OPERATIONALIZING FACILITY-BASED HIV SELF-TESTING: LAUNCH OF THE IMPLEMENTATION TOOLKIT AND TRAINING MODULES

12 June 2025

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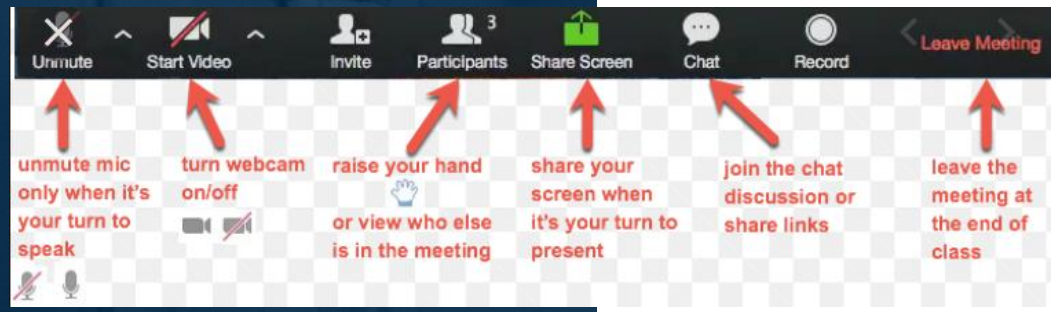
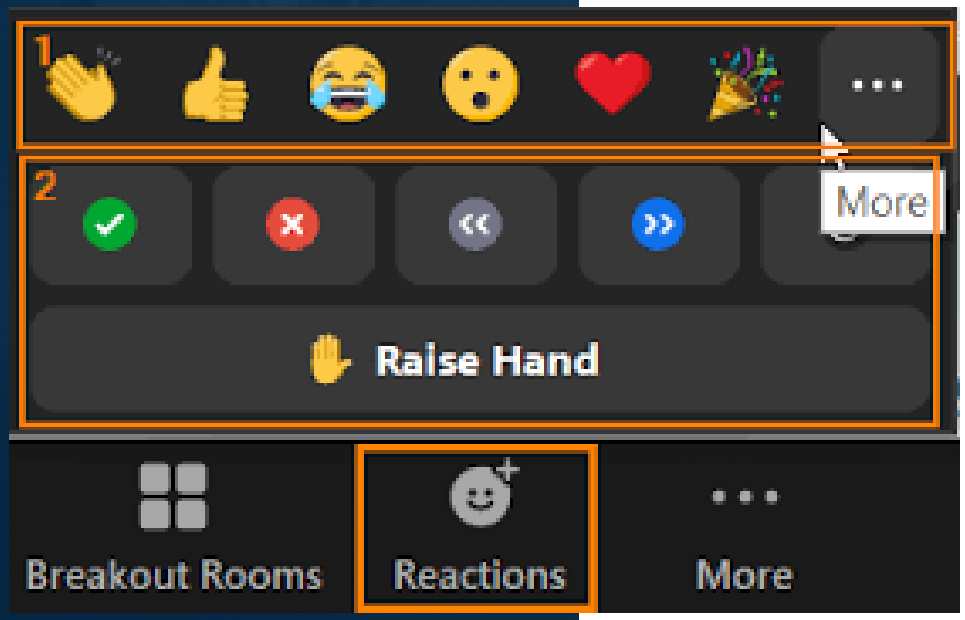
Housekeeping rules





Introduce yourself

- Say hi in chat and update your name (name, country and affiliation)
- We will record for note keeping and sharing content internally.
- Slides will be shared after webinar.

We want to hear from you – but time is limited

- Ask questions ask in the Q&A or chat – or raise your hand
- Be concise and provide space for others to share and talk
- Stay muted and keep videos off unless presenting and speaking
- No AI bots for notetaking allowed

We are available for further follow-up

- Busi Msimanga: msimangaradebeb@who.int
- Cheryl Johnson: johnsonc@who.int

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Webinar objectives

Launch of the Facility-Based HIV Self-Testing Training Tool

Position countries to meet the moment and steps to accelerate facility-based HIVST training

Today's programme

		Moderator: Carlota Baptista da Silva (WHO)
14:00- 14:05	Welcome & and webinar overview	Carlota BAPTISTA DA SILVA, WHO
14.05– 14:25	Setting the scene: Facility-Based HIV Self-Testing, WHO guidance and new guidance + toolkit presentation	Busi MSIMANGA, WHO
14:25 – 14:40	Highlights of the Facility based HIV Self-testing Implementation Toolkit and Training Modules	Bernhard Kerschberger, PSI
14:40 – 14:50	Leveraging Facility-Based HIV Self-Testing to Drive Access and Efficiencies	Christian Stilton, CHAI
14:50 – 15:00	Country experience #1: Eswatini Screen, Test, Treat: Eswatini's Experience with Facility-Based HIV Self-Testing	Lenhle Dube, MOH Eswatini,
15:00– 15:10	Country Experience #2: Lesotho Facility based HIV self-testing in Lesotho from pilot to scale up	Tlhomola Mphotleng, MoH Lesotho
15.10– 15:20	Q&A	Moderation by Karin Hatzold. PSI
15:20 – 15: 30	Closing remarks	Carlota BAPTISTA DA SILVA, WHO

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OPERATIONALIZING FACILITY-BASED HIV SELF-TESTING: LAUNCH OF THE IMPLEMENTATION TOOLKIT AND TRAINING MODULES

Setting the scene: Facility-Based HIV Self-Testing, WHO guidance

Busi Msimang, WHO HQ
Global HIV, Hepatitis and STI

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HIV testing contributing to global ART scale-up

 # PLHIV Diagnosed (Millions)

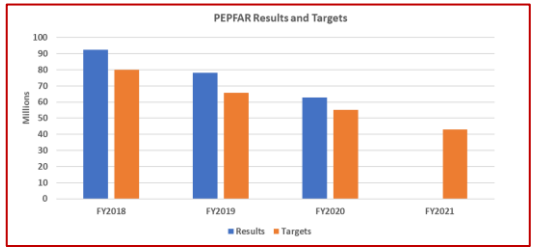
40
35
30
25
20
15
10
5
0

2005
2008
2011
2014
2017
2020
2023

HTS scale-up initially slows. Traditional strategies with RDTs not enough.
Gradual increase begins following scale-up of community HTS, partners testing, network-based testing and self-testing.

Slow start to HTS - limited to complex & costly lab tests.
In 2005 ~10% PLHIV diagnosed.

Transition to RDTs & PITC leads to steep increase in testing and initial ART scale-up; forms backbone of modern HTS programme



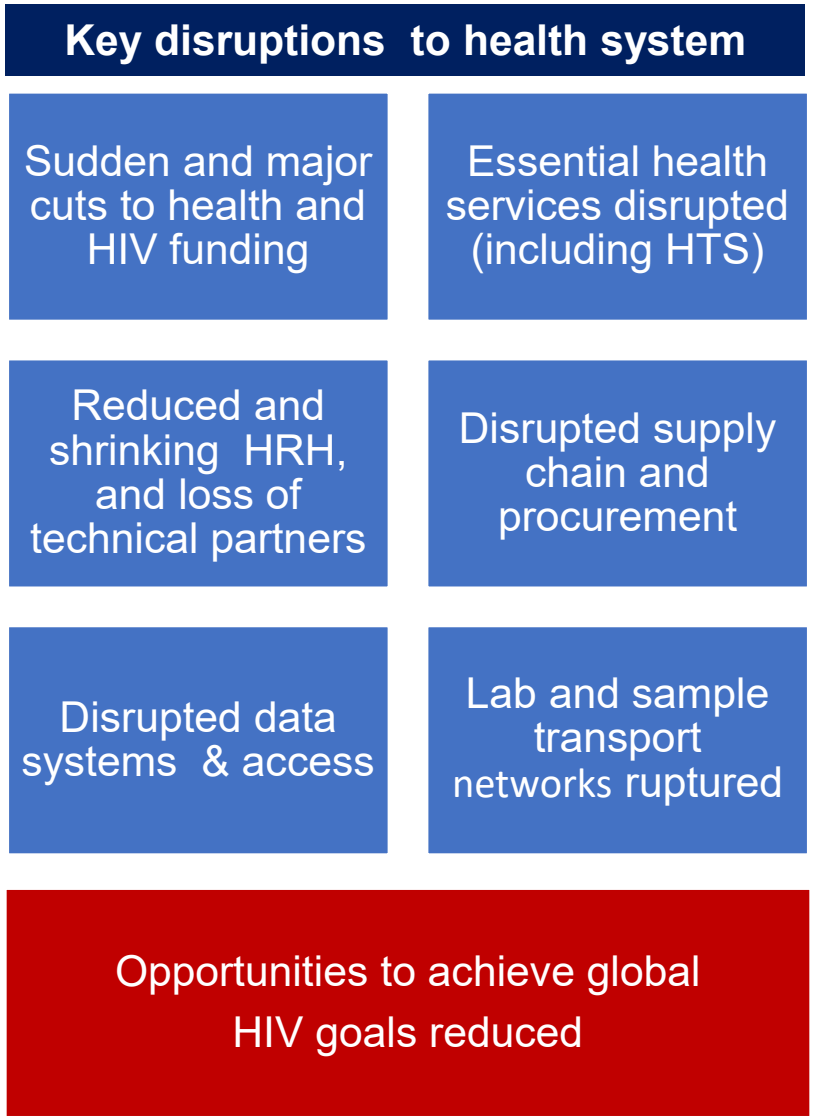
Uncertain future - gaps growing due to policy shifts and budget cuts. How do we reach the 6 million undiagnosed PLHIV?

86% of PLHIV diagnosed in 2023 – **yet progress slows**

HTS slow down: Decreased donor targets, COVID-19 & delayed testing rebound

Self-testing becomes critical in many settings

Reduced funding and policy shifts impact HIV services



Key findings from WHO rapid country assessments post policy and funding shifts:

- Substantial programme disruptions, but variable by country and region
- Many adopting '*integration of HIV into PHC*'
- Focusing adaptations to maintain ART for PLHIV
- Other areas such as **HIV testing and prevention** under review and/or being deprioritized

It is critical to provide strategic insight and guidance on sustaining cos-efficient HIV testing

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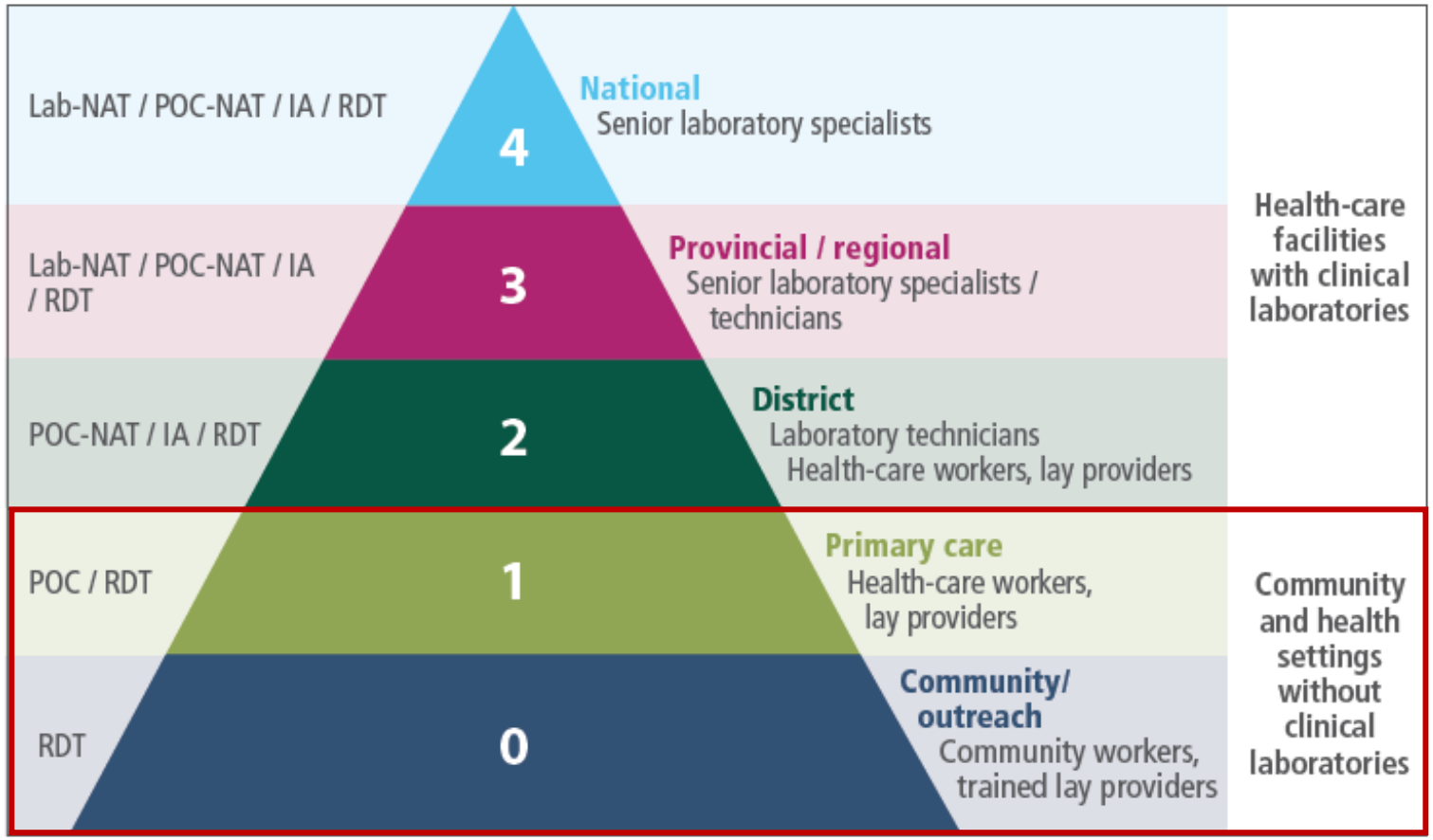
Rapid tests are the most common HIV tests



IA: enzyme immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; RDT: rapid diagnostic test, including HIV self-testing.

