
HIV self-testing for PrEP

A history and the future to come

Global HIV, Hepatitis and STIs Programmes

WHO, Geneva, Switzerland

Dr Cheryl Johnson on behalf of WHO PrEP & HTS Teams



World Health
Organization

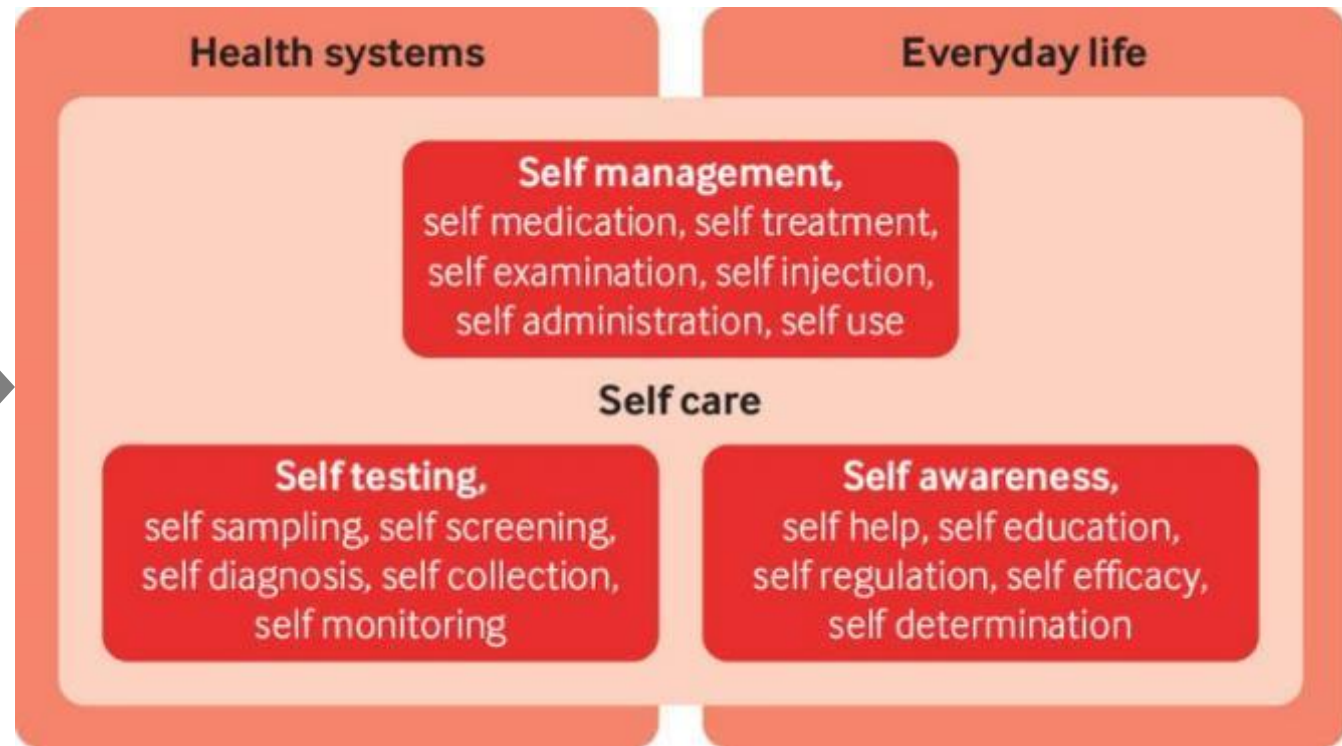
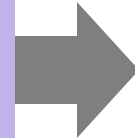
Outline

- Self-testing 101
- Public health problem – need to increase access to PrEP
- WHO guidance and country experiences
- Future directions and way forward

Self-care and self-testing

Self-care

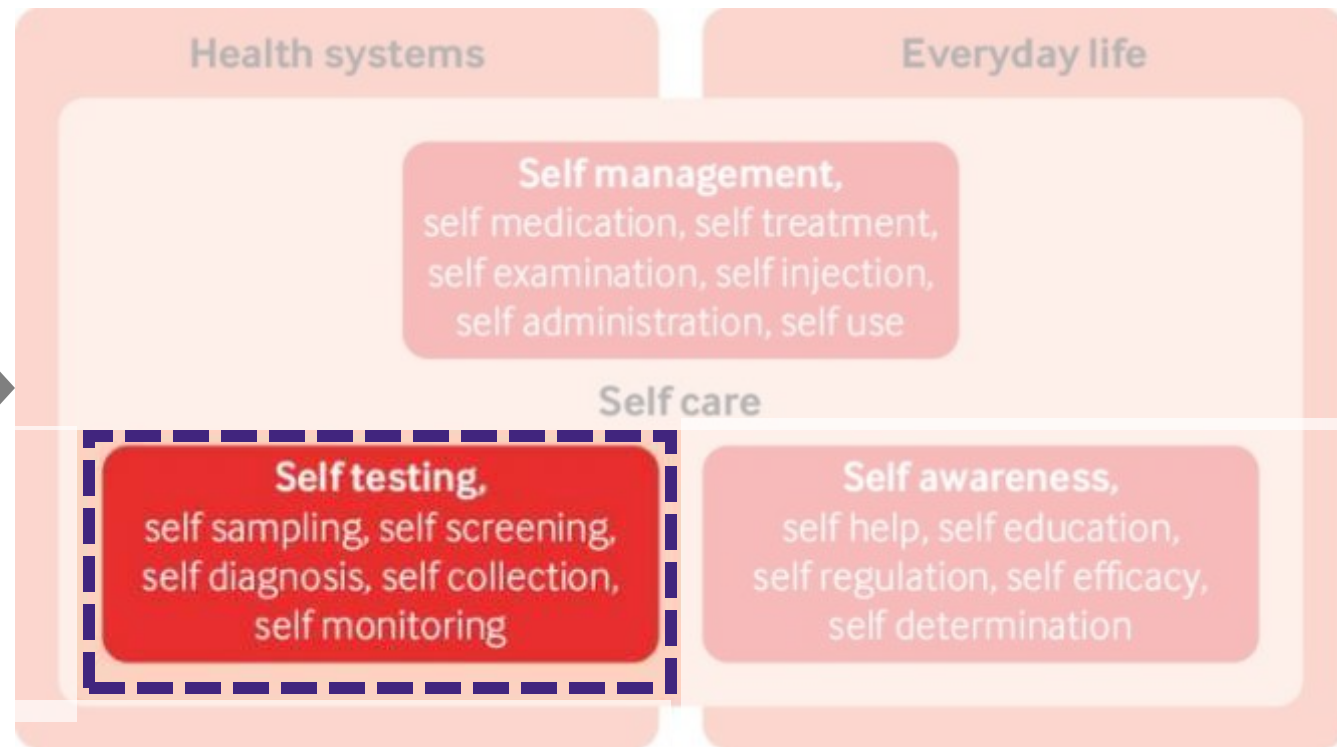
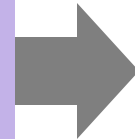
The ability of individuals to promote health, prevent disease, maintain health, and cope with illness and disability with or without support of a healthcare provider.



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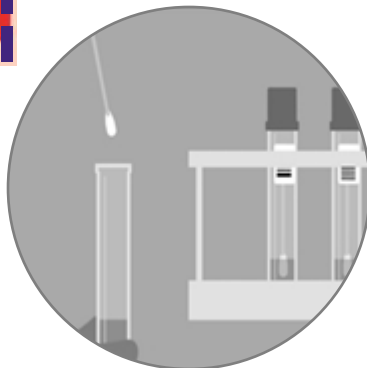
Self-testing vs Self-sampling

Self testing,
self sampling, self screening,
self diagnosis, self collection,
self monitoring



Self-testing

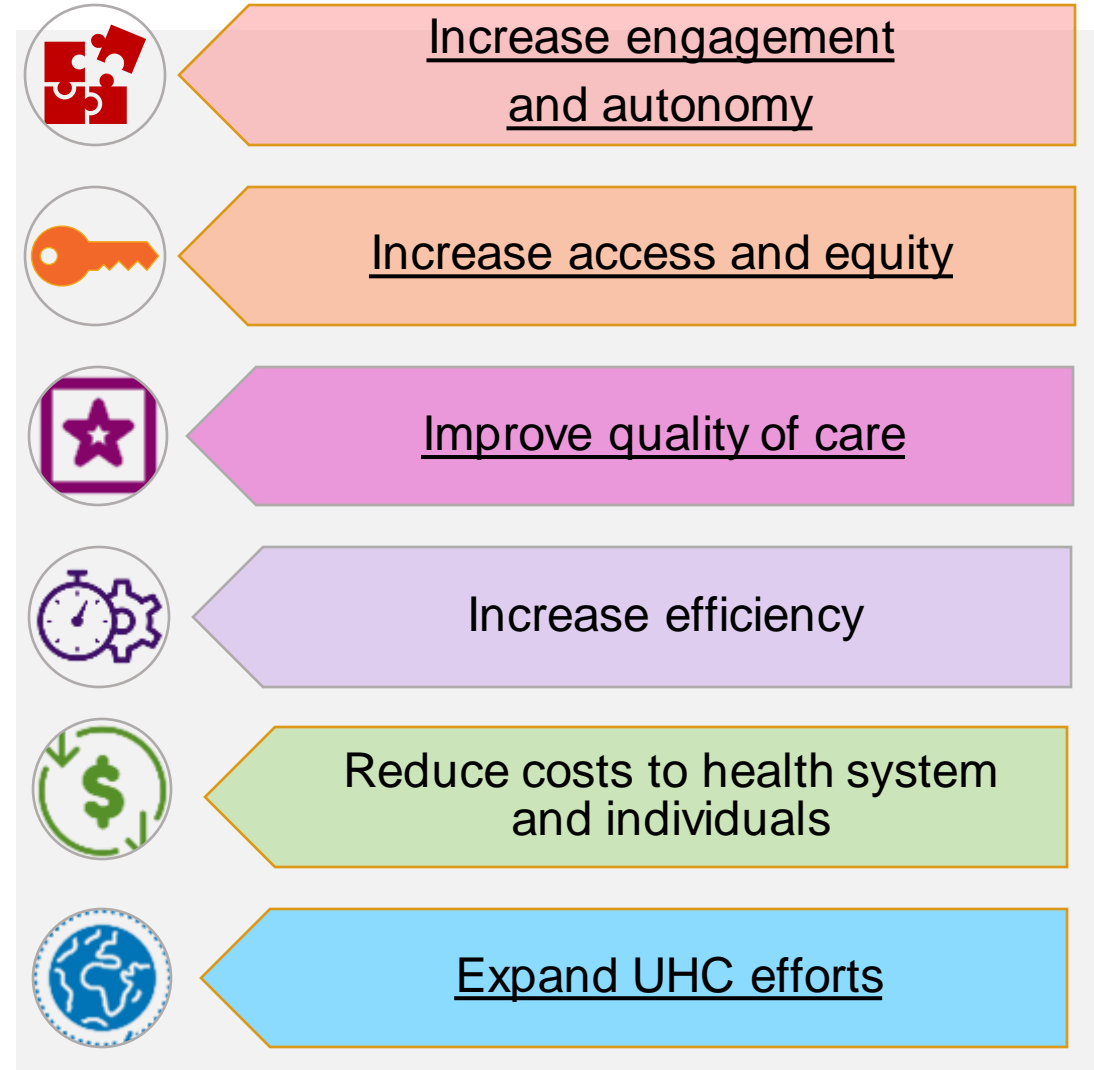
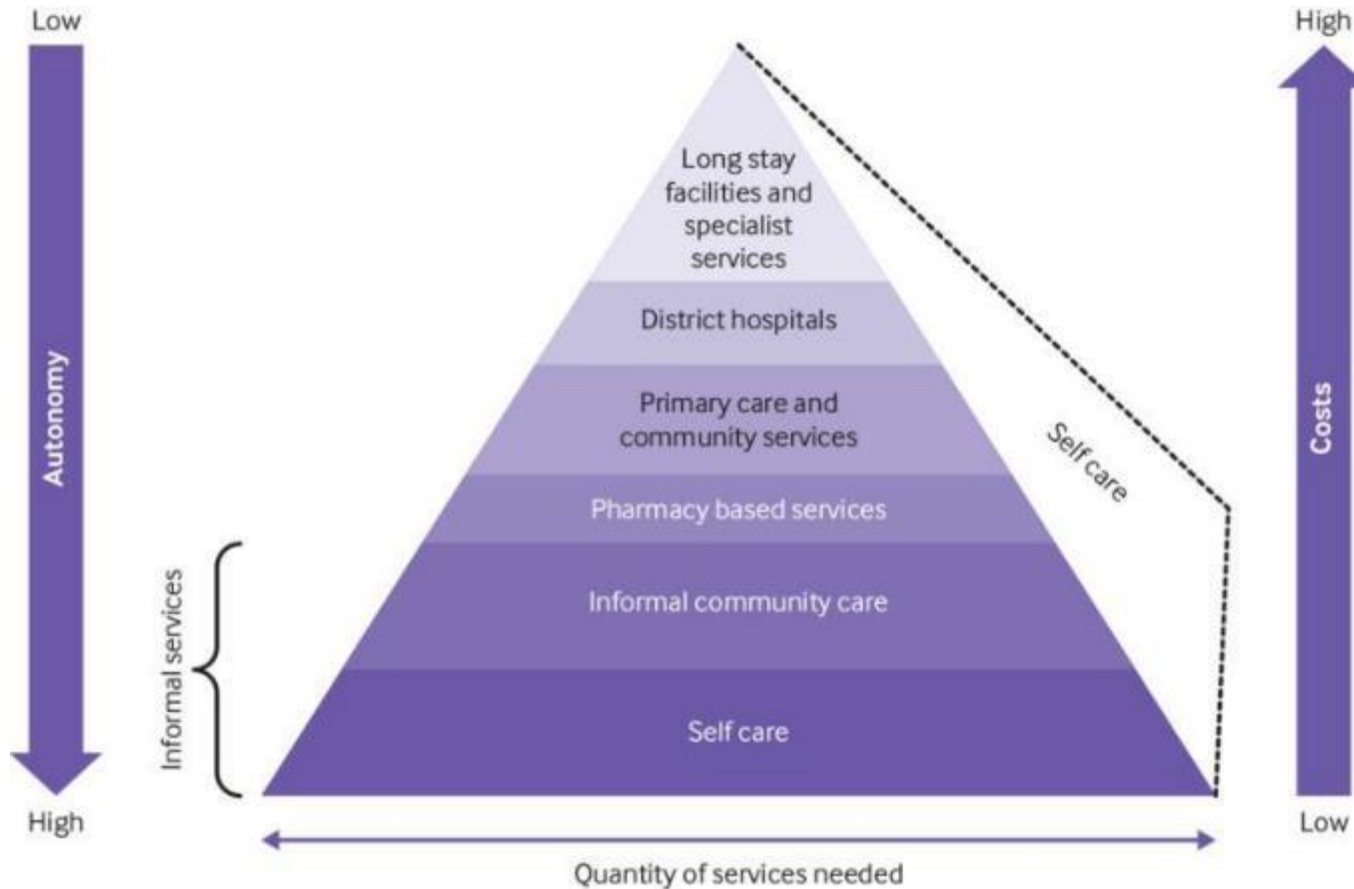
- Individuals collect their specimen, performs the test, and interprets result alone and in private or with someone they trust.



