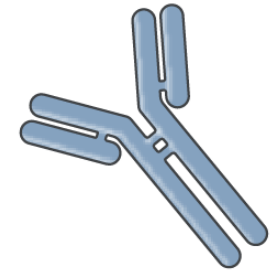
2-monthly

Lenacapavir SC injection (Gilead)

Capsid Inhibitor

6-monthly




















































ANTIBODY



Broadly neutralizing antibody infusion

2-monthly

Implementation considerations of long-acting PrEP products

	Frequency of product use	Administration (itself, lay provider, nurse, doctor)	Integration with HIV/STI testing schedule	VL testing for early detection of HIV infection	Adherence support for effective use	Drug interactions including GAHT	Cost, generic product availability, positioning in national guidelines
 Oral TDF/FTC: daily and event-driven							
 Injectable cabotegravir: every 2 months		 Injectors, sharp disposals	 	 	 	 	
 Oral islatravir: every 1 month				 	 		
 Injectable lenacapavir: every 6 months		 		 	 		
 Islatravir implant: every 1 year				 	 		

KP-led PrEP service:

Concerns with CAB-LA integration

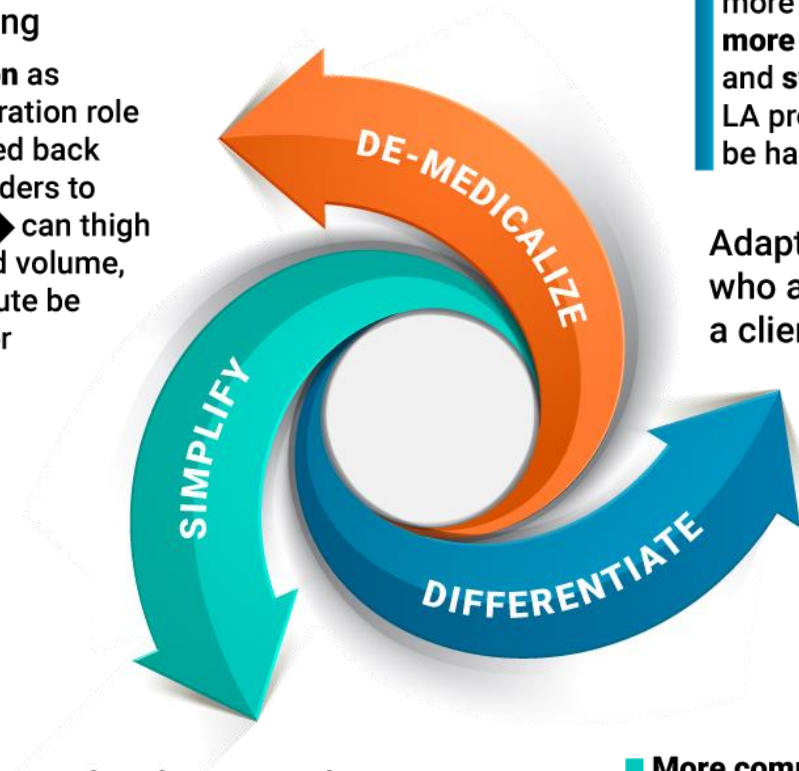
De-medicalize.

Simplify.

Differentiate

Different steps offered by lay providers, or through HCW task-shifting

Re-medicalization as product administration role will be task-shifted back from KP lay providers to nurses/doctors → can high injection, reduced volume, subcutaneous route be made possible for **self-injection?**



Various user patterns with more PrEP products → how can **more frequent CAB-LA visits** and **switching** between oral and LA products/missed injection be handled?

Adapting the when, where, who and what based on a client-centered approach

Finding less complex ways to deliver care, to promote increased access and lower cost, while retaining efficacy and quality

More complex as HIV testing algorithm will need HIV RNA assay → can 3rd/4th gen rapid test, 3rd/4th gen self-testing, pooled POC HIV RNA be used?

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