+95% of all HIV testing worldwide is done at level 0 or 1 (health centres & community) with rapid tests

Self-testing growing here, 100+ country policies

Source: WHO, 2024: https://iris.who.int/bitstream/handle/10665/378162/9789240096394-eng.pdf

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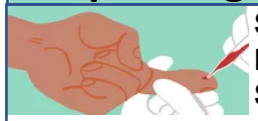
In vitro diagnostic medical devices (IVDs) for HIV testing services

1 Rapid diagnostic tests



Steps: Minimal
Results: 1-20 min, same day results
Specimen: Fingerprick blood & oral fluid

Throughput: 5-10 per 5-15 min
Price per test: ~$0.50-$3.00
Performance: WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 23-90 days
Where: Virtually anywhere (PHC & Community level, as well as higher level facilities and labs)
Who: Virtually anyone (trained lay providers, HCW, lab techs etc)
Storage: Generally, no electricity or refrigeration needs

2 Self-test

Steps: Minimal
Results: 1-20 min, same day results
Specimen: Fingerprick blood & oral fluid

Throughput: Vast, but variable by distribution approach
Price per test: ~$0.95-5.00; but can be quite costly in high-income countries & the private sector
Performance: WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 23-90 days
Where: Virtually anywhere (PHC & community level etc)
Who: Most anyone (videos/demonstrations can help users)
Storage: No electricity or refrigeration needs

3 Other simple assays & Immunoassays

Steps: Moderate to complex
Results: ~30 min–3hrs, turnaround time varies by setting generally next day
Specimen: Serum, plasma

Throughput: 9 per 15-30 min to 90 per hr (varies with batching)
Price per test: Highly variable (>$1.00-24)
Performance: WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 18-45 days; WB & Line Immunoassays can be longer
Where: Health facilities (some PHC, but mostly higher-level facilities and labs as some assays need automation
Who: Trained facility staff and lab techs only etc
Storage: Electricity and refrigeration needs

4 Nucleic acid testing (NAT)

Steps: Moderate to Complex
Results: ~1hrs–4hrs, turnaround up to 35 days (varies by setting), turnaround time not same day
Specimen: Plasma & DBS (RNA and TNA)

Throughput: Widely variable by device (8-384 per 8hr shift)
Price per test: $22-85 (not including $$$ device)
Performance: Data must support Dx claim (%PA) - WHO PQ standard ≥99% sensitivity & ≥98% specificity
Window period: 10-33 days
Where: Health facilities (some PHC, higher level facilities & labs)
Who: Highly trained facility staff and lab techs only etc.
Storage: Electricity and (mostly) refrigeration needs

Factors for product selection

Operational characteristics for consideration:

- Test purpose (aid for diagnosis, diagnosis, monitoring)
- Specimen type
- Detection type
- Time to result
- Storage and stability
- Staff and skill level
- Equipment and consumables required
- Quality control (internal/external)

Additional considerations

- Aims and population
- Contributing to best algorithm and programme need
- Programme & public health impact
- Implementation and feasibility
- Price and service costs
- Training needs
- Support and supervision

Source: WHO, 2024, Fajardo/WHO 2025 forthcoming

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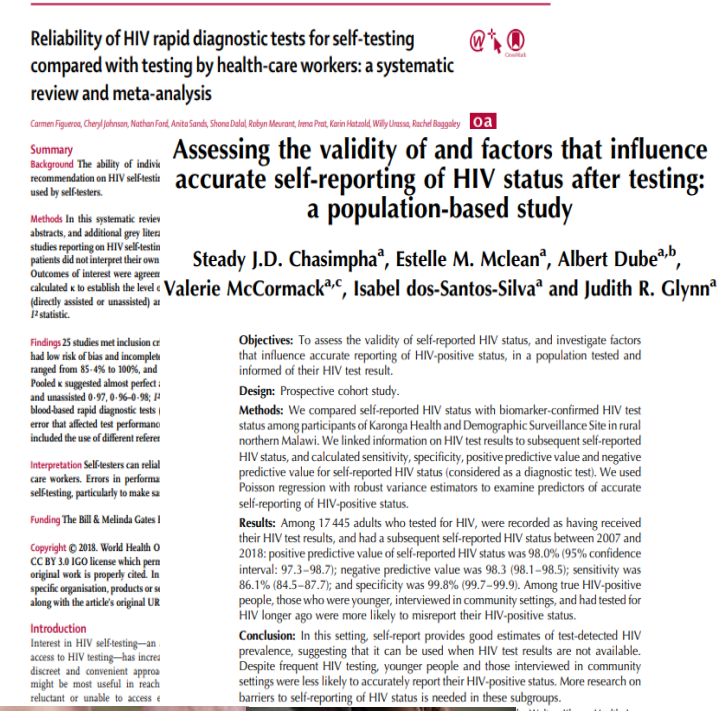
HIV rapid tests and self-tests are accurate


Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis

Carmen Figueroa, Cheryl Johnson, Nathan Ford, Anita Sands, Shona Dalal, Robyn Meurant, Irena Prat, Karin Hatzold, Willy Urassa, Rachel Baggaley

Assessing the validity of and factors that influence accurate self-reporting of HIV status after testing: a population-based study

Steady J.D. Chasimpha[a], Estelle M. Mclean[a], Albert Dube[a,b], Valerie McCormack[a,c], Isabel dos-Santos-Silva[a] and Judith R. Glynn[a]

Objectives: To assess the validity of self-reported HIV status, and investigate factors that influence accurate reporting of HIV-positive status, in a population tested and informed of their HIV test result.

Design: Prospective cohort study.

Methods: We compared self-reported HIV status with biomarker-confirmed HIV test status among participants of Karonga Health and Demographic Surveillance Site in rural northern Malawi. We linked information on HIV test results to subsequent self-reported HIV status, and calculated sensitivity, specificity, positive predictive value and negative predictive value for self-reported HIV status (considered as a diagnostic test). We used Poisson regression with robust variance estimators to examine predictors of accurate self-reporting of HIV-positive status.

Results: Among 17 445 adults who tested for HIV, were recorded as having received their HIV test results, and had a subsequent self-reported HIV status between 2007 and 2018: positive predictive value of self-reported HIV status was 98.0% (95% confidence interval: 97.3–98.7); negative predictive value was 98.3 (98.1–98.5); sensitivity was 86.1% (84.5–87.7); and specificity was 99.8% (99.7–99.9). Among true HIV-positive people, those who were younger, interviewed in community settings, and had tested for HIV longer ago were more likely to misreport their HIV-positive status.

Conclusion: In this setting, self-report provides good estimates of test-detected HIV prevalence, suggesting that it can be used when HIV test results are not available. Despite frequent HIV testing, younger people and those interviewed in community settings were less likely to accurately report their HIV-positive status. More research on barriers to self-reporting of HIV status is needed in these subgroups.

- For decades rapid tests and self-tests have been accurate enough to assist with starting people (>18+ months} on lifelong treatment
- International standards for performance for rapid tests and self-tests:
  - ≥99% sensitivity & ≥98% specificity
  - used in 3-test strategy to achieve ≥99% positive predictive value (less than one false positive per 100 people diagnosed with HIV)
- Research suggests that most people report accurately HIV testing history and HIVST results
- HIVST data shows no difference in uptake between blood and oral options – WHO guidance supports both
- Blood based HIVST are less expensive than oral fluid HIV ST
- Trained lay workers can deliver all testing services

Source: WHO 2025; Cox 2024; WHO 2024; Henderson 2023; Figueroa 2018

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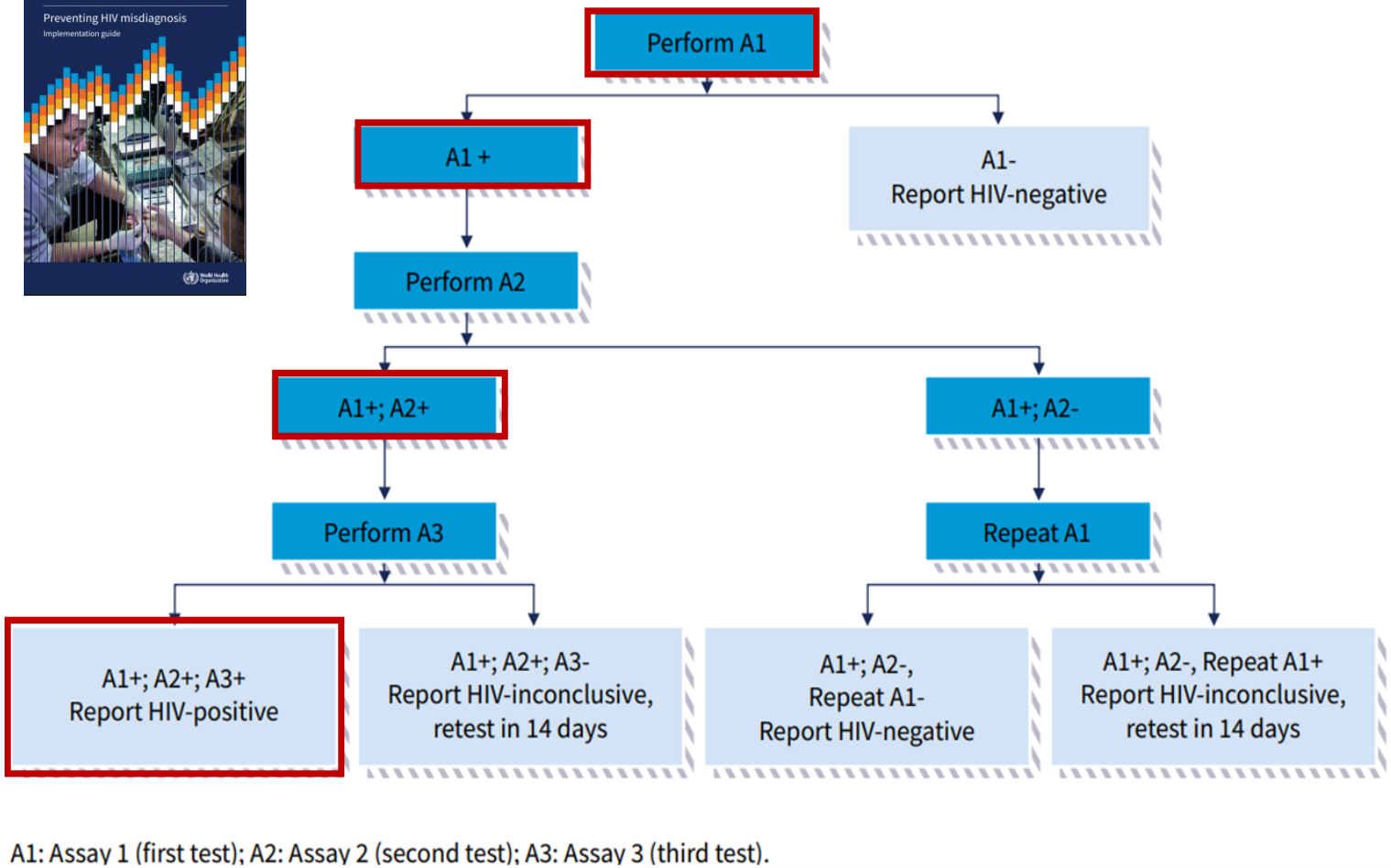
WHO recommendations for accurate diagnosis (>18 months)



A1: Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test).