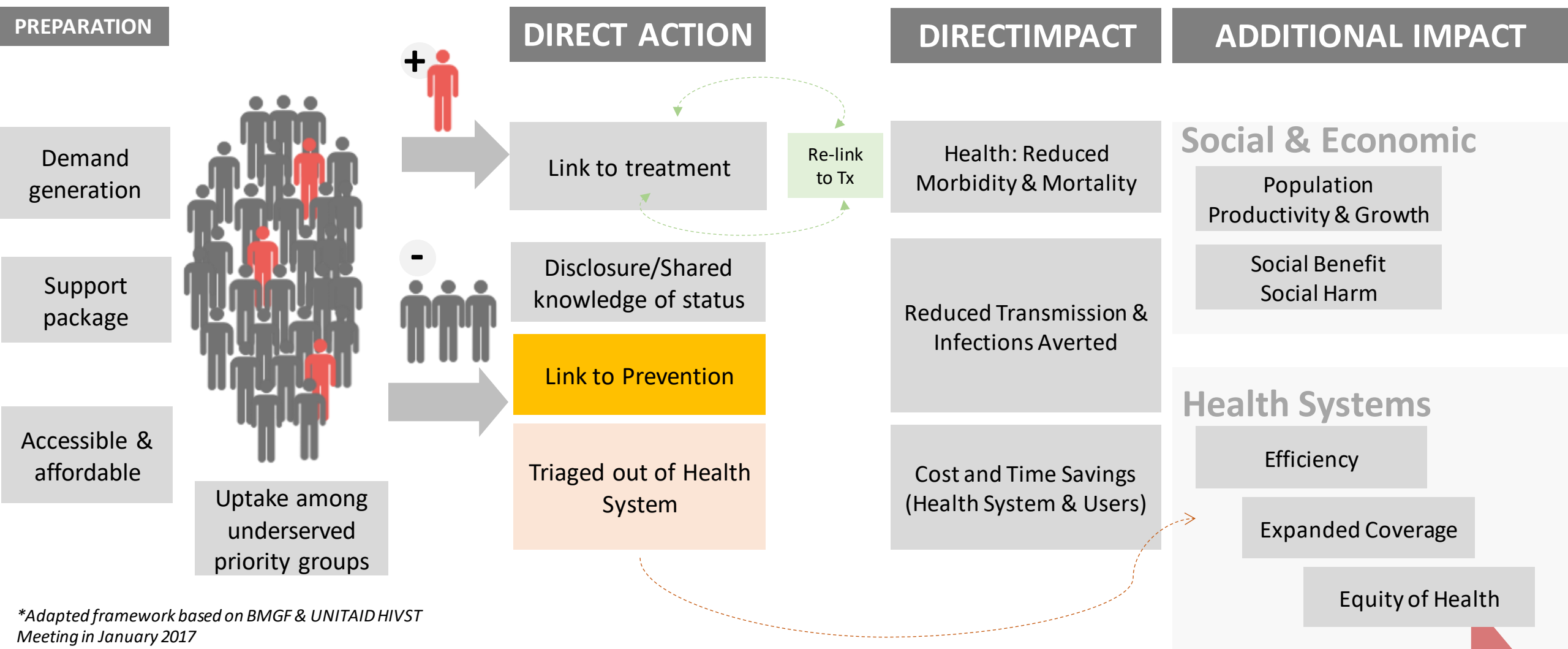
Self-sampling

- Individuals collect specimen which is then sent to a lab.
- The lab conducts test and interprets result and then returns the information to the individual.

Self-care and self-testing: critical to health system



Self-testing framework



**Adapted framework based on BMGF & UNITAID HIVST Meeting in January 2017*

DIFFERENT POPULATIONS

DIFFERENT CONTEXTS

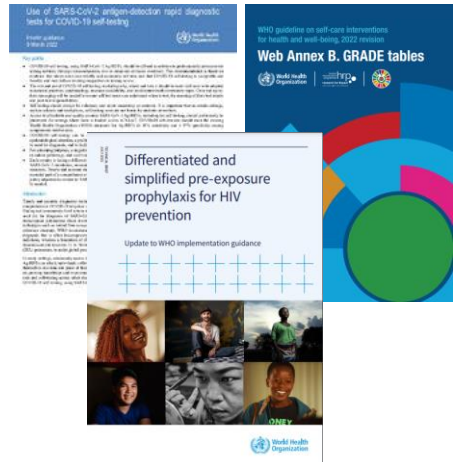
DIFFERENT GEOGRAPHIES

WHO recommendations on self-testing

WHO recommends HIVST as additional approach & 1st product PQed



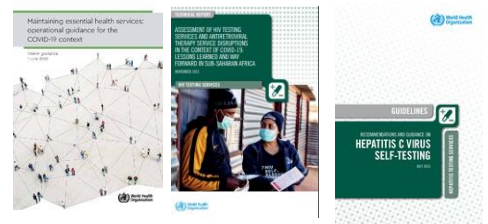
HIVST recommended to maintain essential health services during C19 pandemic
 WHO recommends HCVST as additional approach, PQ TSS & Global Fund ERPD launch
 WHO recommends GC/CT self-collection



2016/17 2019 2020/21 2022 2023/24



WHO self-care guidance including recommends self-collection for HPV, syphilis & trichomonas
 Update on HIVST, 4 PQ products, ~7 million procured



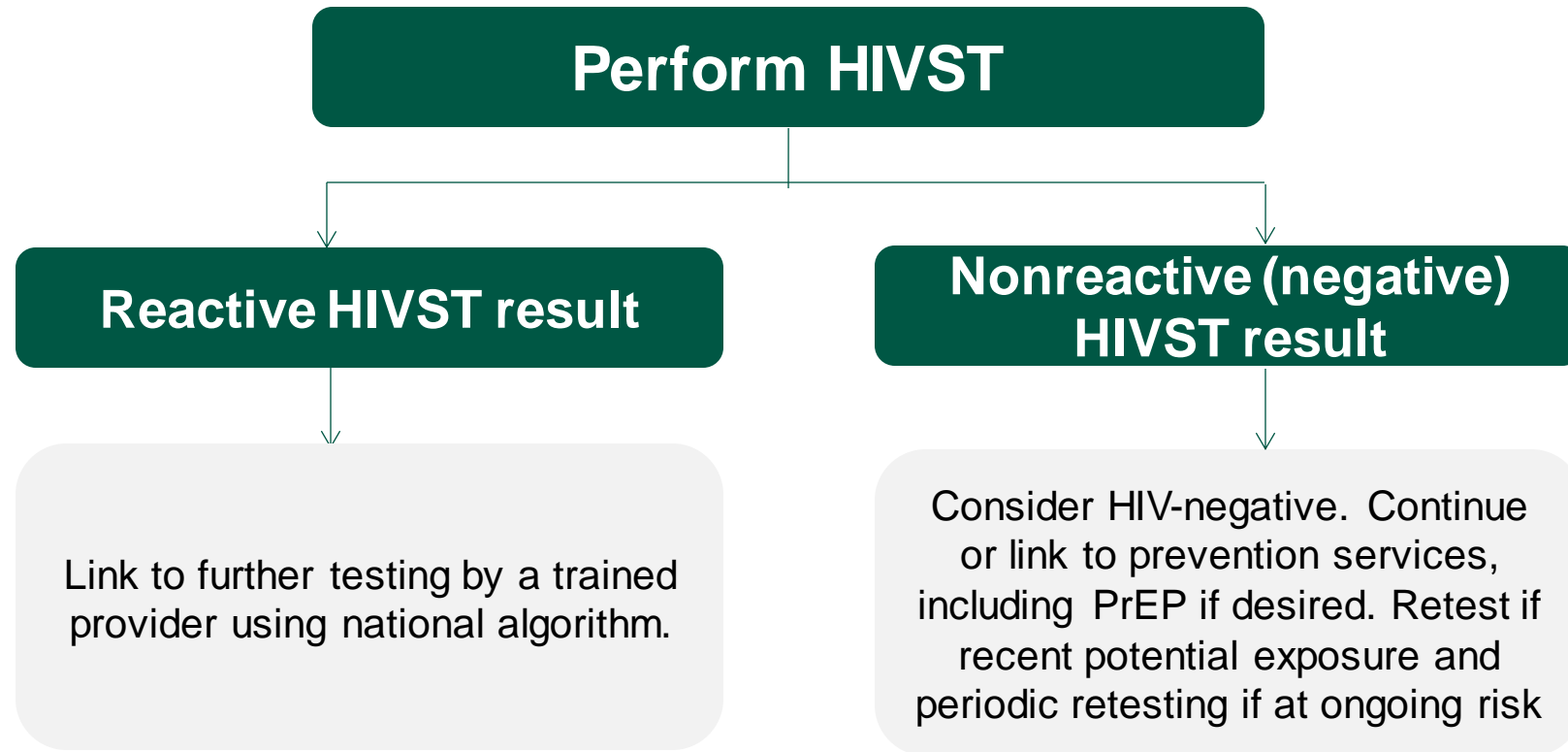
WHO recommends COVID-19 self-testing; plus new implementation guidance on HIVST for PrEP delivery & ST in pregnancy
 WHO guidance on self-testing for syphilis & dual HIV/syphilis in development
 HIVST procurement >10 million, 98 national policies, > 92 countries with registration
 Access to ST remains challenge important to re-double efforts

WHO recommends HIVST for PrEP* initiation, re-initiation and continuation
 CAB-LA implementation projects exploring the use of self-testing
 WHO recommends HIVST in facilities
 WHO recommends syphilis self-testing including HIV/syphilis dual self-tests



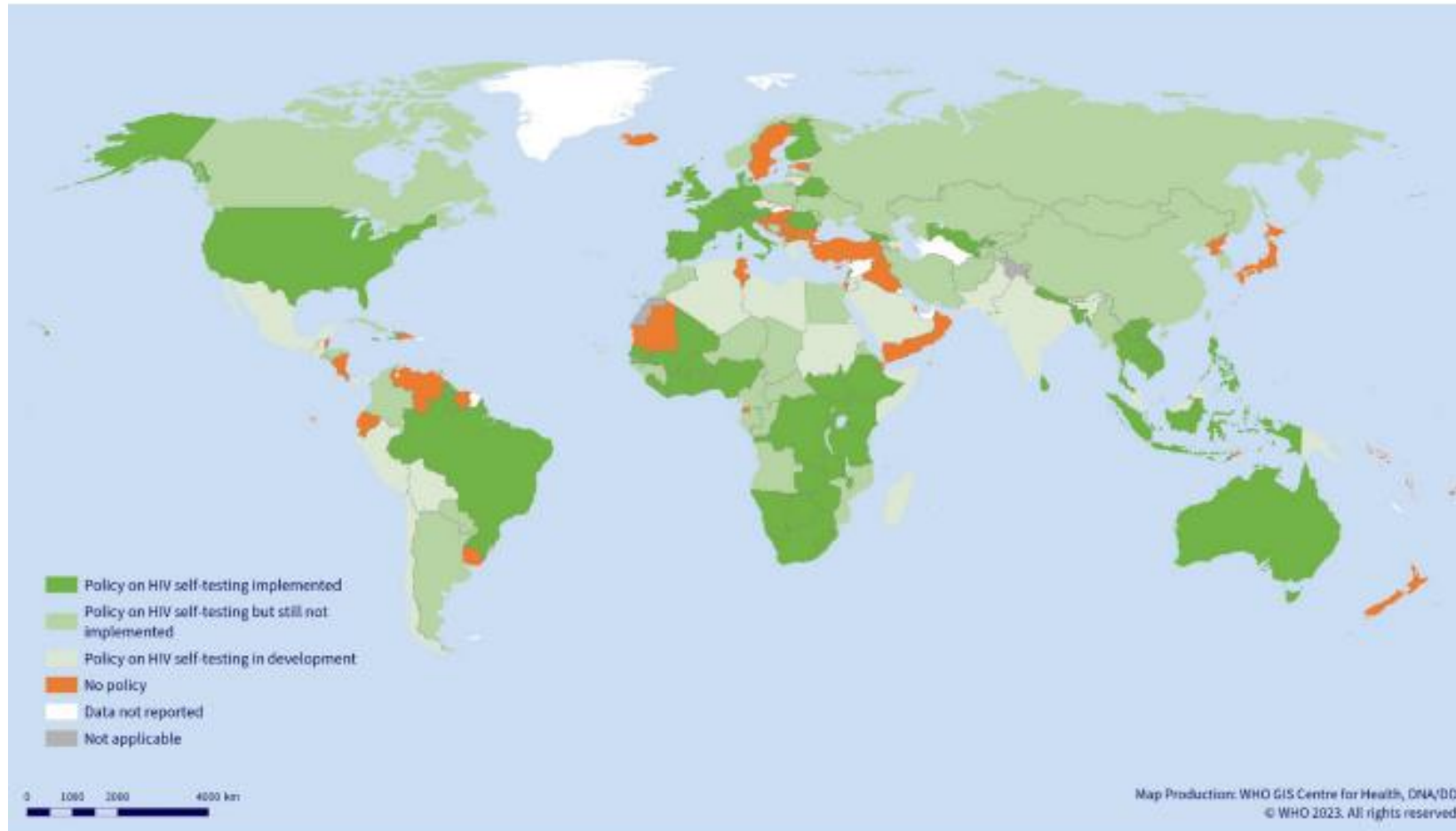
*WHO PrEP guidance covers oral PrEP and DVR and can also be applied to PEP.

WHO HIVST for PrEP recommendation



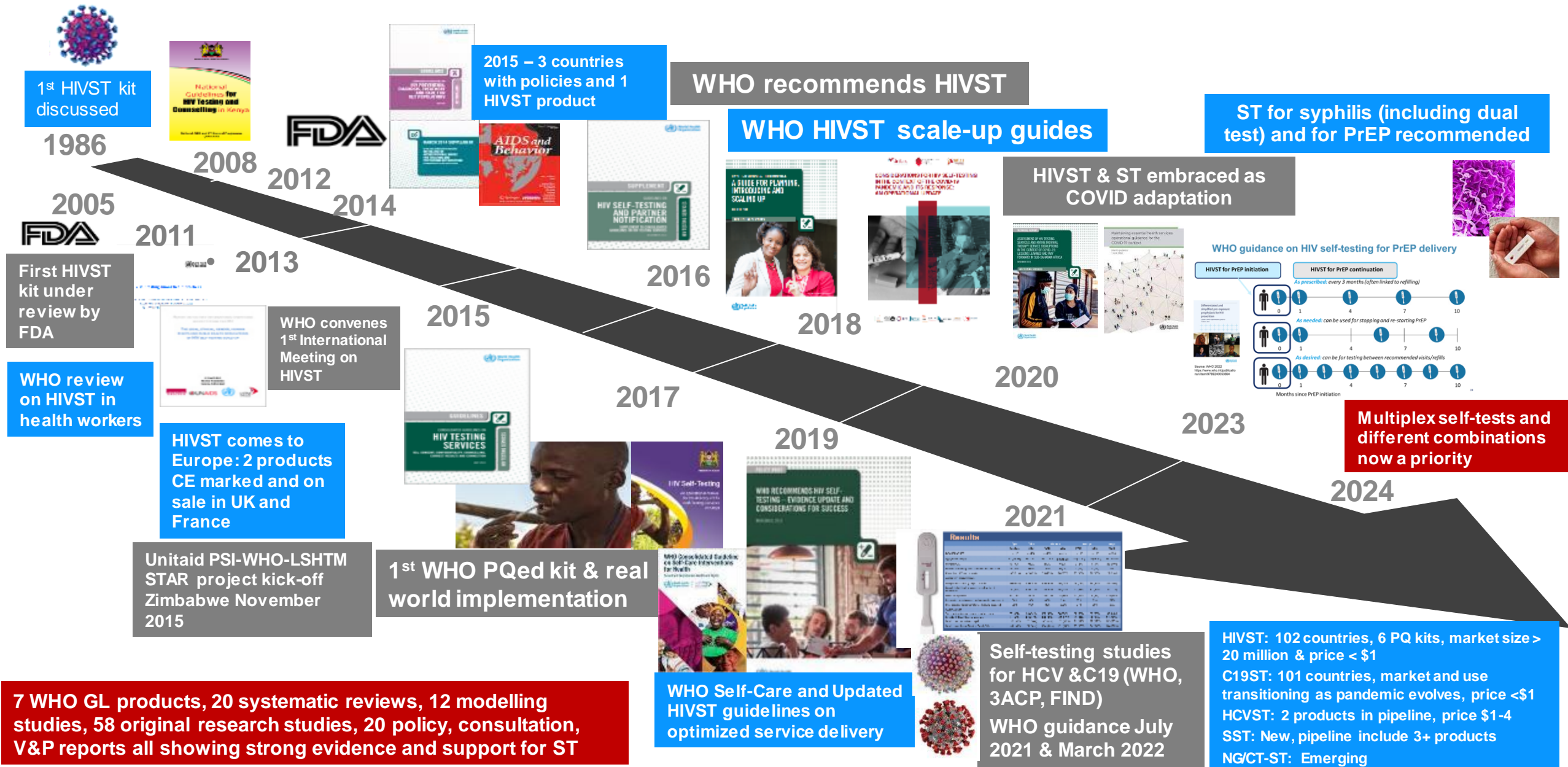
No further testing needed after a negative self-test to initiate, re-initiate or continue PrEP.

HIVST policy uptake across countries, as of July 2023



Sources: Global AIDS Monitoring (UNAIDS/WHO/UNICEF) and WHO Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes, 2023.

Self-testing evidence, implementation and policy scale-up



WHO HIVST evidence reviews

Johnson et al. *Journal of the International Society for Sexual Health* 2021, 10:1193
<https://doi.org/10.1093/issj/10.1193>

Review article

Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis

Cheryl C Johnson^{1*}, Catlin Kennedy², Virginia Fommi³, Nandi Siegfried⁴, Carmen Figueroa⁵, Shona Datta⁶, Anca Scah⁷ and Rachel Baggage⁸

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Abstract: HIV self-testing (HIVST) is a discrete and convenient way to reach people with HIV who do not know their status, including many who may not otherwise test. To inform World Health Organization (WHO) guidance, we assessed the effect of HIVST on uptake and frequency of testing, as well as identification of HIV-positive persons, linkage to care, social norms, and risk behavior.

Methods: We systematically searched for studies comparing HIVST to standard HIV testing until 1 June 2020. Meta-analyses of studies reporting comparable outcomes were conducted using a random-effects model for relative risks (RR) and 95% confidence intervals. The quality of evidence was evaluated using GRADE.

Results: After screening 638 citations, we identified five randomized controlled trials (RCTs) comparing HIVST to standard HIV testing services among 4,155 total participants from four countries. All offered free and fast rapid tests for HIVST and were among men. Meta-analysis of three RCTs showed HIVST doubled uptake of testing among men (RR = 2.12, 95% CI 1.51, 2.98). Meta-analysis of two RCTs among men who were men with men showed frequency of testing nearly doubled (Rate ratio = 1.88, 95% CI 1.17, 3.01), resulting in two more tests in a 12–15 month period (Mean difference = 2.13, 95% CI 1.55, 2.68). Meta-analysis of two RCTs showed HIVST also doubled the likelihood of an HIV-positive person being diagnosed (RR = 2.02, 95% CI 1.37, 3.10). Across all RCTs, there was no indication of harm attributable to HIVST and potential increases in risk taking behavior appeared to be minimal.

Conclusions: HIVST is associated with increased uptake and frequency of testing in RCTs. Such increases, particularly among those at risk who may not otherwise test, will likely identify more HIV-positive individuals as compared to standard testing services alone. However, further research on how to support linkage to confirmatory testing, prevention, treatment and care services is needed. WHO now recommends HIVST as an additional HIV testing option.

Keywords: HIVST2
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5 RCTs – KP & GP
25 studies on accuracy



A systematic review and network meta-analyses to assess the effectiveness of HIV self-testing distribution strategies

Ingrid Eshun-Wilson¹, Muhammad S Jamil, Witzel T. Charles, Dave V Glidden, Johnson Cheryl, Trouneau Noelle, Nathan Ford, Kathleen McGee, Kemp Chris, Baral Stefan, Sheree Schwartz, Geng H Elvin

Clinical Infectious Diseases, ciab029, <https://doi.org/10.1093/cid/ciab029>
Published: 20 January 2021 Article history

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Abstract

Background

We conducted a systematic review and network meta-analysis to identify which HIV self-testing (HIVST) distribution strategies are most effective.