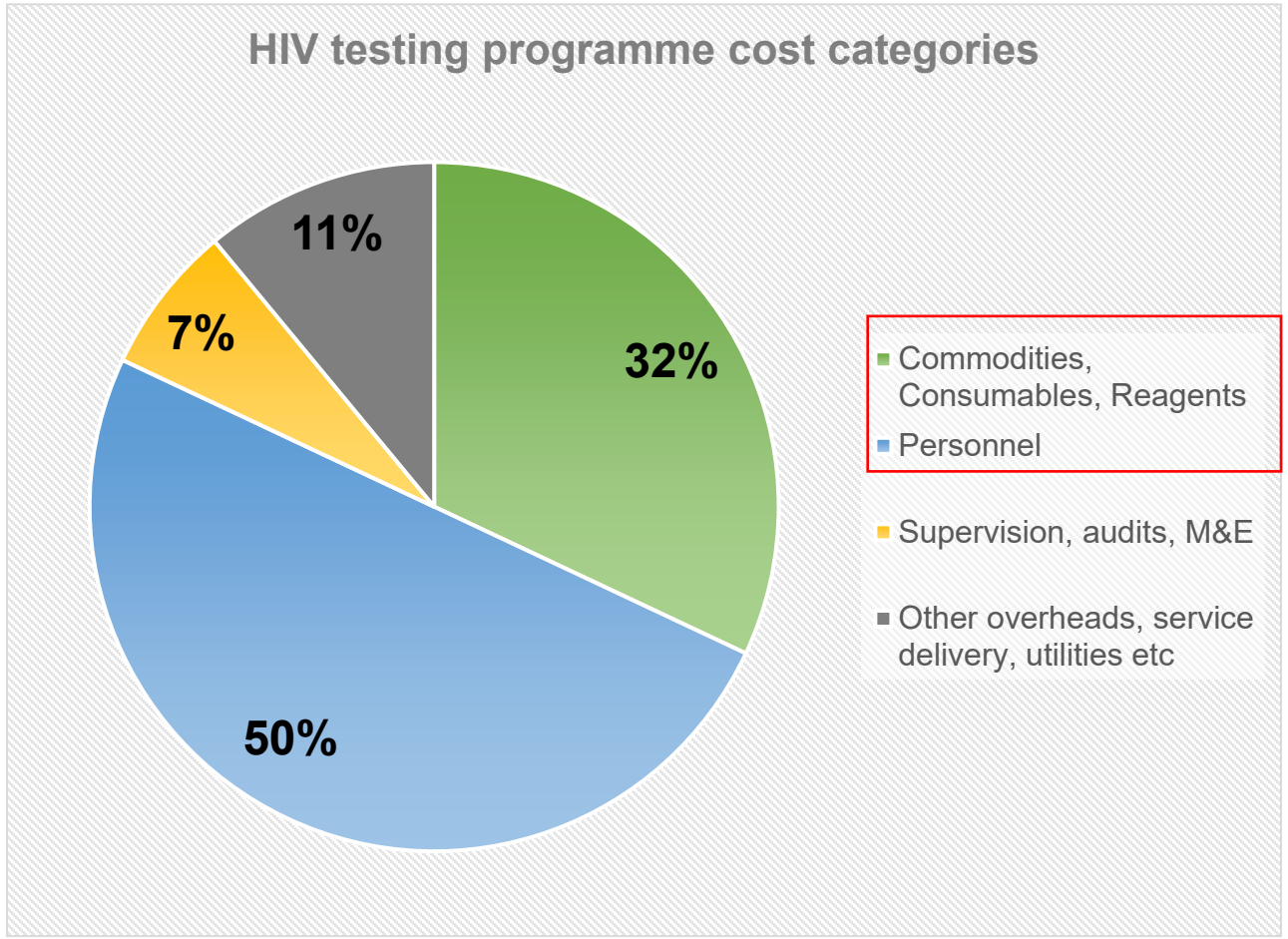
- WHO recommends simple and affordable 3-test strategy to ensure accurate diagnosis for all
- Quality **rapid tests**: affordable and enable same day diagnosis and ART
- Misdiagnosis, esp false positive diagnosis, is costly & difficult to resolve once ART is started
- Simple quality management systems (QMS) remain important
- Costs of life-long ART costs far exceed those of accurate testing

WHO recommends serology (RDT/EIA) tests and does not recommend routine HIV testing using recency, WB/IB, NAT (RNA or DNA)

**This guidance and messaging is focused on testing for those >18 months of age and who receive serology testing through rapid tests or enzyme immunoassays*

Source: WHO 2024, https://iris.who.int/bitstream/handle/10665/379478/9789240092136-eng.pdf; WHO 2019; Eaton 2019; Eaton 2017

Understanding HIV testing costs



+1 billion HIV RDTs were procured in 101 LMICs 2015-2023.

18% increase in HIV RDTs procured from 2021 to 2023*.

Main HIV testing costs are personnel (**testers**) and commodities (**test kits**)

Focusing on these two areas is a strategic way to cut costs

**This represents much of large procurers and donor resources not direct procurement figures from EIC/WHO report 2024.*

Graph is illustrative and adapted from Vyas et al 2020 https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-05446-5

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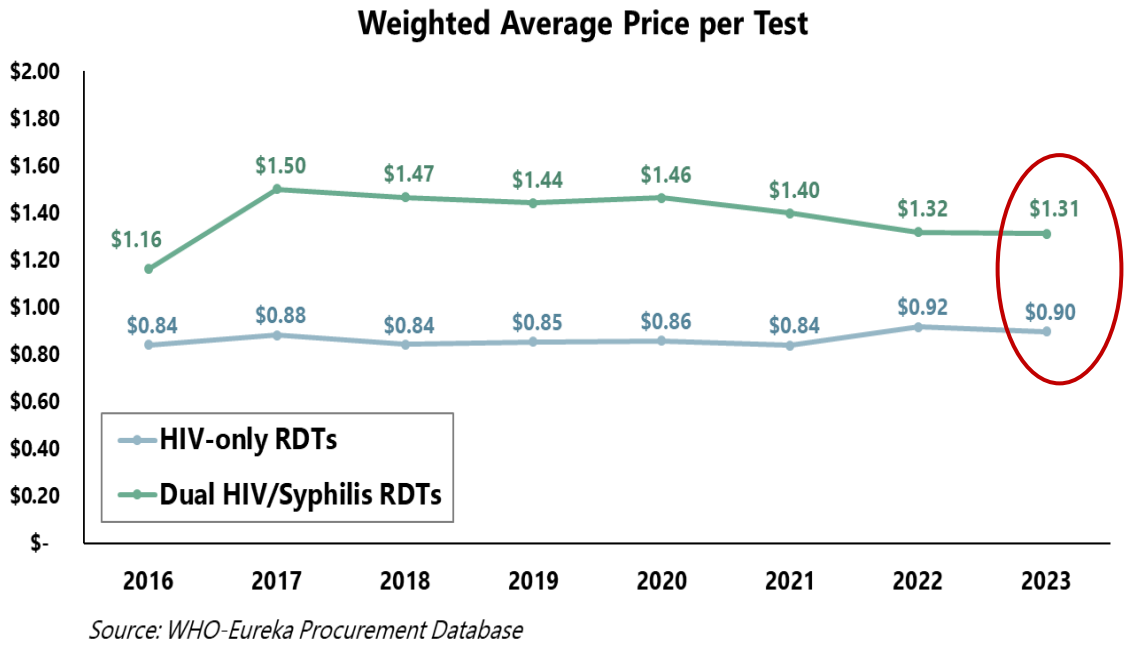
Average weighted price of HIV tests remains high, yet low-cost quality-assured options are available



Source: WHO-Eureka Procurement Database

Average weighted price of HIV tests:

- HIV RDT: $0,90
- HIV/syphilis RDT: $1,31
- HIVST: $2,00

Yet, lower cost quality-assured tests exist

Current opportunities in the WHO catalogue

- **HIV RDT:** +21 PQ'ed ($0,53-$2,79)
  - 5 manufacturers have tests **<$0,70-0,75** (**Premier, Meril, SD Biosensor, Abon** and **Trinity**)
  - 4 manufacturers have tests **<$0,70** (**Wantai, Wondfo, KHB** and **InTec**)
  - All with A1 characteristics
- **HIV/Syph RDT**: 3 PQ'ed ($0,90-$0,95)
  - **SD Bionsensor, Abbott (SD Bioline)** and **Premier**
- **HIVST**: 7 PQ'ed ($1-$3,29)
  - 2 manufacturers have tests **<$1,50** (**Wondfo** and **Abbott)**

**Note price information includes cost of accessories per WHO sources and catalogue as of 5 May 2025*
Reference information: EIC/WHO 2024, WHO catalogue 2025; WHO tool kit 2021; Global Fund 2025

***Abon – owned by Abbott*
*** SD Bioline – subsidiary of Abbott*

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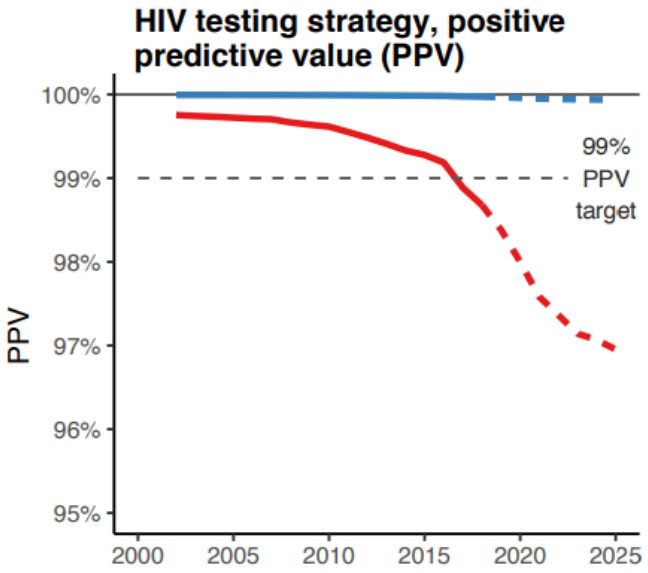
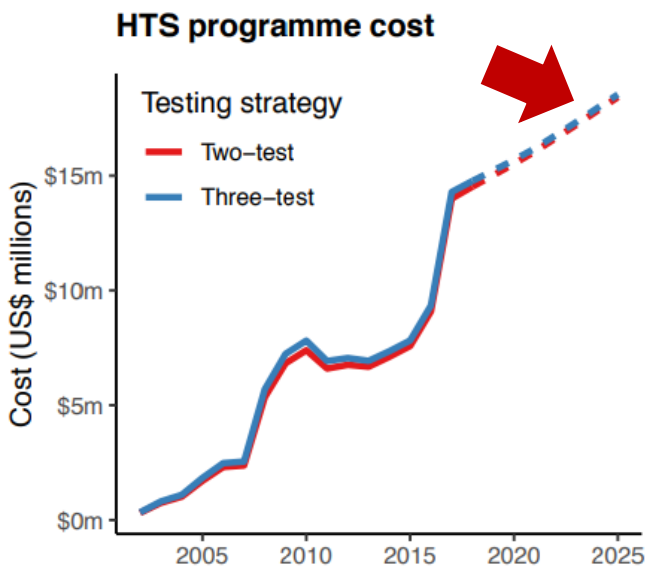
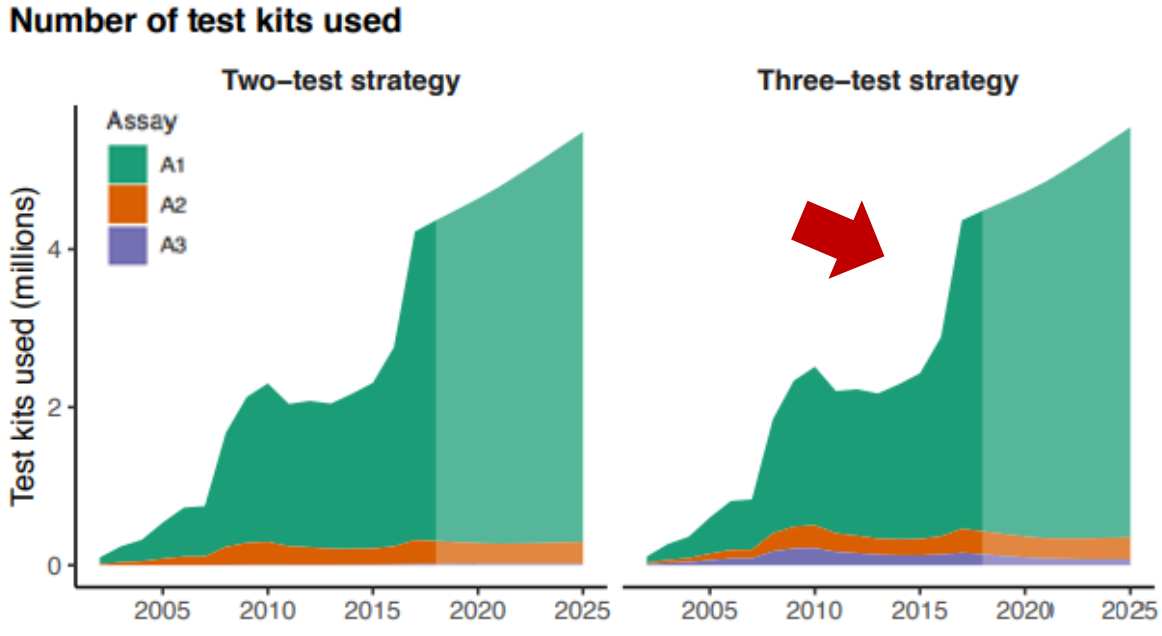
Focusing on adopting a low-cost first test (A1) in algorithm will have greatest impact on savings







3-test strategy remains best buy

- Removing 3rd test does not lead to sufficient savings (cost virtually the same)
- Avoiding misdiagnosis and cost of unnecessary lifelong ART remains critical for countries