Methods

We abstracted data from randomized controlled trials and observational studies published between June 4, 2006 and June 4, 2019.

Results

We included 33 studies, yielding six HIVST distribution strategies. All distribution strategies increased testing uptake compared to standard testing: in sub-Saharan Africa, partner HIVST distribution ranked highest (78% probability); in North America, Asia and the Pacific regions, web-based distribution ranked highest (93% probability), and facility-based distribution ranked second in all settings. Across HIVST distribution strategies HIV positivity and linkage was similar to standard testing.

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Witzel T. Charles et al. BMC Medicine 2020, 18:181
<https://doi.org/10.1186/s12916-020-01815-z>

Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis

T. Charles Witzel¹, Ingrid Eshun-Wilson², Muhammad S. Jamil³, Nestra Tlouche⁴, Carmen Figueroa⁵, Cheryl C. Johnson⁶, David Red⁷, Rachel Baggage⁸, Fiona M. Burns⁹, Alison J. Rodger¹⁰ and Peter Weatherburn¹¹

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Abstract

Background

We updated a previous systematic review to inform new World Health Organization HIV self-testing (HIVST) recommendations. We compared the effects of HIVST to standard HIV testing services to understand which service delivery models are effective for key populations.

Methods

We did a systematic review of randomized controlled trials (RCTs) which compared HIVST to standard HIV testing in key populations published from 1 January 2008 to 4 June 2019 in PubMed, Embase, Global Index Medicus, Social Policy and Practice, PsycInfo, Health Management Information Consortium, BECO/CIH, Plus, Cochrane Library and Web of Science. We abstracted study characteristics and outcome data and conducted risk of bias assessments using the Cochrane ROB tool version 1. Random effects meta-analyses were conducted, and pooled effect estimates were assessed along with other evidence characteristics to determine the overall strength of the evidence using GRADE methodology.

Results: After screening 5900 titles and abstracts, we identified 10 RCTs which reported on testing outcomes. These included 6079 participants, of whom 5485 were men who have sex with men (MSM), 72 were trans people and 421 were female sex workers. Service delivery models included facility-based, on-site and peer distribution. Support components were highly diverse and ranged from helpline to training and supervision. HIVST increased testing uptake by 145 times (95% CI 126, 178). For MSM and small numbers of trans people, HIVST increased the mean number of HIV tests by 2.36 over follow-up (mean difference = 2.56, 95% CI 1.36, 3.88). There was no difference between HIVST and SOT in regard to uptake (RR = 0.91, 95% CI 0.70, 1.18). In sensitivity analysis of positivity among randomized HIVST identified significantly more HIV infections among MSM and trans people (RR = 2.21, 95% CI 1.26, 4.08) and in on-site distribution systems (RR = 2.21, 95% CI 1.14, 4.33). Yield of positive results in PSM was significantly different between HIVST and SOT. HIVST reduced linkage to care by 1.96 compared to SOT overall (RR = 0.83, 95% CI 0.74, 0.93). Impact on STI testing was mixed: two RCTs showed no decrease in STI testing while one showed significantly lower STI testing in the intervention arm. There were no negative impacts on condom use (RR = 0.95, 95% CI 0.81, 1.08), and sex harm was very rare.

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Results: After screening 5900 titles and abstracts, we identified 10 RCTs which reported on testing outcomes. These included 6079 participants, of whom 5485 were men who have sex with men (MSM), 72 were trans people and 421 were female sex workers. Service delivery models included facility-based, on-site and peer distribution. Support components were highly diverse and ranged from helpline to training and supervision. HIVST increased testing uptake by 145 times (95% CI 126, 178). For MSM and small numbers of trans people, HIVST increased the mean number of HIV tests by 2.36 over follow-up (mean difference = 2.56, 95% CI 1.36, 3.88). There was no difference between HIVST and SOT in regard to uptake (RR = 0.91, 95% CI 0.70, 1.18). In sensitivity analysis of positivity among randomized HIVST identified significantly more HIV infections among MSM and trans people (RR = 2.21, 95% CI 1.26, 4.08) and in on-site distribution systems (RR = 2.21, 95% CI 1.14, 4.33). Yield of positive results in PSM was significantly different between HIVST and SOT. HIVST reduced linkage to care by 1.96 compared to SOT overall (RR = 0.83, 95% CI 0.74, 0.93). Impact on STI testing was mixed: two RCTs showed no decrease in STI testing while one showed significantly lower STI testing in the intervention arm. There were no negative impacts on condom use (RR = 0.95, 95% CI 0.81, 1.08), and sex harm was very rare.

Conclusions: HIVST is associated with increased uptake and frequency of testing in RCTs. Such increases, particularly among those at risk who may not otherwise test, will likely identify more HIV-positive individuals as compared to standard testing services alone. However, further research on how to support linkage to confirmatory testing, prevention, treatment and care services is needed. WHO now recommends HIVST as an additional HIV testing option.

Keywords: HIVST2
To access the full text of this article, please visit <https://www.who.int/publications/m/item/who-hiv-st-evidence-reviews>

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Witzel T. Charles et al. BMC Medicine 2020, 18:181
<https://doi.org/10.1186/s12916-020-01815-z>

Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis

Muhammad S. Jamil¹, Ingrid Eshun-Wilson², T. Charles Witzel³, Nandi Siegfried⁴, Carmen Figueroa⁵, Lantinn Chitamba⁶, Busiswe Muzungu-Radebe⁷, Muhammad S. Pasha⁸, Karin Hatzold⁹, Elizabeth Corbett¹⁰, Magdalena Barr-Dichiaro¹¹, Alison J. Rodger¹², Peter Weatherburn¹³, Elvin Geng¹⁴, Rachel Baggage¹⁵, Cheryl Johnson¹⁶

Clinical Infectious Diseases, ciab029, <https://doi.org/10.1093/cid/ciab029>
Published: 20 January 2021 Article history

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Abstract

Background

We updated a 2017 systematic review and assessed the effects of HIV self-testing (HIVST) to standard HIV testing services to understand effective service delivery models among the general population.

Methods

We did a systematic review of randomized controlled trials (RCTs) comparing testing outcomes with HIVST to standard HIV testing in the general population and published between January 1, 2006 and June 4, 2020. Evidence synthesis analysis was conducted and pooled risk ratios (RR) were reported. The certainty of evidence was determined using the GRADE methodology.

Results: We identified 14 eligible RCTs, 11 of which were conducted in sub-Saharan Africa. Studies provided to self-testers ranged from helpline support to one-on-one person support. HIVST increased testing uptake overall (RR = 2.26, 95% CI 1.56, 3.26, p < 0.0001) (13 RCTs) and mean certainty uptake (RR = 1.88, 95% CI 1.17, 3.01, p < 0.0001) (10 RCTs) compared to standard HIV testing. HIVST increased the mean number of HIV tests by 2.36 over follow-up (mean difference = 2.56, 95% CI 1.36, 3.88). There was no difference between HIVST and SOT in regard to uptake (RR = 0.91, 95% CI 0.70, 1.18). In sensitivity analysis of positivity among randomized HIVST identified significantly more HIV infections among MSM and trans people (RR = 2.21, 95% CI 1.26, 4.08) and in on-site distribution systems (RR = 2.21, 95% CI 1.14, 4.33). Yield of positive results in PSM was significantly different between HIVST and SOT. HIVST reduced linkage to care by 1.96 compared to SOT overall (RR = 0.83, 95% CI 0.74, 0.93). Impact on STI testing was mixed: two RCTs showed no decrease in STI testing while one showed significantly lower STI testing in the intervention arm. There were no negative impacts on condom use (RR = 0.95, 95% CI 0.81, 1.08), and sex harm was very rare.

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WHO HIVST evidence reviews

HVST increased uptake and frequency of testing, positivity, no harm

Facility-based HVST distribution performed well in all settings. For SSA, partner distribution had substantial impact. In Americas and Asia, web-based & mail worked particularly well. Acceptable, feasible, no harm.

HVST safe, accurate & reliable using blood and oral RDTs

5 RCTs – KP & GP
25 studies on accuracy

Additional indirect evidence across ST approaches shows high acceptability, accuracy, feasibility etc



ACCEPTED MANUSCRIPT
A systematic review and network meta-analyses to assess the effectiveness of HIV self-testing distribution strategies
Ingrid Eshun-Wilson, Muhammad S Jamil, Witzel T. Charles, Dave V Glidden, Johnson Cheryl, Trouneau Noelle, Nathan Ford, Kathleen McGee, Kemp Chris, Baral Stefan, Shere Schwartz, Geng H Elvin
Clinical Infectious Diseases, ciab029, <https://doi.org/10.1093/cid/ciab029>
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Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis
Background: The ability of individuals to use HIV self-tests correctly is essential to reduce the HIV burden. This systematic review and meta-analysis assessed the reliability and performance of HIV self-diagnostic tests.
Methods: We searched PubMed, Embase, Cochrane, and Web of Science for studies comparing HIV self-testing to standard HIV testing. We included 33 studies, yielding 56 HIVST studies. All distribution strategies increased testing uptake compared to standard testing: in sub-Saharan Africa, partner HIVST distribution ranked highest (78% probability); in North America, Asia and the Pacific regions, web-based distribution ranked highest (93% probability), and facility-based distribution ranked second in all settings. Across HIVST distribution strategies HIV positivity and linkage was similar to standard testing.

33 studies (RCTs and cohorts)

Among KP, HIVST >2x HTS uptake, frequency and positivity, no harm

Abstract
Background: We update a previous systematic review to inform new World Health Organization HIV self-testing (HVST) recommendations. We compared the effects of HVST to standard HIV testing services to understand which service delivery models are effective for key populations.
Methods: We did a systematic review of randomized controlled trials (RCTs) which compared HVST to standard HIV testing in key populations published from 1 January 2006 to 4 June 2019 in PubMed, Embase, Global Index Medicus, Social Policy and Practice, PsycINFO, Health Management Information Consortium, BCCO/CINAHL Plus, Cochrane Library and Web of Science. We applied study, characteristic, and outcome data and conducted risk of bias assessments using the Cochrane ROB tool version 1. Random effects meta-analyses were conducted, and pooled effect estimates were assessed along with their evidence characteristics to determine the overall strength of the evidence using GRADE methodology.
Results: After screening 5000 titles and abstracts, we identified 10 RCTs which reported on testing outcomes. These included 9479 participants, of whom 5486 were men who have sex with men (MSM), 72 were trans people and 4371 were female sex workers. Service delivery models included facility-based, on-demand and peer distribution. Support components were highly diverse and ranged from telephone to training and supervision. HVST increased testing uptake by 1.46 times (95% CI 1.03, 1.75). For MSM and small numbers of trans people, HVST increased the mean number of HIV tests by 2.55 (95% CI 1.36, 3.88). There was no difference between HVST and SUT in regard to positivity among sexual overall (RR = 0.91, 95% CI 0.73, 1.15); in seropositivity analysis among randomized HVST identified significantly more HIV infections among MSM and trans people (RR = 2.31, 95% CI 1.03, 4.98) and in on-demand distribution systems (RR = 2.21, 95% CI 1.14, 4.35). Yield of positive results in PSW was not significantly different between HVST and SUT. HVST reduced linkage to care by 17% compared to SUT overall (RR = 0.83, 95% CI 0.74, 0.92). Impact on STI testing was mixed: two RCTs showed no difference in STI testing which one showed significantly lower STI testing in the intervention arm. There were no negative impacts on condom use (RR = 0.95, 95% CI 0.83, 1.08), and social harm was very rare.



11 RCTs – Key Populations

Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis
Muhammad S. Jamil^{1,2}, Ingrid Eshun-Wilson¹, T. Charles Witzel¹, Nandi Siegfried¹, Carmen Figueroa¹, Lastone Chitembo¹, Busiwive Msimanga-Radebe¹, Muhammad S. Pasha¹, Karim Hatfield¹, Elizabeth Corbett¹, Magdalena Barr-Dickman¹, Alison J. Rodger¹, Peter Weatherburn¹, Elvin Geng¹, Rachel Barzalay¹, Cheryl Lubiano¹

HIVST increased HTS uptake & achieved comparable linkage and # diagnoses in SSA, no harm.

Background: We update a previous systematic review to inform new World Health Organization HIV self-testing (HVST) recommendations. We compared the effects of HVST to standard HIV testing services to understand which service delivery models are effective for key populations.
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14 RCTs – General Population

Linkage to confirmatory testing and ART post-HVST is generally high, particularly with assisted HVST and SNA

Linkage to Care and Prevention after HIV Self-Testing: A Systematic Review and Meta-Analysis
Ying Zhang¹, Su Ma², Gah Hui³
Hui Zhang¹, Madeline Gosselin¹
Su Ma²
Hui Zhang¹, Madeline Gosselin¹
Su Ma²
Hui Zhang¹, Madeline Gosselin¹
Su Ma²

Abstract
Background: Effective linkage to prevention and care is a crucial step following HIV self-testing. We conducted a systematic review to determine the proportion of individuals who are linked to care after HIV self-testing (HVST) and describe factors associated with linkage.
Methods: An initial search was conducted across eight databases, including conference abstracts, up to October 2021. Linkage to care after HVST was defined as getting a confirmatory test or antiretroviral therapy (ART) if the self test was reactive, and/or pre-exposure prophylaxis (PrEP) if the self test was non-reactive. A meta-analysis was conducted to determine the proportion of individuals who are linked to care after HVST. Heterogeneity was assessed using I² and tau-squared. Subgroup analyses were conducted to determine the proportion of individuals who are linked to care after HVST by region, service delivery model, and support component. The proportion of individuals who are linked to care after HVST was compared to the proportion of individuals who are linked to care after standard HIV testing services. The proportion of individuals who are linked to care after HVST was compared to the proportion of individuals who are linked to care after standard HIV testing services. The proportion of individuals who are linked to care after HVST was compared to the proportion of individuals who are linked to care after standard HIV testing services.
Results: We included 14 RCTs which reported on linkage to care outcomes. These included 10,111 participants. The proportion of individuals who are linked to care after HVST was 78% (95% CI 73%, 83%). The proportion of individuals who are linked to care after standard HIV testing services was 75% (95% CI 70%, 80%). There was no difference between HVST and standard HIV testing services in regard to linkage to care (RR = 1.04, 95% CI 0.88, 1.21). Support components were highly diverse and ranged from telephone to training and supervision. HVST increased linkage to care by 1.46 times (95% CI 1.03, 1.75). For MSM and small numbers of trans people, HVST increased the mean number of HIV tests by 2.55 (95% CI 1.36, 3.88). There was no difference between HVST and SUT in regard to positivity among sexual overall (RR = 0.91, 95% CI 0.73, 1.15); in seropositivity analysis among randomized HVST identified significantly more HIV infections among MSM and trans people (RR = 2.31, 95% CI 1.03, 4.98) and in on-demand distribution systems (RR = 2.21, 95% CI 1.14, 4.35). Yield of positive results in PSW was not significantly different between HVST and SUT. HVST reduced linkage to care by 17% compared to SUT overall (RR = 0.83, 95% CI 0.74, 0.92). Impact on STI testing was mixed: two RCTs showed no difference in STI testing which one showed significantly lower STI testing in the intervention arm. There were no negative impacts on condom use (RR = 0.95, 95% CI 0.83, 1.08), and social harm was very rare.

174 studies on linkage

- Jamil 2021 *Elin Med* [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(21\)00271-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00271-6/fulltext)
- Zhang 2024 Pre-print: <https://tinyurl.com/4vtyd6dm>
- Kiptinness 2022 *Curr HIV/AIDS Rep*: <https://pubmed.ncbi.nlm.nih.gov/35904695/>
- Cox 2024 *Lancet HIV*: <https://pubmed.ncbi.nlm.nih.gov/38301668/>

Examining the Use of HIV Self-Testing to Support PrEP Delivery: A Systematic Literature Review
Catherine Kiptinness^{1,2}, Alexandra K. Furr¹, Ashana M. Nandy¹, Cheryl C. Johnson¹, Kenneth Njiru^{1,3}, Ajay D. Muganyizi¹, Katrina F. Orloff¹

HVST comparable effects on effective PrEP use, acceptable, feasible and preferred, compared to HTS

HVST-supported PrEP has low risk of drug resistance, similar health effects and costs compared to HTS

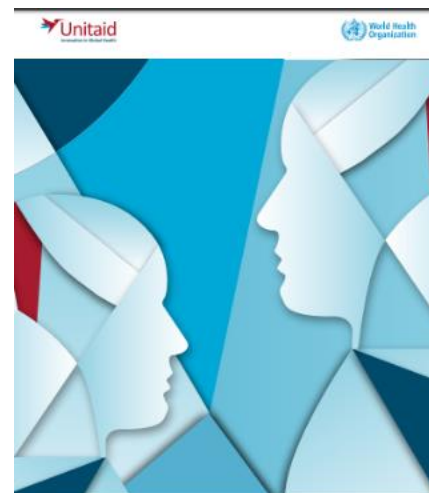
3 RCT & 5 V&P Modelling analysis

How to do a self-test?



Self-testing products with WHO PQ, ERPD or IMDRF* approval

HIVST		
Test (manufacturer)	Specimen	Approval
Mylan HIV Self Test (Atomo Diagnostics, Australia)	Blood	WHO PQ
autotest VIH® ** (AAZ Labs, France)	Blood	CE mark
BioSURE HIV Self Test ** (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD
Exacto® Test HIV (Biosynex, France)	Blood	CE mark ERPD
INSTI® HIV Self Test ** (bioLytical Lab., Canada)	Blood	WHO PQ
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA, CE Mark
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	WHO PQ
Check Now HIV Self-Test (Abbott Rapid Diagnostics, Jena GmbH, Germany)	Blood	WHO PQ
Wondfo HIV self-test (Guangzhou Wondfo Biotech Co., Ltd.)	Blood	WHO PQ



MARKET AND TECHNOLOGY LANDSCAPE
HIV RAPID DIAGNOSTIC TESTS FOR SELF-TESTING
 4th EDITION
 JULY 2018

- WHO PQ products available for US\$0.95-3.10 through Global Fund
- Private sector availability in Europe
- PAHO strategic fund access for LAC
- Pipeline for products remains strong
- **Blood and oral both WHO PQed**
- **WHO systematic review found no difference in uptake between oral and blood self-tests**

PQ approval of HIVST shows the availability of safe, affordable and accurate self-tests

HCV self-testing

- 2 products in the pipeline
- 1 advanced in PQ pathway

Syphilis self-testing

- 2 dual HIV/syphilis product in pipeline
- 1 single syphilis product in pipeline
- WHO PQ making amendment to TSS in August 2024 to start accepting submissions

HIC, high-income countries; FDA, Food and Drug Administration; ERPD, Expert Review Panel for Diagnostics; Gen, test generation; LMIC, low- and middle-income countries, MRSP: maximum suggested retail price; NA, not available.

* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaid/Global Fund Expert Review Panel for Diagnostics. ** These products sold in more than one packaging format.

Note: Product details based on information provided by the manufacturers at the time of report preparation.

WHO PrEP recommendations and guidance

HIVAIDS 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

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

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

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

JULY 2021

Differentiated and simplified pre-exposure prophylaxis for HIV prevention

Update to WHO implementation guidance

TECHNICAL BRIEF

New guidance on PEP and expanded self-care and differentiated service delivery for PrEP guidance