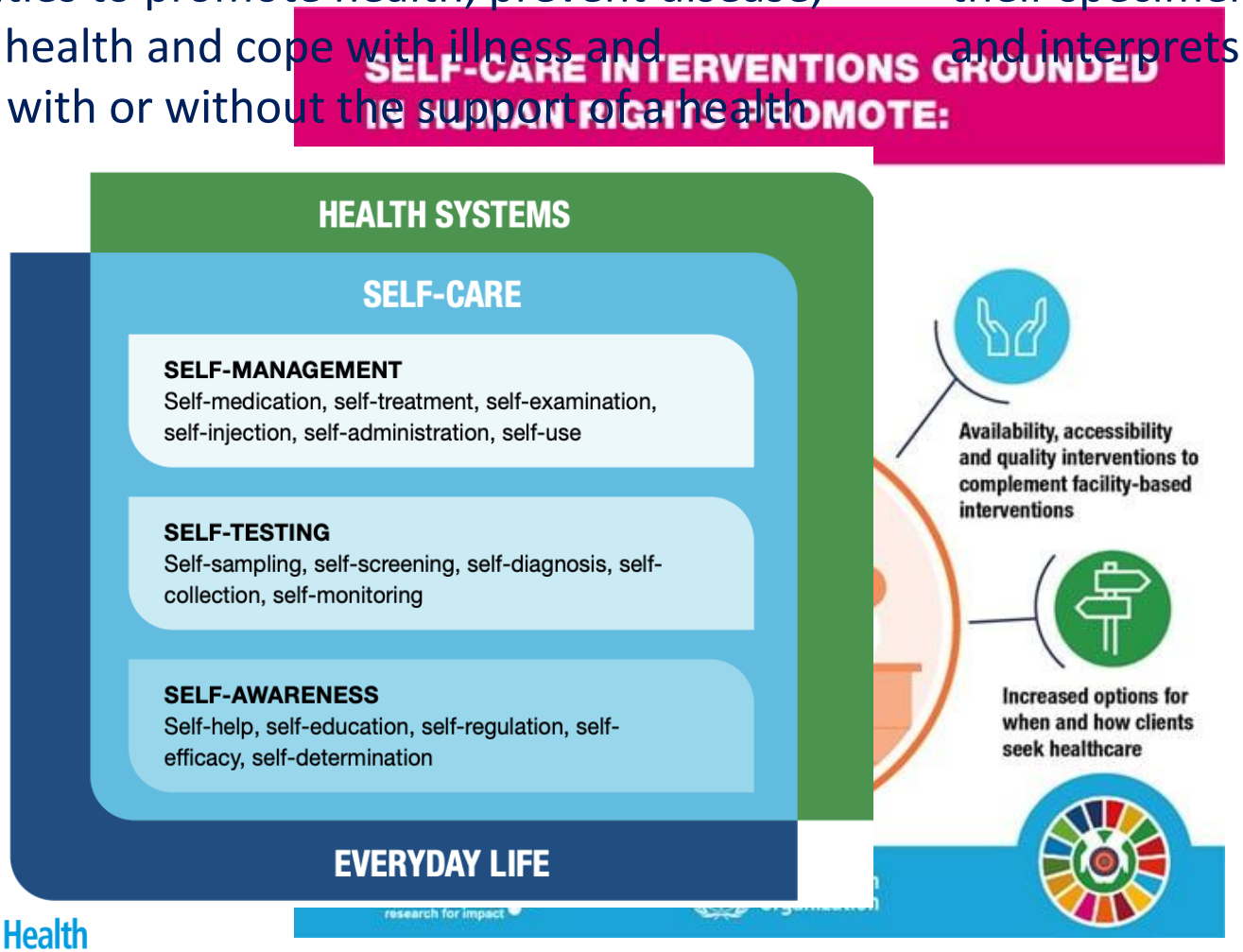
Strategic savings by focusing on first test

- Cost of the first test drives HIV testing programme costs
- Changing to low-cost delivery and test kits (A1) will lead to greatest saving

The self-care revolution: Why self-care?

Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health worker.

Self-testing is a process in which an individual collects their specimen using a simple RDT, performs the test, and interprets their result, when and where they want.



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HIV self-testing (HIVST) - a critical approach and adaptation

HIVST could lead to savings if replacing provider testing

- WHO recommends facility-based self-testing (2024)
- HIVST filled important gaps during COVID-19, especially in facilities
- HIVST provides flexibility – enables triage model
- HIVST can fill gaps in work force and save health worker time

Additional adaptations can further enhance savings

- Continue task-sharing testing wherever incomplete
- Revamp delivery to include pay for virtual services, convenience models, private sector, workplace, and pharmacy for population segments and settings where feasible

Source: WHO 2024, WHO 2021, WHO 2023, WHO 2015

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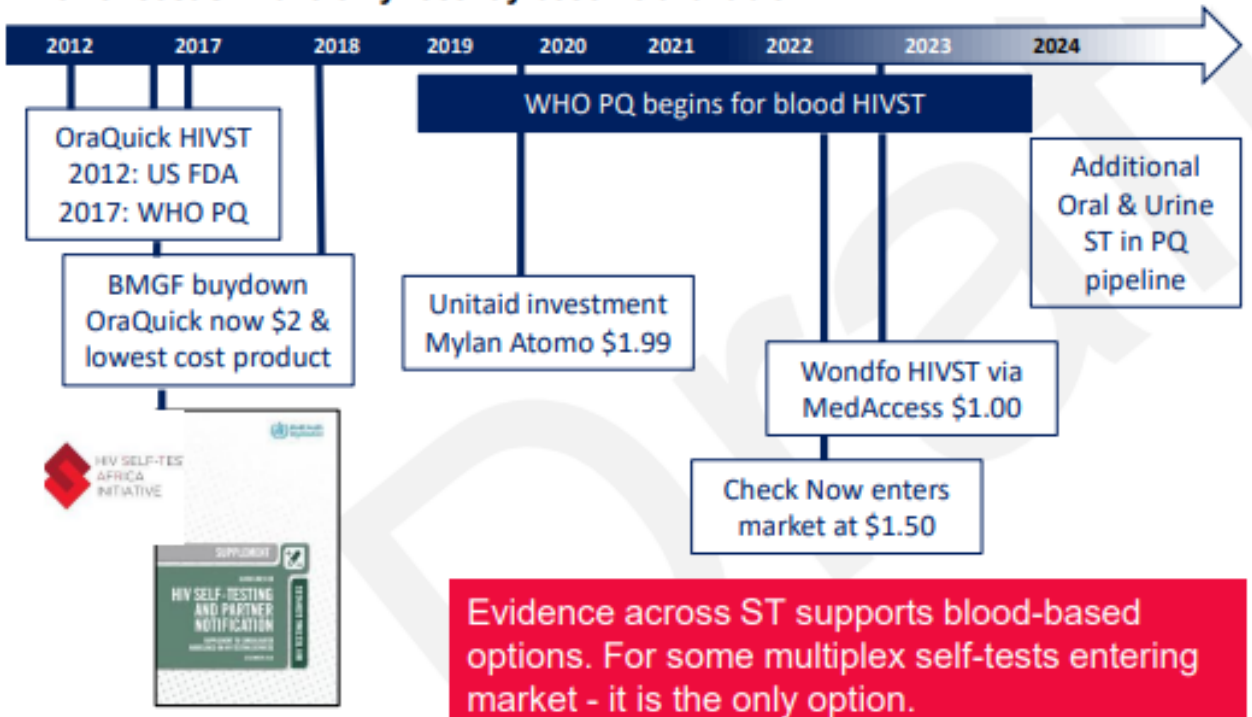
HIVST data shows no difference in uptake between blood and oral options – WHO guidance supports both

Market evolution

Many programmes **started with Oral ST as it was the only test available**, particularly STAR countries which continue to drive volumes. **Blood-based and lower cost ST have only recently become available**.



Evidence across ST supports blood-based options. For some multiplex self-tests entering market - it is the only option.

Evidence on uptake of blood vs oral tests

WHO conducted an evidence review (2023) to assess the impact of specimen type on test uptake and found **no significant difference in uptake, acceptability, usability or accuracy.** An interchangeability polic across all tests, irrespective of specimen type, may be possible.

Key findings

- **Uptake** between oral and blood ST did not significantly differ (1 RCT, oral: 139/163 (85%) vs blood: 135/166 (81%); RR= 1.05, 95%CI: 0.95-1.16)
- **Acceptability** varied – some participants may be more likely to choose oral ST if given the option but no significant differences. Preferences do appear to vary to some degree (7 studies).
- **Positivity** no significant difference between blood and oral ST (4 studies)
- **Usability/Feasibility** both oral and blood ST reported to be easy to use and interpret, similar usability and all PQ products of which there are 6 blood and 1 ST meet established usability and feasibility criteria (1 RCT, 2 studies)
- **Accuracy** both oral and blood ST have good performance. Blood ST has higher sensitivity, but both types of tests perform well and meet standards (3 studies).
- **Linkage** not assessed by any study, but likely no difference based on indirect evidence and programmatic experiences reported
- **Social harm** not assessed by any study, but likely no difference based on indirect evidence and programmatic experiences reported.

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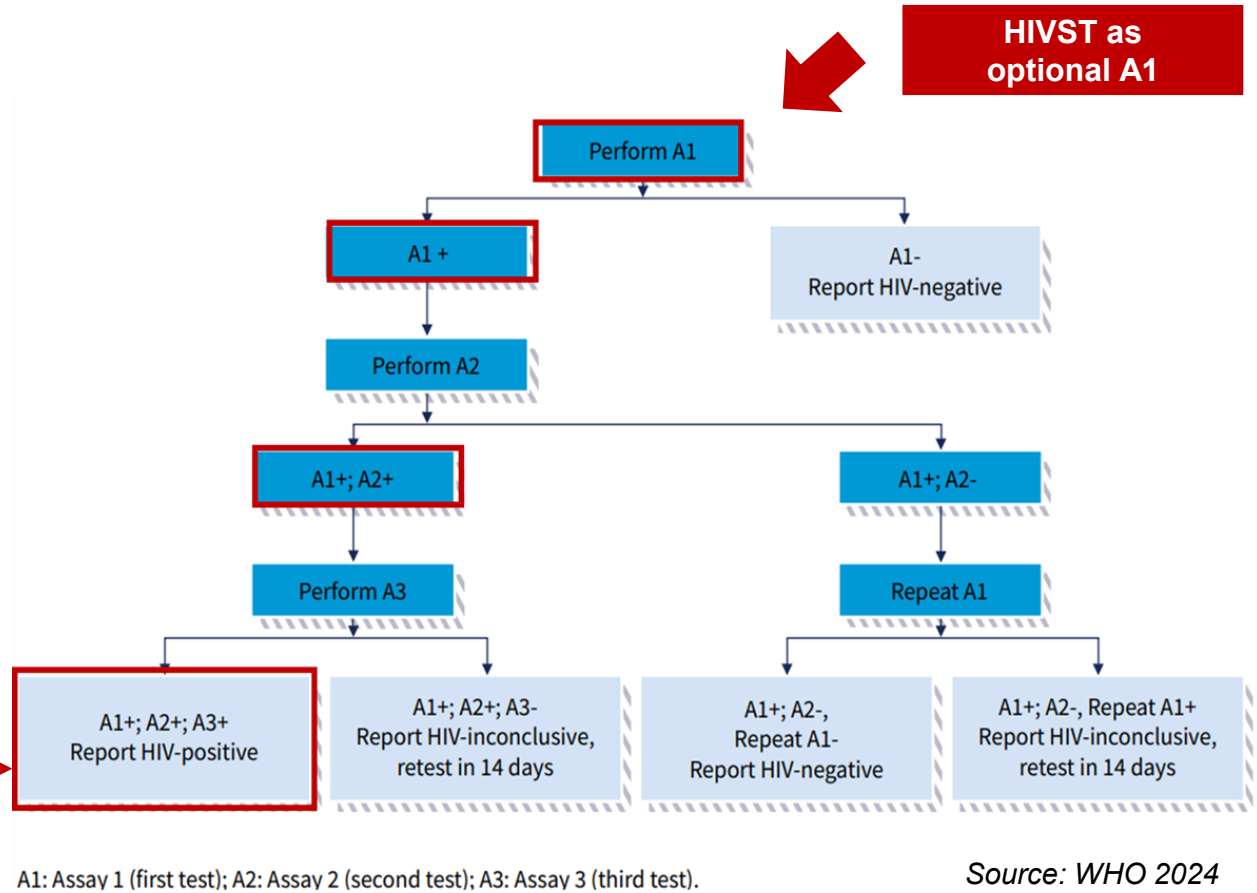
Countries already using HIVST to address ongoing disruptions

HIVST is recommended as a "test for triage"

- Countries need flexibilities now due to limited HRH capacity and stock-outs
- When needed (awaiting stock) use HIVST as A1
- Prioritize quality-assured HIVST kits
- Prioritize confirming all reactive self-test results with available A2 and A3 (per WHO 3-test strategy)
- Do not start ART based on a single reactive test
  - Substantial risk of misdiagnosis and unnecessary ART initiation

Adapted HIV testing strategy implementation considerations



A1: Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test).

Source: WHO 2024

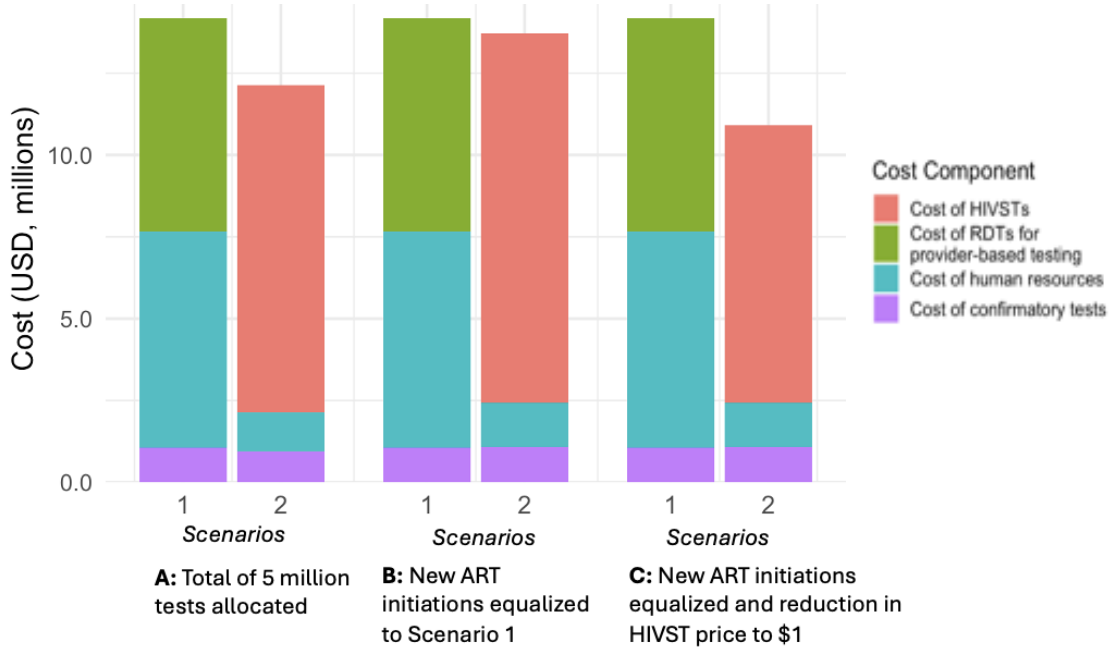
WHO already recommends facility-based HIV self-testing, expanded use could lead to more savings

Modelling on the cost-effectiveness of using HIVST in facilities to fill HRH gaps shows:

- **At least 15% cost-saving – up to 23% savings if using $1 WHO PQ HIVST**
- **Up to 85% reduction in staff-time**
- **If considering local economic impact (putting $$ toward jobs versus commodities)**
  - Return of investment (ROI) is the same at $1.50 but is favorable with high ROI at $1
- **Cost of change and scale-up?**
  - Costs still 1.5–3.0% lower, and total staff-time for testing still falls by 40% and 80% respectively, when considering scale-up costs

Preliminary results

Total cost, by component, of HIVST vs provider-testing scenarios



Country-facing calculator in development for local planning for optimal savings for HRH and HIVST

Source: WHO 2024, Nichols, Edun, Imai-Eaton, Bernsteyn, Johnson 2025 in preparation; for copy of the country calculator that is in beta-testing email johnsonc@who.int

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Additional strategies to support cost-effective HIV testing

- **Task-sharing to trained lay providers and community health workers**, who can provide these services at a low cost and with little infrastructure, per WHO guidance;
- Discontinue the **use of recency assays, western blot/LIA, NAT** (RNA or DNA) for routine HIV testing
  - **Reserve NAT for infant diagnosis** (< 18 months of age);
- **Adopt serial testing algorithms and discontinue parallel testing**, which is more expensive;
- **Streamline quality systems** by using **rapid assessments**, **simplified verification studies** with data collection during or after algorithm transition;
- **Further simplify testing** – such as **HIVST for PEP and PrEP** (initiation, continuation and re-initiation);
- **Utilize virtual platforms and private sector partnerships** (including workplace and pharmacies).