2012 2014 2015/16 2017 2019 2021 2022 2023 2024

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

Imp tool

MODULE 1 CLINICAL

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

JULY 2017

DPV-VR

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

CAB-LA

World Health Organization

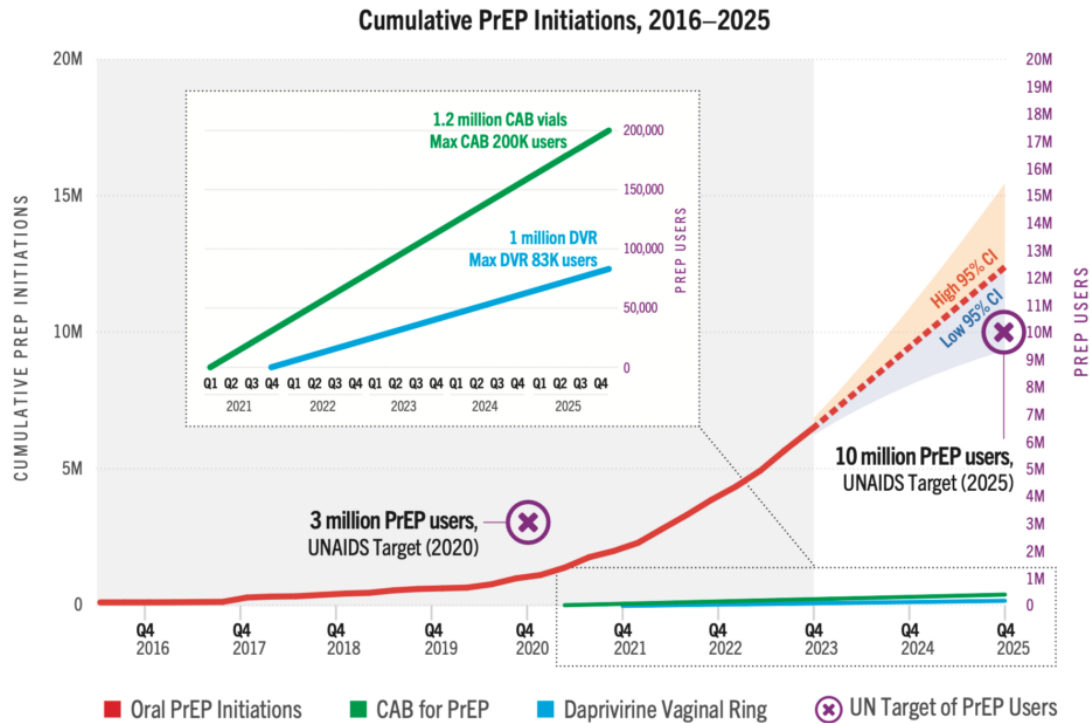
GUIDELINES ON LONG-ACTING INJECTABLE CABOTEGRAVIR FOR HIV PREVENTION

WHO implementation tool for pre-exposure prophylaxis of HIV infection

Provider Module for Oral and Long-Acting PrEP



Cumulative PrEP initiations



AVAC 2024:
<https://ava.c.org/resource/cumulative-prep-initiations/>

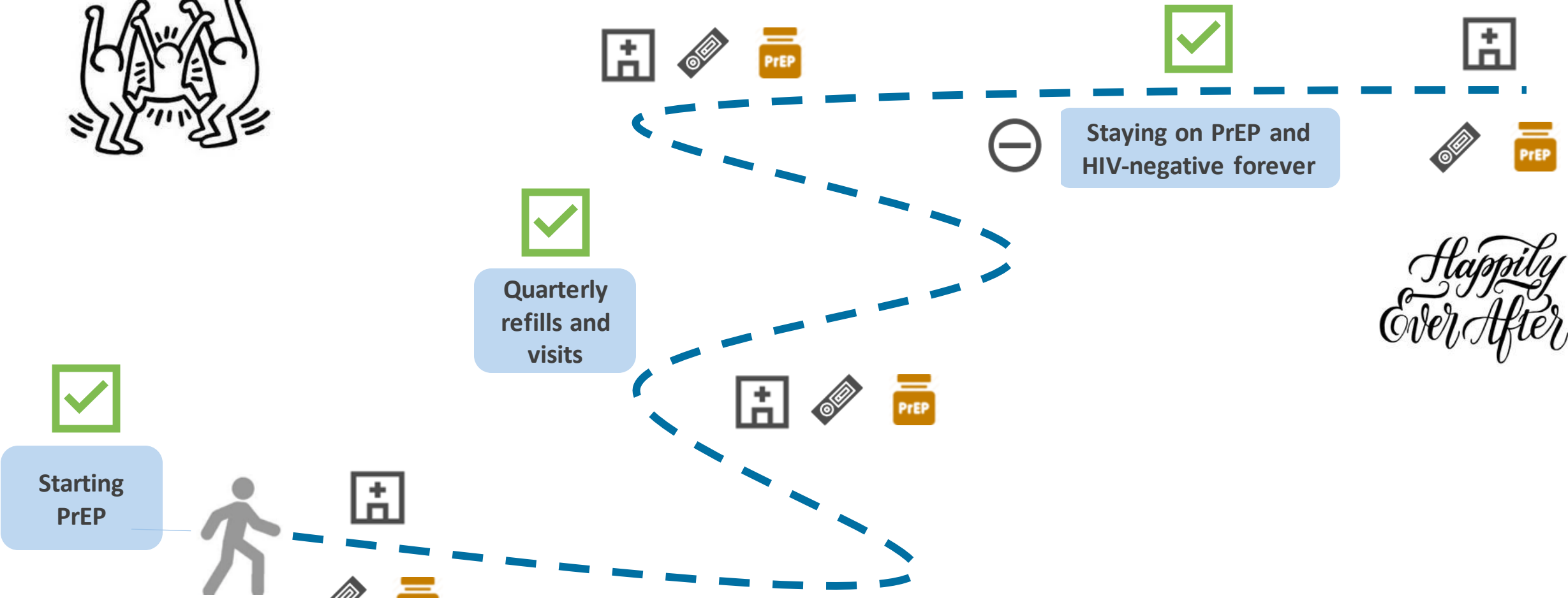
Considerable further expansions of PrEP services forecasted but large growth necessary to reach 2025 target

Need for simplified and differentiated implementation to improve uptake and effective use

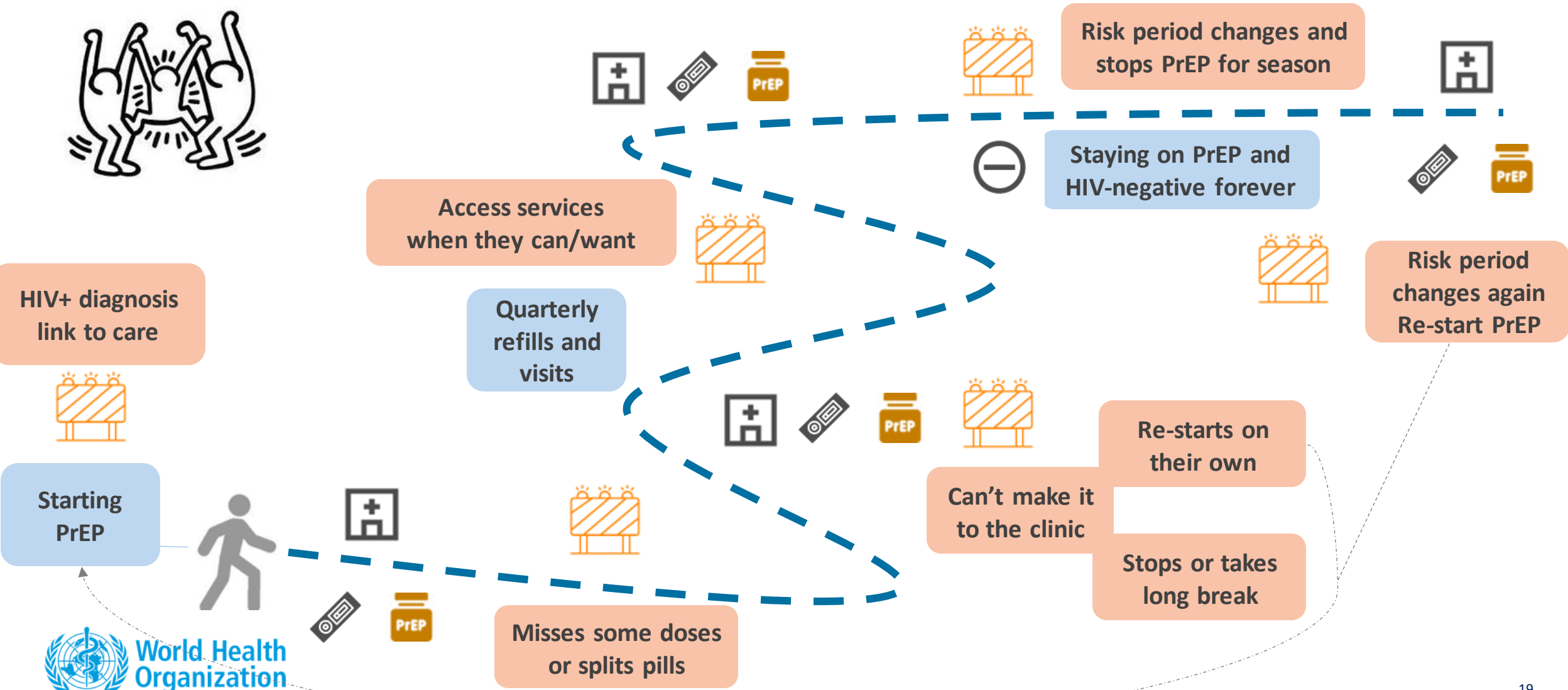


Without increasing PrEP uptake and effective use we won't achieve WHO prevention targets to have fewer than 335 000 infections by 2030

How we sometimes think about a person's PrEP Journey



In reality: People's lives and PrEP journeys are more complicated



In reality: People's lives and PrEP journeys are more complicated



Risk period changes and stops PrEP for season



Staying on PrEP and HIV-negative forever



Access services when they can/want

Need to simplify and differentiate PrEP service delivery to accommodate people's complex lives

Quarterly refills and visits

Risk period changes again Re-start PrEP



HIV+ diagnosis link to care



Starting PrEP



Can't make it to the clinic

Re-starts on their own

Stops or takes long break

Misses some doses or splits pills



Community-based PrEP delivery

Mobile PrEP services, South Africa



Photo credit: Project PrEP – Unitaid

Tele-health for PrEP, Brazil



Photo credit: Project PrEP1519 – Unitaid

Home PrEP delivery, Thailand



Photo credit: Mplus Foundation, Chiang Mai

Pharmacy PrEP, USA



Photo credit: Washington University in St. Louis

Community-based PrEP delivery

Mobile PrEP services, South Africa



Tele-health for PrEP, Brazil



Home PrEP delivery, Thailand



Pharmacy PrEP, USA



Self-testing can facilitate these differentiated service delivery models

Photo credit: Project PrEP1519 – Unitaid

Photo credit: Project PrEP1519 – Unitaid

Photo credit: Mplus Foundation, Chiang Mai

Photo credit: Washington University in St. Louis

Options for HIV self-testing for PrEP delivery

WHO recommends HIVST-supported PrEP delivery

HIVST for PrEP initiation

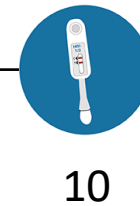
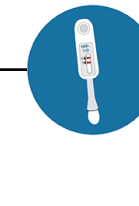
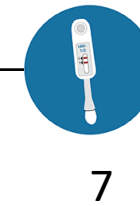
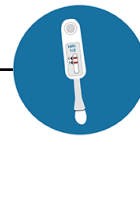
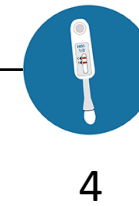
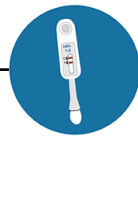
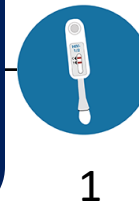
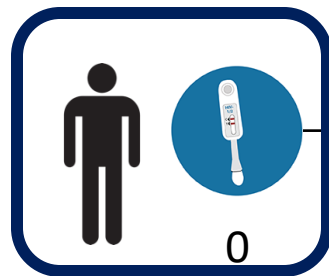
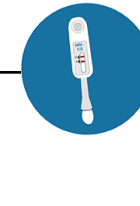
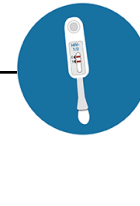
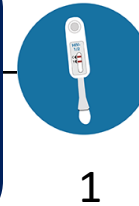
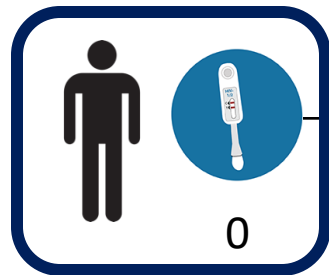
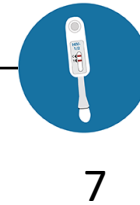
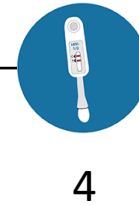
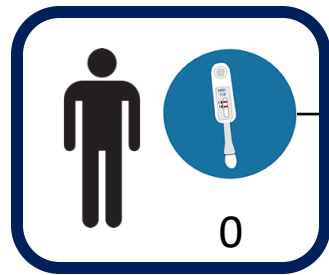
HIVST for PrEP continuation

As prescribed: every 3 months (often linked to refilling)

As needed: can be used for stopping and re-starting PrEP

As desired: can be for testing between recommended visits/refills

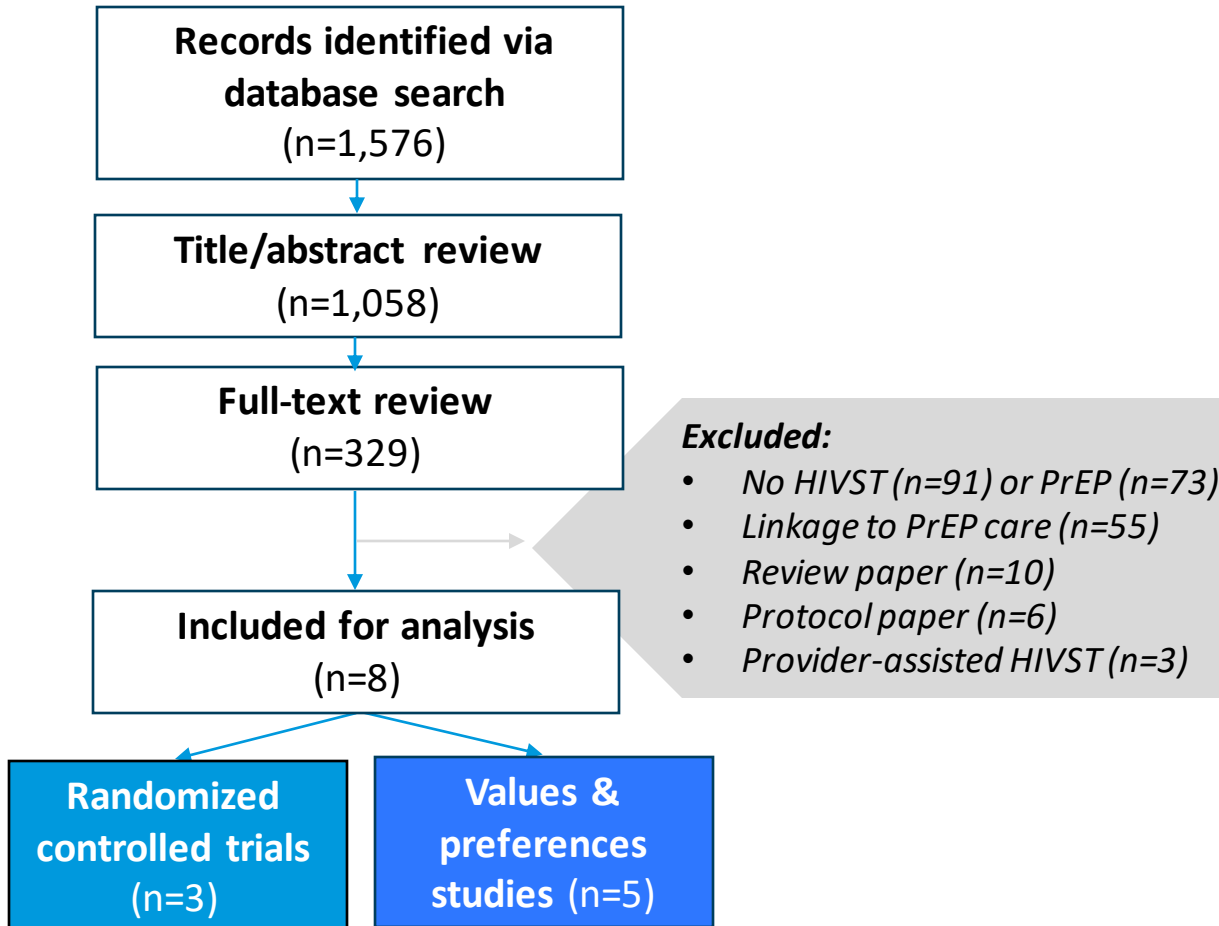
HIVST for PrEP demand creation



Months since PrEP initiation

Slide adapted, courtesy of Katrina Ortblad

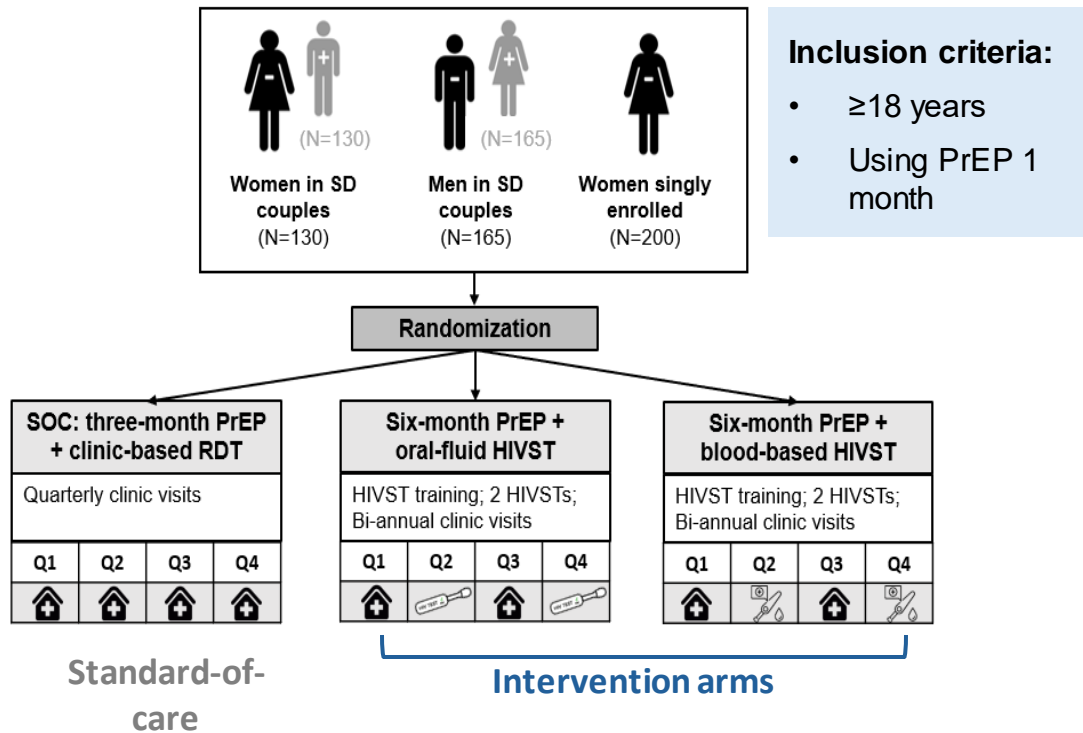
Evidence on HIVST-supported PrEP



- **Benefits of HIVST-supported PrEP continuation appear to outweigh the risks.**
 - No studies directly evaluated the use of HIVST to support PrEP initiation.
 - Only the JiPime-JiPrEP study used HIVST to simplify, not add complexity, to PrEP delivery.
- **In the RCTs, HIVST-supported PrEP delivery, compared to standard facility-based delivery, achieved:**
 - Similar or higher PrEP adherence
 - Similar levels of PrEP retention and refills
 - Good HIV testing uptake and use; increase in male partner testing of post-partum women
 - No adverse events or social harms
- Use of HIVST for PrEP delivery is perceived to be **feasible** and **acceptable**, can be **comparable in terms of resource use** (preliminary results)

Case study: HIVST to support 6-monthly PrEP dispensing – findings from the JiPime-JiPrEP trial

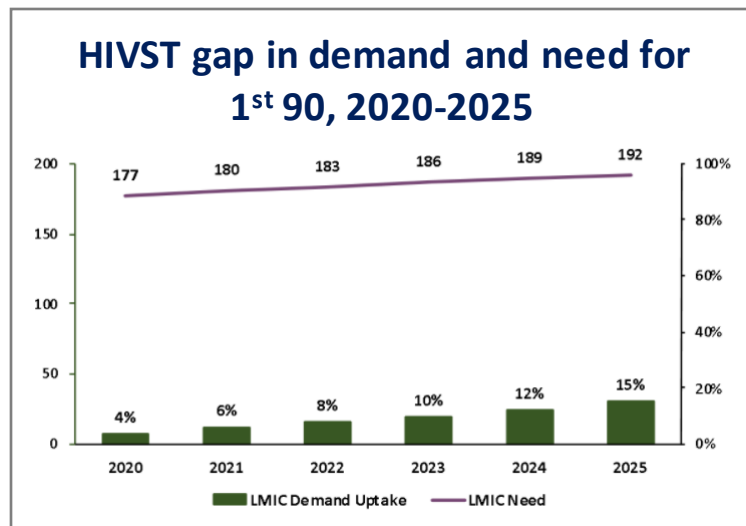
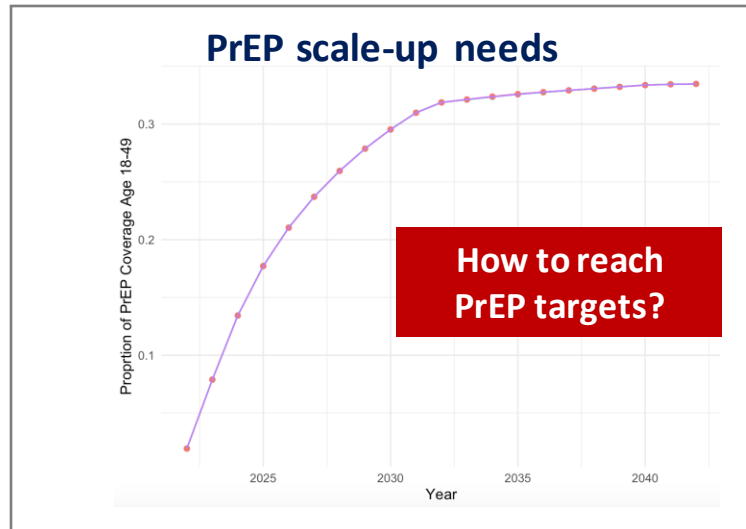
1:1:1 non-inferiority individual-level randomized trial:



Primary outcomes: Recent HIV testing; PrEP refilling (continuation); PrEP adherence (assessed via DBS samples)

- 6-monthly PrEP dispensing with HIVST between semiannual clinic visits **simplified PrEP delivery without compromising clinical outcomes**—HIV testing, PrEP refilling, PrEP adherence—at 6 and 12 months.
 - Among women not in known HIV serodifferent couples, the intervention **significantly increased PrEP adherence**.
- The intervention was perceived as **highly acceptable** among clients who experienced in.
- The intervention was **cost saving**; it decreased the per client annual cost of PrEP delivery
 - By \$7.77 USD in the intervention scenario and \$3.30 USD in the MOH scale-up scenario
- More evidence needed to estimate effects in real-world public clinics and identify implementation strategies that could support scale up.

Considering the risks and benefits of HIVST for PrEP



• Simplify PrEP and adapt services for the real world

- More options and flexibility for taking PrEP based on client needs and preferences
- Greater convenience, user engagement, empowerment, and ownership
- Use with community-based and online services and virtual interventions, e.g. Tele-PrEP
- Increased access to PrEP through HIVST could help achieve scale-up and thereby substantially reduce new HIV infections.

• Similar or can bring lower cost PrEP services to more people

- Simplifies delivery systems & enables more task-sharing
- Reduces health worker time & facility visits
- Reduces client opportunity costs, e.g. travel

• Will HIVST miss a substantial number of people and increase risk of PLHIV developing drug resistance?

- Cox et al 2024 found HIVST-support PrEP would result in few missed infections and very low risk of effecting drug resistance at population level when compared to standard HTS
- No substantial difference by HIV test used (including oral vs. blood HIVST)

• Does HIVST mean PrEP users miss out on other important clinical services?

- Not necessarily - HIVST can be used in a clinic
- Also, other tools like dual HIV/syphilis ST, emerging self-collection and self-testing approaches are becoming available and can be leveraged

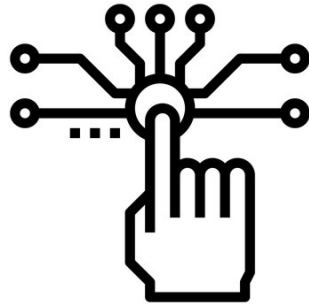
Country uptake of WHO guidance on HIVST-supported PrEP

- Following the WHO recommendation in 2023, WHO started mapping uptake and implementation of this guidance and as of May 2024 we've learned about several experiences and implementation approaches.
- WHO will continue to follow-up and map experiences across countries to support broader implementation and adoption of current guidance.



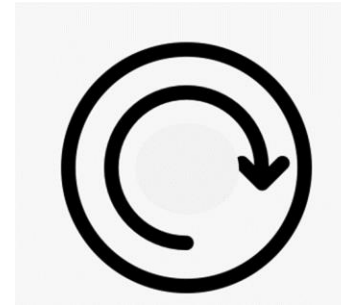
**HIVST for
PrEP demand creation**

Nepal, Zimbabwe,
Kazakhstan, Ghana, South
Africa, Eswatini, Viet Nam



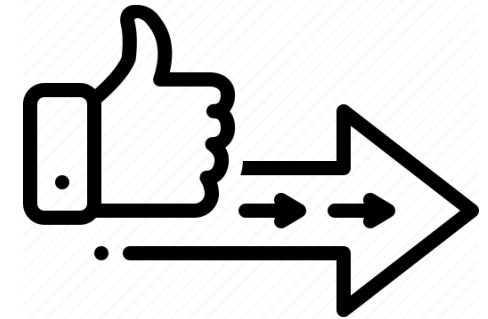
**HIVST for
PrEP initiation**

Philippines, Eswatini
& Thailand



**HIVST for
PrEP re-initiation**

Brazil

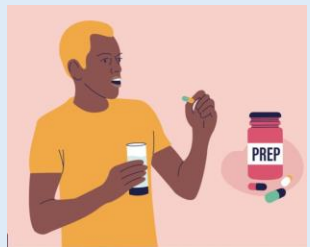
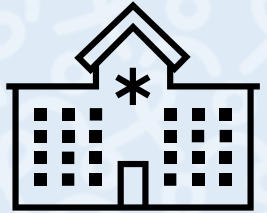
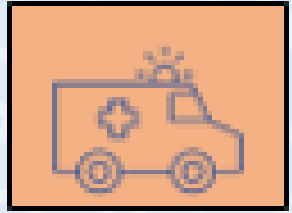


**HIVST for
PrEP continuation**

Zambia, Spain,
Mozambique, Kenya,
South Africa, Viet Nam*

Use of HIVST for PrEP – EpiC Eswatini Experience

- The Meeting Targets and Maintaining Epidemic Control (EpiC) project in Eswatini provides comprehensive clinical health services to key populations (KPs); FSW, MSM, TG & PWID.
- KPs are reached through community outreach workers who provide health education sessions, health screening, and HIVST at hotspots, before they are referred for clinical services at mobile clinics and two KP DICS.
- In March 2024, the MOH updated the PrEP implementation guidelines and HIVST has been approved for initial HIV screening, and for PrEP initiation (oral PrEP or PrEP ring) for clients who accept the service.
- To promote self-care, HIVST kits will also be given to the clients during the second refill (Month 4). During this refill, PrEP is given for six months. Clients are educated on the use of HIVST and without the need to come to the facility.
- Clients on daily oral PrEP or the PrEP ring are also provided with an HIVST to take home and are encouraged to use it as an exit test in case of a decision to discontinue PrEP when their risks change.
- During ART initiation, HIVST has also been integrated and secondarily distributed as part of index testing.