Key Take Home Messages – (low cost RDTs)

- **Cut costs without cutting quality**
  - Stick to the 3-test strategy and discontinue complex and costly testing practices
  - Only use serial testing algorithm with HIV RDTs or EIA (stop parallel testing – it is more expensive)
  - Discontinue use of recency assays, NAT (RNA or DNA), WB/LIA for routine HIV testing and diagnosis (>18 months of age) and question Ag/Ab RDT

- **Support rapid country transition**
  - Focus on switching out A1 (first test in algorithm) for greatest savings) and keep the existing A2/A3
  - Use policy waivers for WHO PQ products to accelerate importation and implementation
  - Focus on accelerated verification studies with different A1 options
  - Adopt streamlined, simplified training & QMS activities.
  - Push industry to fund training and QA/QC in new agreements and tenders

- **Place orders as soon as possible** with prices at or below those in WHO catalogue, pooled procurement and Wambo or direct procurement if lower cost available **(negotiate landed prices)**

- **Collect data in parallel or after algorithm transition** per WHO toolkit with low-cost candidate products and share data and experiences with WHO to inform updates

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Key Take Home Messages (leveraging HIVST)

- **Switch to lower cost quality-assured HIVST option (≤ $1.50)**
  - As countries – work with partners to drive prices down further (e.g. set-up coordinated procurement across countries, data and tool sharing, flexible algorithms)
  - Support flexible use of HIVST to maintain testing services
  - Support policies that include HIVST as A1
  - Highlight benefits of HIVST: it's flexible, fills staffing gaps, allows private sector use, used in COVID-19

- **Optimize resources to maintain testing services**
  - Review staffing plans and HIVST data to find the right balance based on country needs and gaps due to reduced personnel and testers
  - Review and use WHO country calculator (for details, contact johnsonc@who.int
  - Share HIVST data with WHO to help update operational guidance

Self-testing toolkit

WHO developed a self-testing implementation tool for HIV, HCV and syphilis

https://iris.who.int/handle/10665/380174

Become familiar with self-testing concept and guidance

Based on requirement and relevance, select thematic area

Find technical resources according to needs and context

Start here…

Module 1:
Understanding self-testing as part of self-care for HIV, HCV and syphilis

Module 2:
Planning and preparing for self-testing implementation

Module 3:
Product selection, registration, procurement, and supply chain

Module 4:
Implementation of self-testing

Module 5:
Monitoring and evaluation

Find relevant resources;

1. Overview of self-testing including algorithms
2. SOPs for planning and preparations
3. Demand creation for self-testing including awareness raising material
4. Distribution models
5. WHO prequalified products

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Modules

Planning and preparation

When considering HIVST, HCVST or SST introduction, developing a plan that will guide implementation, policy and regulatory development is important.

More information and resources

Demand creation

Demand generation strategies for self-testing involve community mobilization, social media campaigns, digital marketing, and coordination mechanisms with stakeholders to integrate self-testing.

More information and resources

Distribution models for self-testing

A range of service delivery and distribution models are effective in increasing the uptake of testing for HIV, HCV and syphilis and reaching people with the disease who are undiagnosed or those at ongoing risk.

More information and resources

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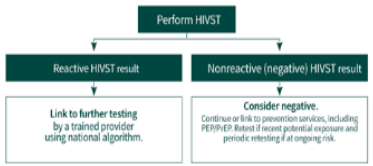
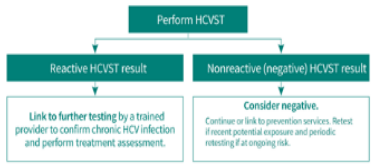
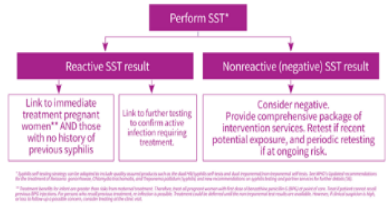
Key messages

- **Self-testing is a process in which an individual collects their specimen using a simple rapid diagnostic test, performs the test, and interprets their result, when and where they want.**
- **Self-testing increases access to and uptake of testing, prevention, and treatment services**. Self-testing can also increase patient autonomy, help decentralize services, and alleviate the burden of testing at facilities. Most people are willing and able to self-test.
- **Self-testing has been shown to be safe, accurate, acceptable, and feasibl**e, among diverse populations (particularly key populations) and across settings in various regions.
- **Reactive self-test results require follow-up and further testing**. HIVST and HCVST do not provide a diagnosis but require further testing by a trained provider using the national testing algorithm to confirm HIV or HCV infection and link individuals to care. A reactive SST result can be used to link to immediate treatment among pregnant women and those with no report of previous syphilis infection, however further testing is still needed to confirm an active infection in need of treatment.
- **Self-care approaches recognize the central and active role that people play in managing their own health care** and is increasingly becoming important as an additional strategy in expanding access to and utilization of health services, across various disease areas and conditions.

Self-testing strategies







Link

https://www.who.int/tools/self-testing-implementation-toolkit-for-hiv-hcv-and-syphilis

Facility-Based HIV Self-Testing: Implementation Toolkit and Training Modules

https://drive.google.com/drive/folders/1QSvhUk5O5DPfPPkgoAE5Cwl32kmlAGrS?usp=sharing

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WEBINAR SERIES

TEST. ADAPT. DELIVER.
HIV Testing Services in a Shifting Landscape

Navigating change, driving innovation and delivering impact in HIV testing services and beyond.

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HIV testing services are in crisis due to funding reductions, with rapid funding shifts prompting changes and interruptions in service delivery. Ensuring testing services remain accessible is critical to sustaining HIV treatment and prevention outcomes. More than ever, evidence-based guidance is critical to the prioritization, focusing, and planning of services across countries and regions.

This webinar series presents the latest evidence-based innovations, tools, and guidance in HIV testing services. It features experts sharing global guidance, country implementation experiences, practical toolkits, and strategies for maintaining quality and access in a rapidly evolving landscape. Topics include HIV testing in pregnancy, virtual-space interventions, self-testing, network-based approaches, and testing in prevention. Whether a policymaker, implementer, or researcher, this series offers valuable insights to strengthen HIV responses worldwide.

Each session will be conducted with simultaneous interpretation in English and in French.

DATE & TIME	SESSION
May 12, 2025 12:30 pm - 2 pm CAT/CET	**Prioritizing High-Quality, Low-Cost Diagnostics to Sustain HIV Testing Services**
May 15, 2025 2 pm – 3:30 pm CAT/CET	**Elimination: Maximizing the Impact of HIV Testing for Pregnant and Postpartum Women**
June 12, 2025 2 pm – 3:30 pm CAT/CET	**Operationalizing Facility-Based HIV Self-Testing: Launch of the Implementation Toolkit and Training Modules**
June 26, 2025 2 pm – 3:30 pm CAT/CET	**Launching of Budgeting and Resource Planning Guidance for Implementing Virtual Interventions as Part of HIV Responses**
July 9, 2025 2 pm – 3:30 pm CAT/CET	**Closing the Gaps: Launch of a Network-Based Testing Toolkit to Expand HIV, Hepatitis, and STI Testing Reach**
August 7, 2025 2 pm – 3:30 pm CAT/CET	**Innovating with HIV Self-Testing for Impact in Southern Africa: Lessons Learned from the STAR (Self-Testing Africa) Initiative**
September 4, 2025 2 pm – 3:30 pm CAT/CET	**Supporting PrEP Access: HIV Self-Testing in Uptake and Scale-Up**
October 9, 2025 2 pm – 3:30 pm CAT/CET	**Advancing Testing Quality: Launch of the WHO Management System Toolkit for Non-Laboratory Settings**
November 13, 2025 2 pm – 3:30 pm CAT/CET	**Delivering HIV Testing Services in a Changing Environment: Planning, Prioritization, and Maintaining Access**

For more information about this webinar series, visit our webpage.

Save the date!

- More content available and coming soon
- More WHO webinars on strategic adaptations for efficiency and savings for HIV testing
  - Next webinar is on Thursday **26 June**

Register here: https://www.psi.org/test-adapt-deliver-hiv-testing-services-in-a-shifting-landscape/

- **Need more support?**
  - Connect with the testing team
    - johnsonc@who.int

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Acknowledgements

WHO team:

Celine Lastrucci, Cherly Johnson, Carlota Baptista da Silva, Aliza Moroe-Wise, Anne Bekelynck, Magdalena Barr-Dichiara, Boniface Dongmo Nguimfack
Purvi Shah

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Operationalizing Facility-Based HIV Self-Testing: Launch of the Implementation Toolkit and Training Modules

Bernhard Kerschberger, Population Services International

World Health Organization

🟩 Objective of the Training Toolkit

➡️ To provide a practical and adaptable toolkit to support the orientation and training of health workers in implementing and scaling up **facility-based HIV self-testing** across diverse healthcare settings.

🟩 Module Structure

Progressive Learning & Module Linkages

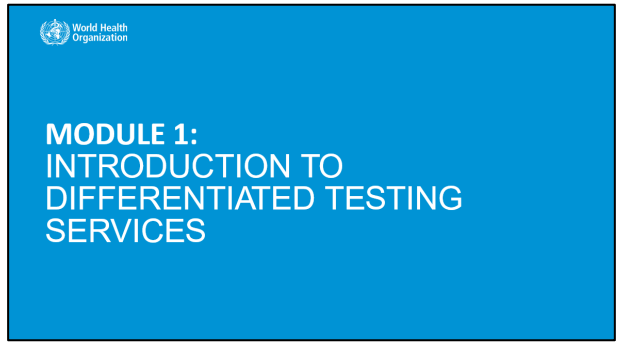
✅ Each module builds upon the previous one, avoiding redundancy and ensuring a coherent learning progression.

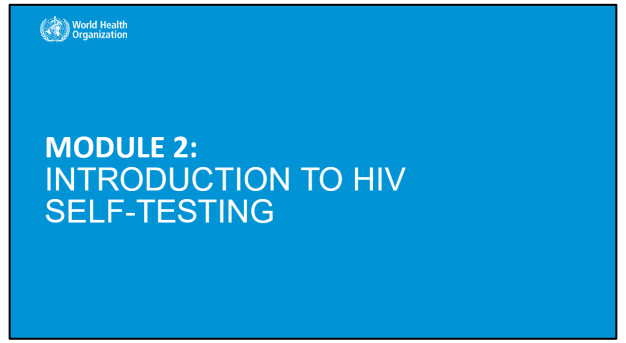
✅ The content evolves from foundational concepts to practical implementation, service delivery optimization, and monitoring & evaluation.

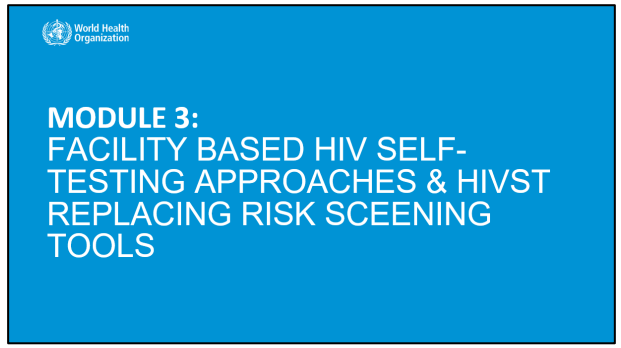
✅ Depending on the participant's background and training needs, all modules or a selected combination can be used flexibly.

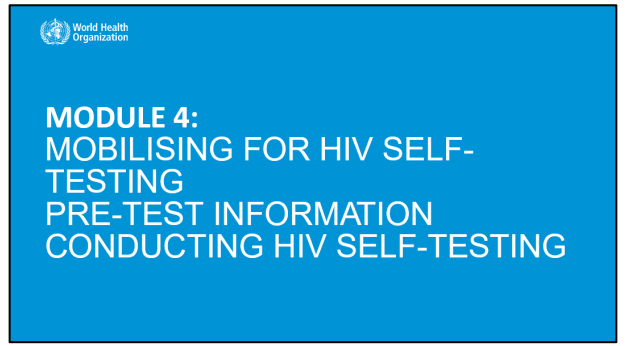
Overview of Modules

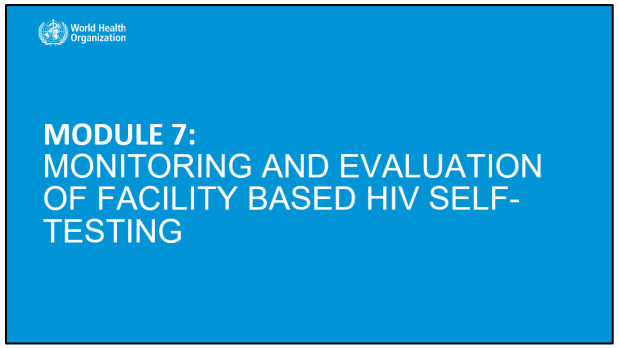
- ✓ MODULE 1: Introduction to differentiated testing services
- ✓ MODULE 2: Introduction to HIV self-testing
- ✓ MODULE 3: Facility based HIV self-testing approaches & HIVST replacing risk screening tools
- ✓ MODULE 4: Mobilising for HIV self-testing pre-test information, conducting HIV self-testing
- ✓ MODULE 5: Facility based HIVST distribution approaches
- ✓ MODULE 6: HIV self-testing flowcharts, services lay-out & SOPs
- ✓ MODULE 7: Monitoring and evaluation of facility-based HIV self-testing





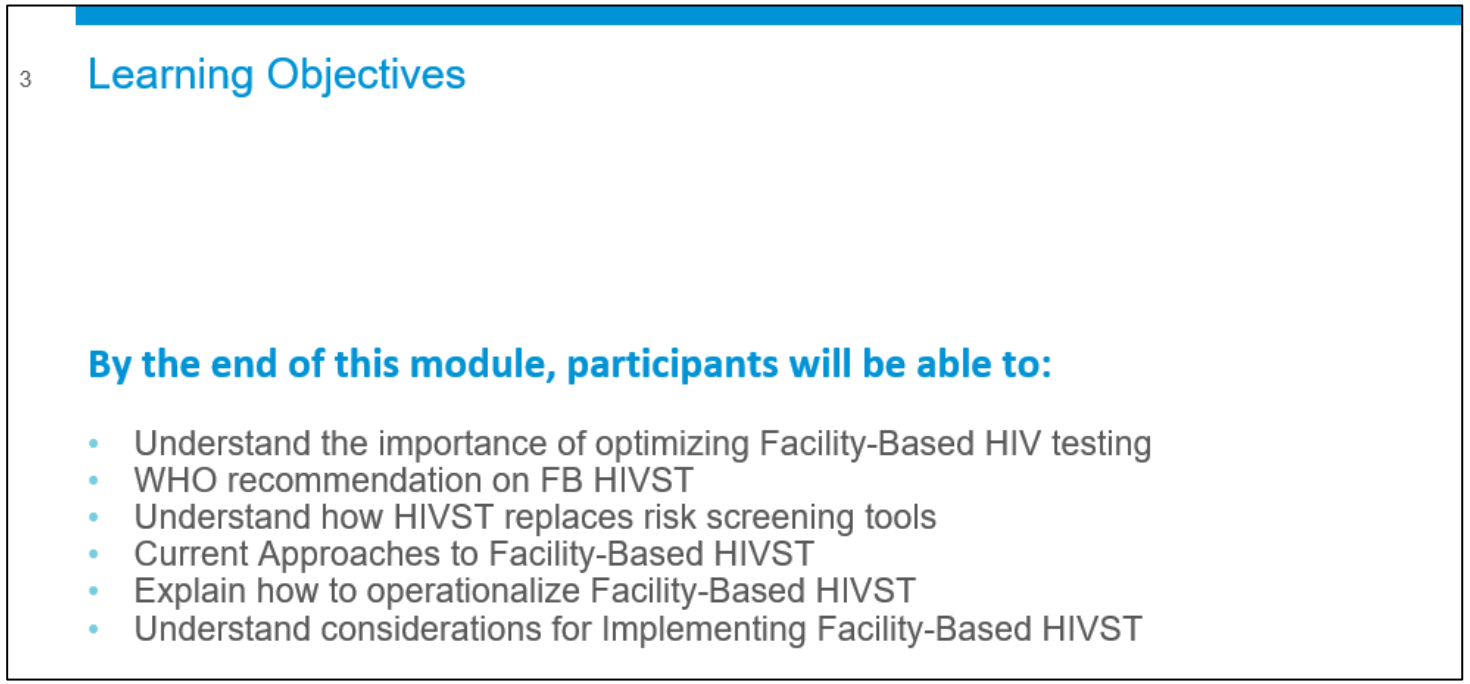






🟩 Learning Objectives

- Each module begins with clearly defined learning objectives.
- These objectives offer a concise overview of the key content covered in the module.



🟩 Module-Specific Questions

- At the end of each module, a set of module-specific questions reinforces the content covered.
- Some questions are also designed to prepare participants for the next module.
- Facilitators may choose to use all or a selection of these questions, depending on the learning context

Questions

What is the main rationale for introducing HIVST in facility-based settings?
- Why might HIVST be preferred over traditional risk-based screening tools in high-prevalence settings?
- How does facility-based HIVST improve testing coverage and access?

What are the current WHO recommended approaches to facility-based HIVST, and how are they implemented?
- Can you explain the difference between primary-and secondary distribution in facility-based HIVST?

How does HIVST replace HIV risk screening tools?

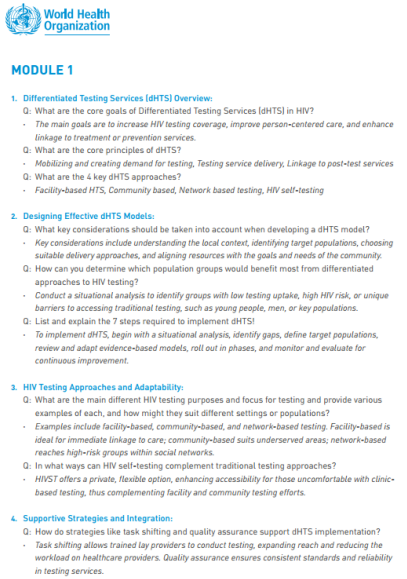
What factors should be considered when implementing HIVST in a healthcare facility?
- Why is it important to consider the local HIV epidemic profile and target populations?
- How do workload and facility setup impact the choice between HIVST and provider-administered testing?

Which populations benefit most from facility-based HIVST?
- Can you identify priority populations that are often underserved in facility-based testing?
- Why might facility-based HIVST be especially useful for PrEP/PEP users, sero-discordant couples, and young adults?

What are the facility –based entry points for HIVST, what are the opportunities?

What are some operational considerations for ensuring the success of facility-based HIVST?
- Why is it crucial to maintain a steady supply of HIVST kits and establish clear testing protocols?
- How can monitoring and feedback mechanisms improve the quality and effectiveness of facility-based HIVST?

⭐ A pdf file is provided that covers the questions of all modules with answers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MODULE 1

1. Differentiated Testing Services (dHTS) Overview:
   - Q: What are the core goals of Differentiated Testing Services (dHTS) in HIV?
   - *The main goals are to increase HIV testing coverage, improve person-centered care, and enhance linkage to treatment or prevention services.*
   - Q: What are the core principles of dHTS?
   - *Mobilizing and creating demand for testing, Testing service delivery, Linkage to post-test services*
   - Q: What are the 4 key dHTS approaches?
   - *Facility-based HTS, Community based, Network based testing, HIV self-testing*

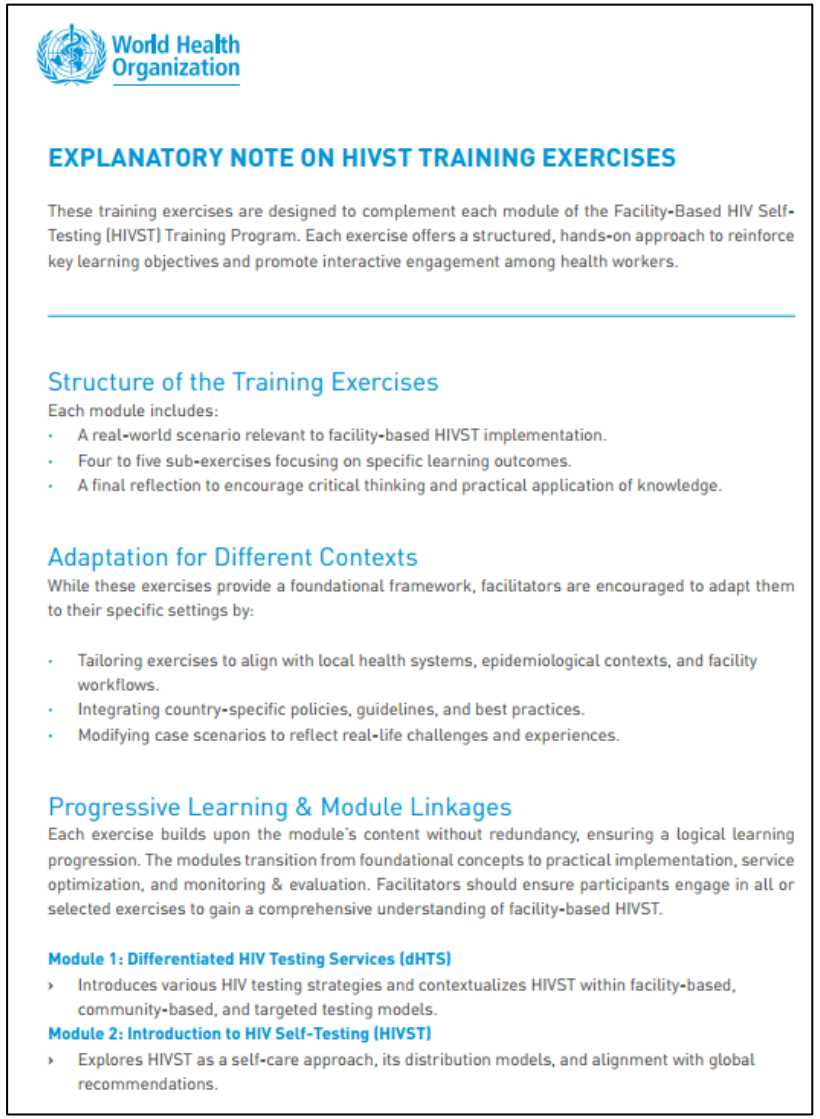
2. Designing Effective dHTS Models:
   - Q: What key considerations should be taken into account when developing a dHTS model?
   - *Key considerations include understanding the local context, identifying target populations, choosing suitable delivery approaches, and aligning resources with the goals and needs of the community.*
   - Q: How can you determine which population groups would benefit most from differentiated approaches to HIV testing?
   - *Conduct a situational analysis to identify groups with low testing uptake, high HIV risk, or unique barriers to accessing traditional testing, such as young people, men, or key populations.*
   - Q: List and explain the 7 steps required to implement dHTS!
   - *To implement dHTS, begin with a situational analysis, identify gaps, define target populations, review and adapt evidence-based models, roll out in phases, and monitor and evaluate for continuous improvement.*

3. HIV Testing Approaches and Adaptability:
   - Q: What are the main different HIV testing purposes and focus for testing and provide various examples of each, and how might they suit different settings or populations?
   - *Examples include facility-based, community-based, and network-based testing. Facility-based is ideal for immediate linkage to care; community-based suits underserved areas; network-based reaches high-risk groups within social networks.*
   - Q: In what ways can HIV self-testing complement traditional testing approaches?
   - *HIVST offers a private, flexible option, enhancing accessibility for those uncomfortable with clinic-based testing, thus complementing facility and community testing efforts.*

4. Supportive Strategies and Integration:
   - Q: How do strategies like task shifting and quality assurance support dHTS implementation?
   - *Task shifting allows trained lay providers to conduct testing, expanding reach and reducing the workload on healthcare providers. Quality assurance ensures consistent standards and reliability in testing services.*

🟩 Additional Exercises (1)

- After each module, a selection of exercises is provided for facilitators to choose from (separate pdf files)
- Facilitators should ensure that participants engage in all or selected exercises to develop a strong understanding of facility-based HIVST.
- Each exercise includes an explanatory note to guide facilitation.
- Exercises can be used as provided or adapted to fit the local context.



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EXPLANATORY NOTE ON HIVST TRAINING EXERCISES

These training exercises are designed to complement each module of the Facility-Based HIV Self-Testing (HIVST) Training Program. Each exercise offers a structured, hands-on approach to reinforce key learning objectives and promote interactive engagement among health workers.

Structure of the Training Exercises

Each module includes:

- A real-world scenario relevant to facility-based HIVST implementation.
- Four to five sub-exercises focusing on specific learning outcomes.
- A final reflection to encourage critical thinking and practical application of knowledge.

Adaptation for Different Contexts

While these exercises provide a foundational framework, facilitators are encouraged to adapt them to their specific settings by:

- Tailoring exercises to align with local health systems, epidemiological contexts, and facility workflows.
- Integrating country-specific policies, guidelines, and best practices.
- Modifying case scenarios to reflect real-life challenges and experiences.

Progressive Learning & Module Linkages

Each exercise builds upon the module's content without redundancy, ensuring a logical learning progression. The modules transition from foundational concepts to practical implementation, service optimization, and monitoring & evaluation. Facilitators should ensure participants engage in all or selected exercises to gain a comprehensive understanding of facility-based HIVST.

Module 1: Differentiated HIV Testing Services (dHTS)

› Introduces various HIV testing strategies and contextualizes HIVST within facility-based, community-based, and targeted testing models.