HIVST for PrEP in Viet Nam

BỘ Y TẾ CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Số: 5968 /QĐ-BYT Hà Nội, ngày 31 tháng 12 năm 2021

QUYẾT ĐỊNH
Về việc ban hành Hướng dẫn Điều trị và chăm sóc HIV/AIDS

BỘ TRƯỞNG BỘ Y TẾ
Căn cứ Nghị định số 75/2017/NĐ-CP ngày 20/6/2017 của Chính phủ quy định chức năng, nhiệm vụ, quyền hạn và cơ cấu tổ chức của Bộ Y tế;
Theo đề nghị của Hội đồng chuyên môn nghiệm thu Hướng dẫn Điều trị và Chăm sóc HIV/AIDS được thành lập theo Quyết định số 5300/QĐ-BYT ngày 16/11/2021 của Bộ Y tế;
Theo đề nghị của Cục trưởng Cục phòng, chống HIV/AIDS.

QUYẾT ĐỊNH:

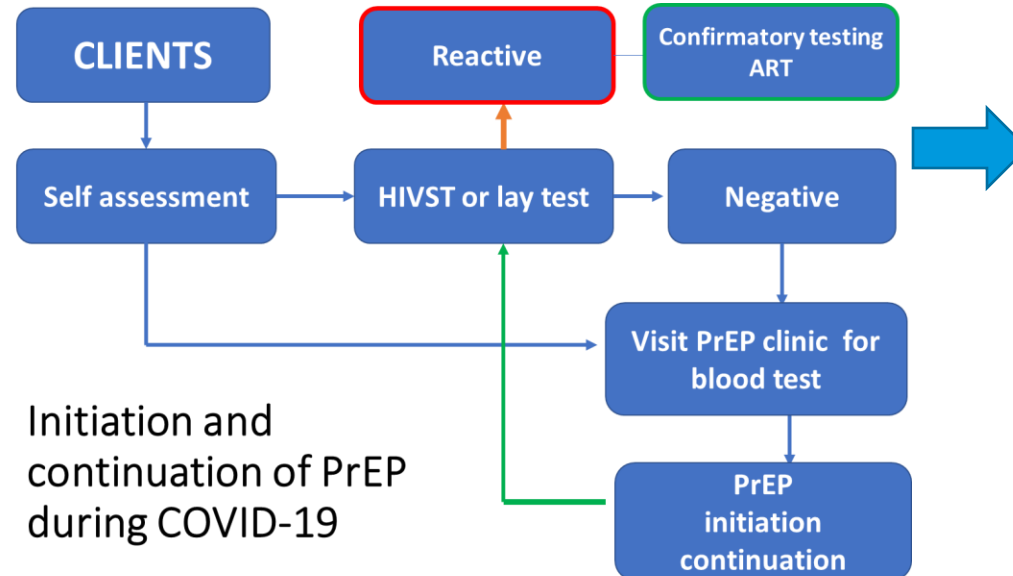
Điều 1. Ban hành kèm theo Quyết định này “Hướng dẫn Điều trị và chăm sóc HIV/AIDS”.

Điều 2. Quyết định này có hiệu lực kể từ ngày ký, ban hành và thay thế Quyết định số 5456/QĐ-BYT ngày 20/11/2019 của Bộ Y tế về “Hướng dẫn điều trị và chăm sóc HIV/AIDS”.

Điều 3. Các ông, bà: Chánh Văn phòng Bộ; Chánh thanh tra Bộ, Tổng Cục trưởng, Vụ trưởng, Cục trưởng các Vụ, Cục thuộc Bộ Y tế, Thủ trưởng các đơn vị trực thuộc Bộ Y tế; Giám đốc Sở Y tế các tỉnh thành phố trực thuộc Trung ương; Thủ trưởng y tế ngành và các đơn vị liên quan chịu trách nhiệm thi hành Quyết định này./.

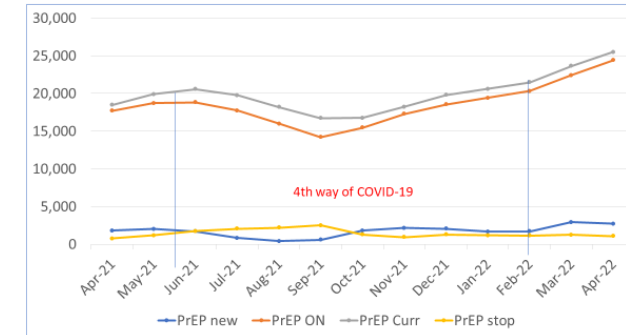
Nơi nhận:
- Như Điều 3;
- Đ/c Bộ trưởng (để báo cáo);
- Các Đ/c Thứ trưởng (để biết);
- Cổng Thông tin điện tử Bộ Y tế;
- Trang thông tin điện tử Cục PC HIV/AIDS;
- Lưu: VT, AIDS.

KT. BỘ TRƯỞNG
PHỤ TRƯỞNG
Nguyễn Trường



11.4: In the situation of disaster, pandemic or any unforeseeable circumstances that prevent clients coming to PrEP clinic:
- Using HIVST for PrEP continuation

Uptake of PrEP during Covid-19



- Clients take self assessment (form) and book an appointment with PrEP clinic
- PrEP users can use self-test or community-based testing to monitor HIV status and inform health staff for PrEP continuation
- This shift made a significant impact on PrEP uptake
- Post-COVID-19 emergency, HIVST is being used to support linkage to PrEP and Tele-PrEP



Tele-PrEP currently being implemented with HIVSS as a pilot

HIVSS* for PrEP in South Africa



HIVSS & PrEP are large programmes in South Africa and growing

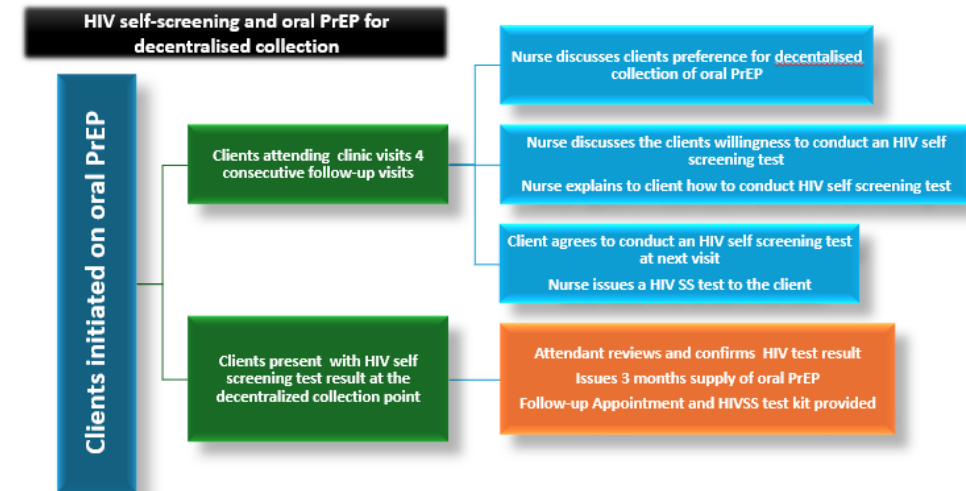
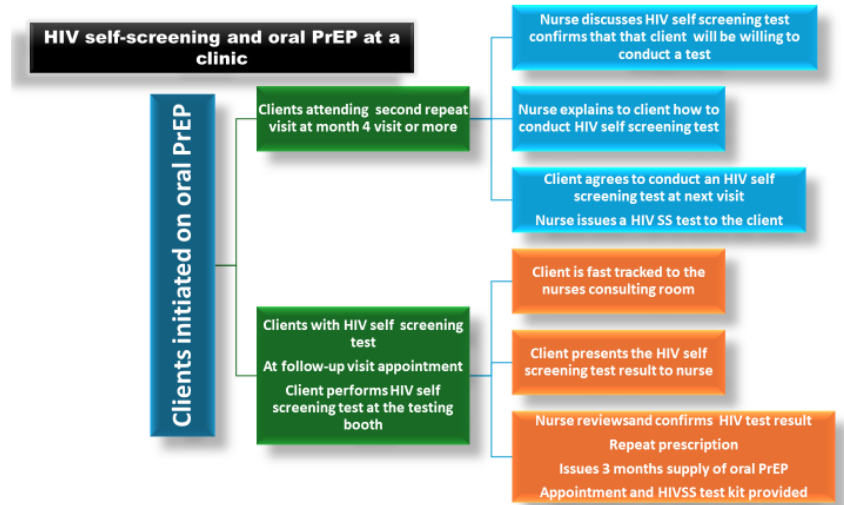
- 2024-27 procurement plan is for ~3.7 million HIVSS kits
- Focus of HIVSS programmes have been men, AGYW and KP
- During COVID-19, HIVSS made a large impact maintaining services and HIV+ yield was ~6.8%
- Current guidance for HIVSS is supports access for those +12 years (youth 12-17 require direct assistance)
- New guidance on HIVSS for PrEP is for:
 - Demand creation
 - Continuation or re-initiation
 - Can only be done with direct assistance from a provider

2024

Standard Operating Procedures for differentiated HIV Testing Services (dHTS) modalities for Adults and Children



*HIVSS = HIVST and is the term used across South Africa



User perspectives on self-testing for PrEP



**ZAMGATSHENI
MBATHA**



Future directions and way forward

- **HIVST-supported PrEP is the future and important for scale-up and achieving HIV prevention goals**
 - Simplified testing and self-testing is essential to increasing PrEP uptake
 - We cant continue with «business as usual» and expect PrEP scale-up to happen on its own
 - Important to apply lessons learned from early adopter countries
 - Need to plan on HIVST scale-up insufficient number of tests procured globally to achieve targets to reduce new infections
- **HIVST for other prevention**
 - HIVST can be used for PEP
 - HIVST is being explored for long-acting PrEP
 - Research is underway and will inform guidance
- **Self-testing doesnt mean just HIV**
 - New tools and technologies for self-testing and self-care can be leveraged, STI self-test/self-collection, multiplex self-tests etc.
 - Offers new opportunities to change PrEP/PEP delivery and support integrated service delivery and tele-PrEP options

Thank you!

Thanks to the WHO and AVAC team for contributions to this presentation and webinar

WHO: Carlota Baptista Silva, Michelle Rodolph, Mateo Prochazka Nunez, Heather-Marie Schmidt

AVAC: Cat Verde Hashim, Wawira Nyagah and Mitchell Warren

Thank you to all the countries and implementers who have shared experiences on HIVST and PrEP delivery with WHO, especially our speakers today from South Africa, Viet Nam and Eswatini.

Thanks to Monisha Sharma and Katrina Ortblad for joining the webinar today, and for their work at University of Washington and Fred Hutch which has supported the generation of evidence including implementation studies, systematic reviews and modelling work.

A special thanks to Ezintsha Mohammed Majam and Angela Tembo for providing a video from users engaged in self-testing as part of PrEP services

For more information on HIV testing services

WHO HIV Testing
Services Dashboard

WHO HIV Testing
Services Info App

WHO HTS GL

Questions?

Contact: Cheryl Johnson johnsonc@who.int