Module 2: Introduction to HIV Self-Testing (HIVST)

› Explores HIVST as a self-care approach, its distribution models, and alignment with global recommendations.

🟩 Additional Exercises (2)

- Each exercise includes its own objectives, learning outcomes, takeaway messages, and a scenario.
- This is followed by up to five tasks, which may involve group work, role play, group discussion, or self-reflection

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MODULE 4 EXERCISE
MOBILISING FOR HIV SELF-TESTING & PRE-TEST INFORMATION, CONDUCTING HIVST

OBJECTIVE
This exercise will help health workers understand and apply effective demand creation strategies, pre-test information delivery, and support for HIV self-testing (HIVST) in diverse facility and community settings.

LEARNING OUTCOMES
By completing this exercise, participants will:
- Describe mobilization approaches for promoting facility based HIVST (primary and secondary distribution).
- Deliver clear and effective pre-test information to different target groups.
- Role-play HIVST procedures and practice client support.
- Provide tailored support to clients learning how to test themselves.

TAKEAWAY MESSAGE
Effective demand creation and pre-test communication are essential for ensuring HIV self-testing (HIVST) accessibility, acceptability, and uptake. Proper mobilization strategies should be client-centered, stigma-free, and inclusive, empowering individuals to make informed decisions following the outcome of their HIV status.

SCENARIO
You are a health worker responsible for mobilizing communities for HIV self-testing (HIVST) at the facility, and ensuring clients receive appropriate pre-test information. Your role includes designing mobilisation and demand creation strategies, delivering pre-test messages, and guiding clients through the HIVST process.

TASKS

1. MOBILIZATION APPROACHES FOR HIVST
Instructions:
- In small groups, analyze different mobilization approaches:
  - Social media & online campaigns
  - Mobile phone-based interventions
  - Health talks & educational sessions
- Develop a brief strategy for promoting HIVST in a chosen setting.

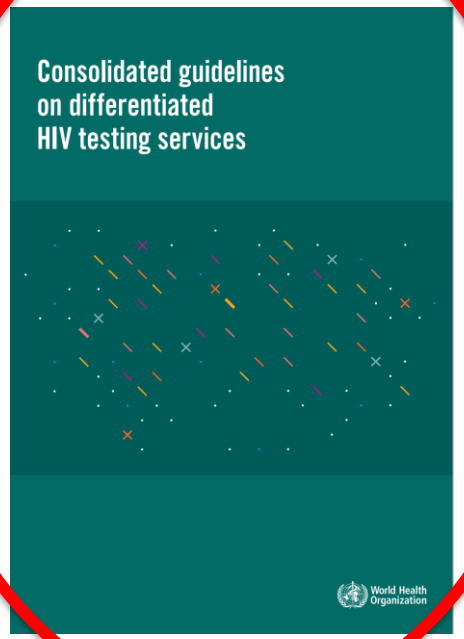
Focus Areas:
- Compare potential costs and reach of different mobilization platforms.
- Identify potential barriers to uptake and propose solutions.

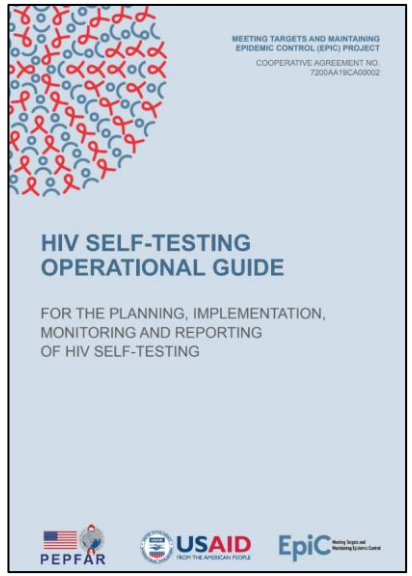
2. EFFECTIVE PRE-TEST INFORMATION DELIVERY
Instructions:
- In pairs, practice delivering pre-test information for HIVST.
- Ensure the message includes:
  - Purpose of HIVST and its benefits.
  - How to use the test kit correctly.
  - Interpreting results (reactive, non-reactive, invalid).
  - Next steps for confirmatory testing and prevention services.

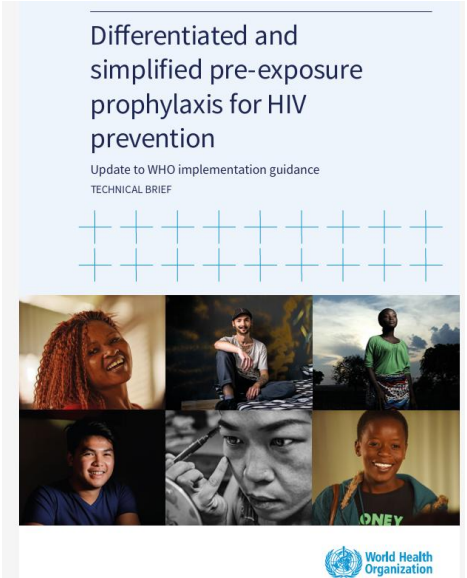
Focus Areas:
- Ensure clarity, client-friendly language, and non-judgmental communication.
- Address common myths and concerns about HIVST.

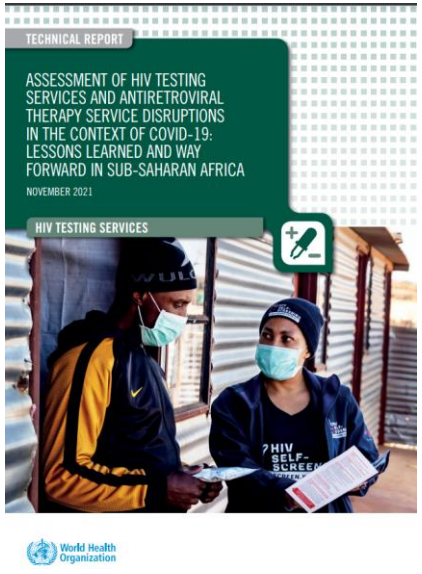
3. ROLE-PLAYING HIVST PROCEDURES
Instructions:
- Pair up and take turns role-playing:
  - One participant acts as a client using an HIVST kit.
  - The other acts as a health worker providing guidance.
- Provide step-by-step instructions on:
  - Opening the test kit.

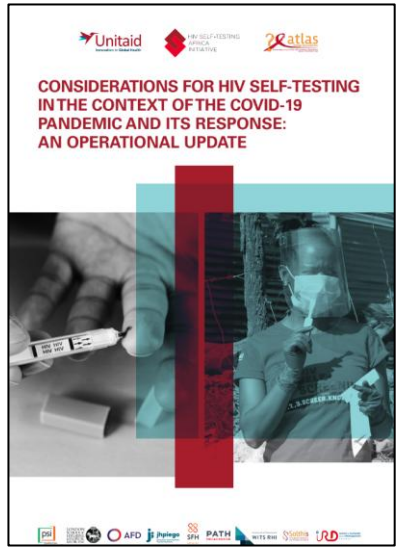
Content Draws on WHO Background Documents, Implementation Guides & Past Lessons Learned











🟦 Highlights from Modules 1 to 7

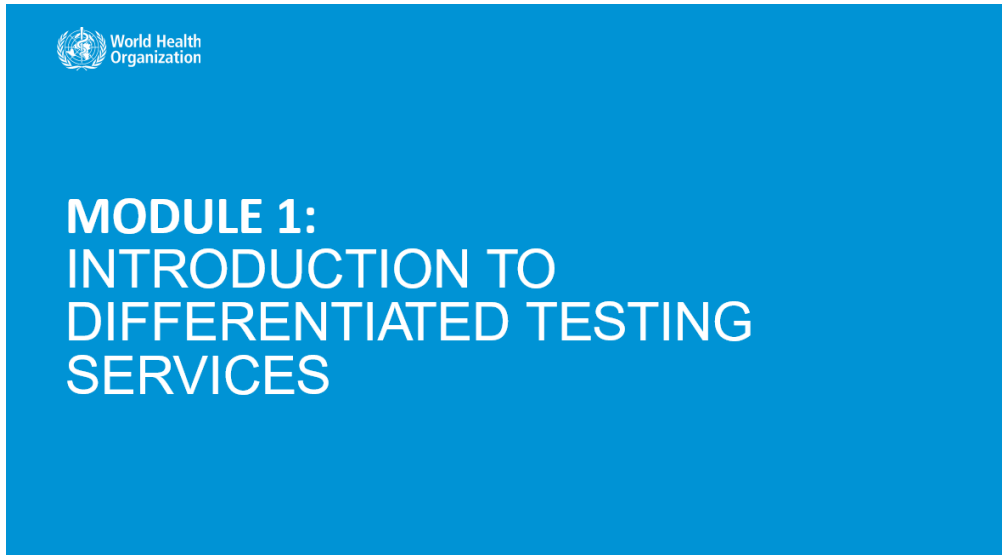
🟦 Module 1

➡️ Objectives

To introduce the principles, approaches, and steps of differentiated HIV testing services (dHTS) and their integration into health systems.

✅ Content

- ✓ Define differentiated service delivery HIV testing services
- ✓ Describe the core principles of dHTS
- ✓ Demonstrate understanding of the 4 different HIV testing approaches
- ✓ Describe the two different HIV testing focuses and provide various examples of each
- ✓ List and explain the 7 steps required to implement dHTS
- ✓ Describe the three Health systems strategies for HTS service delivery14



Case-finding focused HIV testing priorities

Effective Focused Facility-based HTS	
High burden settings: HTS in every health contact – integration	Low burden settings: HTS in hotspots/select services (TB, STI, key pops)

HIVST & Community Approaches	
High burden settings: Outreach for key pops, partners PLHIV, hotspots, consider workplaces, strategic outreach	Low burden settings: Outreach to key pops, partners of PLHIV

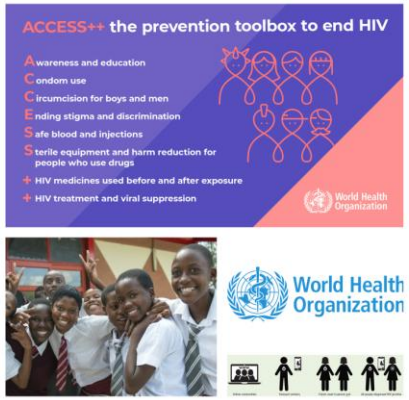
Couples and Partners	
High burden settings: For all partners of KP and PLHIV	Low burden settings: All partners of KP and PLHIV

Focus on identifying PLHIV who are unaware of their status as effectively as possible (ensuring the right populations are reached) and as efficiently as possible (making optimal use of resources).

Prevention focused HIV testing priorities

HIV testing services are also part of implementing and monitoring prevention services to help:	
HIV-Negative people stay negative (monitoring)	Diagnose PLHIV at high risk and start ART as soon as possible

Core HIV Prevention packages with HTS:		
PMTCT (1st ANC visit test for all, late pregnancy 3rd trimester only for KP or in high burden settings)	VMMC – 1 test or self-test	PrEP – frequent testing & self-testing
Key populations testing at least annually (up to 3-6 month based on risk)	Serodiscordant couples package of services annually (up to 3-6 month based on risk)	AGYW in ESA package of services



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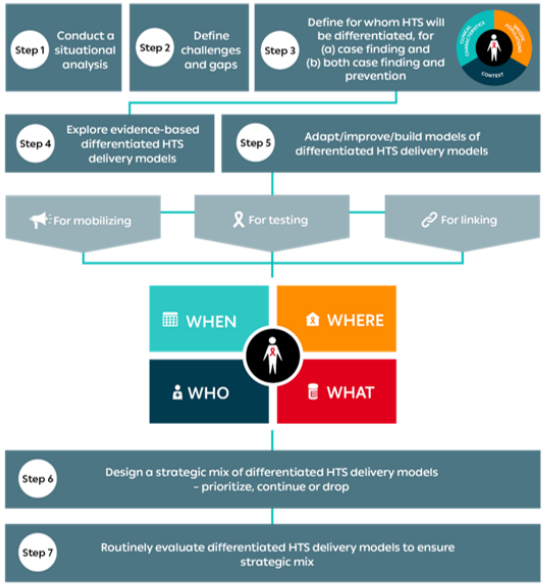
The 7-Step Approach to implementing dHTS



Source: www.differentiatedservicedelivery.org/Models/Testing

1. **Situational Analysis:**
   - Assess current testing services, identify gaps, and understand diverse population needs.
   - Process must be rapid and led by MoH
   - Include stakeholder mapping of partners who will support implementation.
2. **Identify Challenges & Gaps:**
   - Highlight issues to be addressed through DSD approaches.
3. **Define Target Populations:**
   - Determine target populations for tailored testing based on clinical and contextual factors.
4. **Review Evidence-based Models:**
   - Explore proven models to guide effective dHTS strategies.
5. **Adapt & Develop Models:**
   - Modify/create new service delivery models to address identified needs.
6. **Implement Phased Rollout:**
   - Launch adapted models and train in a stepwise approach.
7. **Monitor & Evaluate:**
   - Continuously assess and refine testing services for effectiveness and impact.

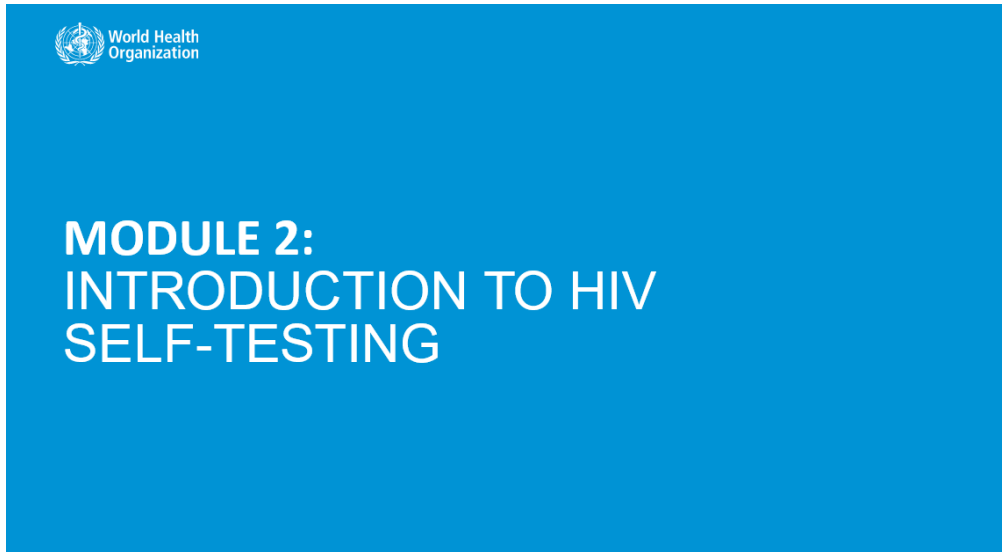
🟦 Module 2

➡️ Objectives

To build foundational knowledge on HIV self-testing (HIVST), including its benefits, use cases, diagnostic tools, and integration into prevention services.

✅ Content

- ✓ Define and describe the concept of HIV Self-Testing (HIVST)
- ✓ Explain HIVST and test for triage
- ✓ Understand the evidence supporting the use of HIVST
- ✓ Describe selfcare and self-testing
- ✓ Know about available HIVST diagnostic test kits
- ✓ Explain the potential benefits of HIVST
- ✓ New recommendations for HIVST use
- ✓ Know about the use of HIVST in PrEP and PEP and country uptake
- ✓ Understand the HIVST distribution methods
- ✓ HIVST distribution models and use cases



2

Self-Testing?

Self-testing recommended across conditions and diseases

Self-testing and self-care becoming standard of care across many differer areas

No difference in blood vs oral self-tests performance
- Both accurate and acceptable - no difference in uptake

HIVST recommended in health facilities
- Complimenting existing provider-administered HIV testing
- Replacing risk-based screening tools

HIVST recommended for PEP and PrEP (oral & DVR)
- Covers PrEP initiation, re-initiation and continuation
- No need for further testing to confirm negative results
- Ongoing research for long-acting injectable PrEP is needed

Syphilis ST, including dual HIV/syphilis ST, recommended
- More multiplex ST likely in the future, Critical opportunity for integration

2

Planning of HIVST Services

Use frameworks for planning

	MOBILIZING	TESTING	LINKING
WHEN	What is the best day/week to distribute HIVST an mobilize the largest number of clients?	What is the best time of the day to provide testing? How frequently should testing be offered?	What is the best time period and interval for linkage and follow up?
WHERE	Where should mobilization activities be focused?	Which sites should be prioritized? Community, health facility, outreach, private sector, etc.	Client preferred facility or IP community services
WHO	Who does the mobilization?	Who distributes the best kits and performs the best test kits?	Who links the client to confirmatory testing or treatment following a reactive self-test result or linkage to prevention for non-reactive results?
WHAT	What is being distributed? HIVST kits alone, or a combination of services and information?	Is HIVST being done alone or in combination with other services?	Could test message, phone or community-based follow up be used to support linkage to prevention or ART initiation?

Source: HIV Self-Testing Operational Guide – For the planning, implementation, monitoring and reporting of HIV self-testing. PEPFAR, USAID, EpiC, 2021

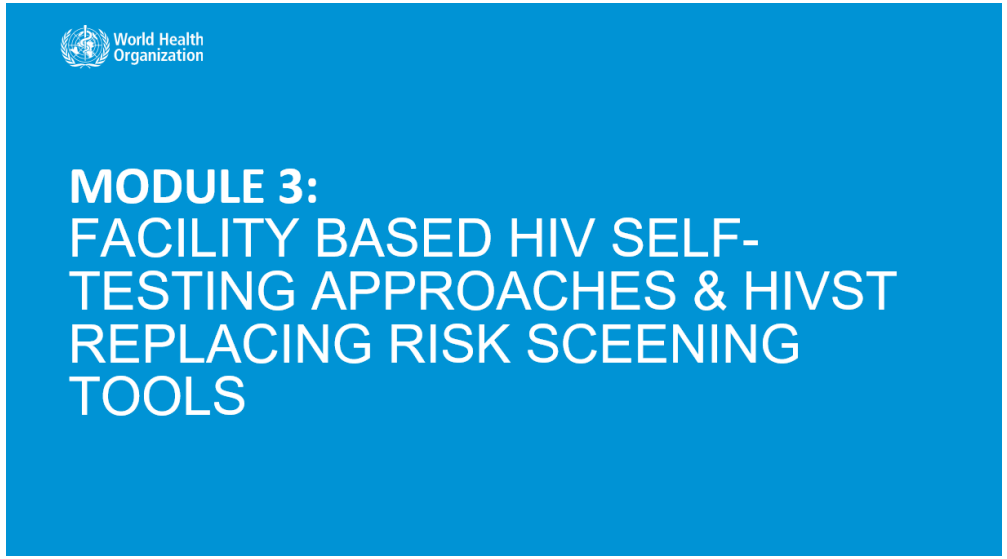
🟦 Module 3

➡️ Objectives

To provide guidance on implementing and optimizing facility-based HIV self-testing approaches, including replacing traditional risk screening tools

✅ Content

- ✓ Understand the importance of optimizing Facility-Based HIV testing
- ✓ WHO recommendation on Facility-Based HIVST
- ✓ Understand how HIVST replaces risk screening tools
- ✓ Current approaches to Facility-Based HIVST
- ✓ Explain how to operationalize Facility-Based HIVST
- ✓ Understand considerations for Implementing Facility-Based HIVST



3

Why replace Screening Tool with HIVST in Facilities?

HIVST can increase detection of HIV:

In high-prevalence areas, risk-based screening tools overlook significant portions of individuals needing testing. HIVST detects 9% more PLHIV than risk-based screening.

Workload reduction:

HIVST reduces healthcare worker time spent on provider-administered testing/ risk-based screening by 82%. Eases facility congestion, allowing staff to focus on higher-need medical cases.

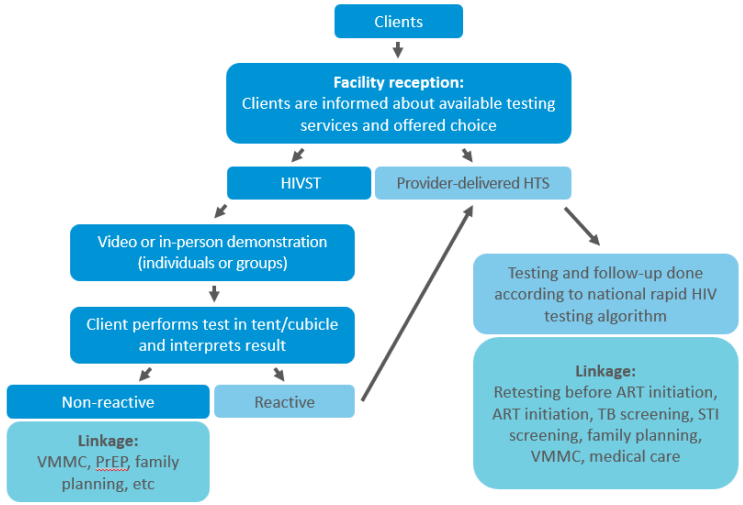
Cost Consideration:

With reduced HIVST kit prices, HIVST is at lower costs compared to risk-based screening approaches, which are provider administered. Need to consider costs for missing HIV positive clients who are not diagnosed and initiate on treatment.

Source: HTS for the Sustainability of the HIV Response. CQUIN dHTS Meeting | July 9 - 12, 2024 – Durban, South Africa

3

Facility Based HIV Self-Testing – Client flow



HIVST can mitigate

- Limited staff capacity
- Time constraints for HTS
- Counsellor workload
- Work-space constraints

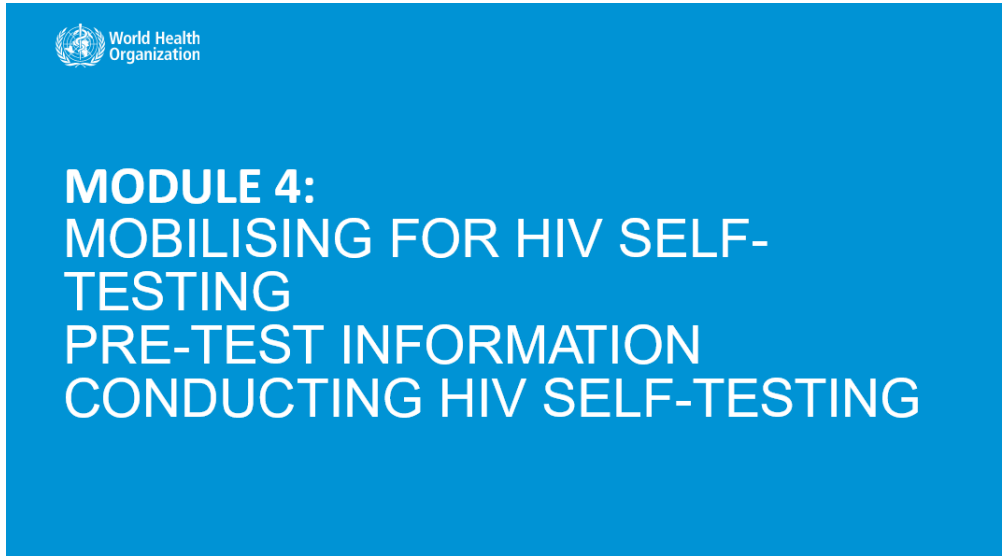
🟦 Module 4

➡️ Objectives

To equip providers with the skills to mobilize clients, deliver pre-test information, and support clients in conducting HIV self-testing

✅ Content

- ✓ Outline key demand creation principles
- ✓ Describe the platforms for demand creation
- ✓ Explain how to provide clear pre-test information for HIVST
- ✓ Describe how HIV self-testing is conducted
- ✓ Role play HIVST procedure
- ✓ Have knowledge of how to support clients learning how to test



4

Step by Step Guide for providers to demonstrate HIV Self-Testing (1)

Introduce the HIVST:

- Explain the purpose of HIVST and briefly describe the testing steps.
- Show the kit components: Display each item in the kit (e.g., swab, test device, buffer solution, lancet for blood-based tests) and explain their use.
- Demonstrate sample collection: For oral tests, show how to swab the gums properly. For blood-based tests, demonstrate finger-pricking safely using a lancet.
- Explain test activation: Show how to place the sample (swab or blood drop) on the test device and activate the test (e.g., adding buffer solution).
- Describe waiting time: Inform the client about the required wait time (usually 20 minutes) before reading the result.
- Guide on result interpretation: Explain how to read the results, covering reactive, negative, and invalid outcomes.
- Discuss disposal: Instruct on safe disposal of test materials after testing.

4

Client Reads the Results

NON-REACTIVE RESULT

- Only one line appears (Control line).
- Interpretation: HIV-negative No detectable HIV antibodies
- Next Steps: No need for further testing.
- Those at high ongoing risk should be offered PrEP and PEP, if and when eligible

REACTIVE RESULT

- Two lines appear (Control and Test lines).
- Interpretation: Possible HIV infection.
- Next Steps: This is not a definitive result. Requires further testing by a trained provider, beginning with the first test (A1) in national testing algorithm
- Initiate post-test counselling as per need. Perform or link to provider-administered RDT testing.

INVALID RESULT

- No lines, or only the test line appears.
- Interpretation: Invalid results. The test did not work correctly and cannot be interpreted
- Next steps: Discard this test and retest with a new kit or the client can be offered provider-administered RDT testing.

🟦 Module 5

➡️ Objectives

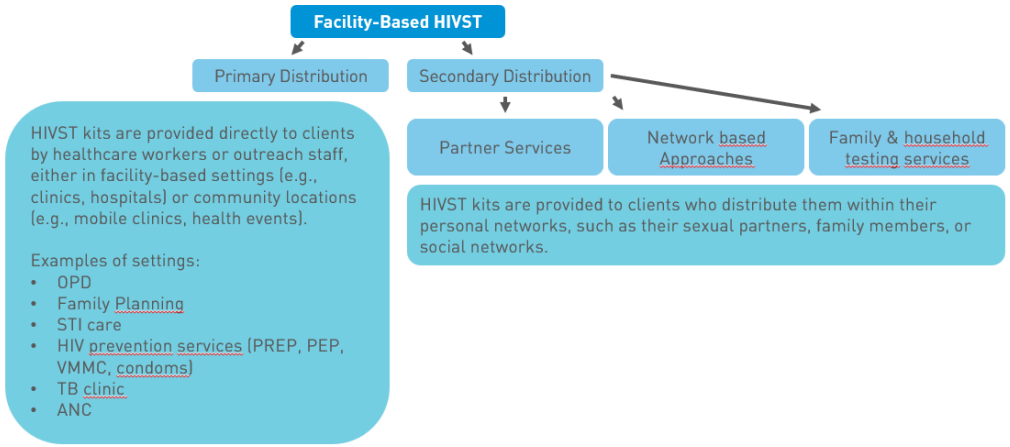
To explain the operational models, logistics, and key considerations for distributing HIVST kits within health facilities

✅ Content

- ✓ Understand facility-based HIVST Distribution Models
- ✓ Explain the difference between primary and secondary HIVST distribution
- ✓ Describe the operational considerations for each distribution model
- ✓ Know about the challenges and solutions related to HIVST Distribution

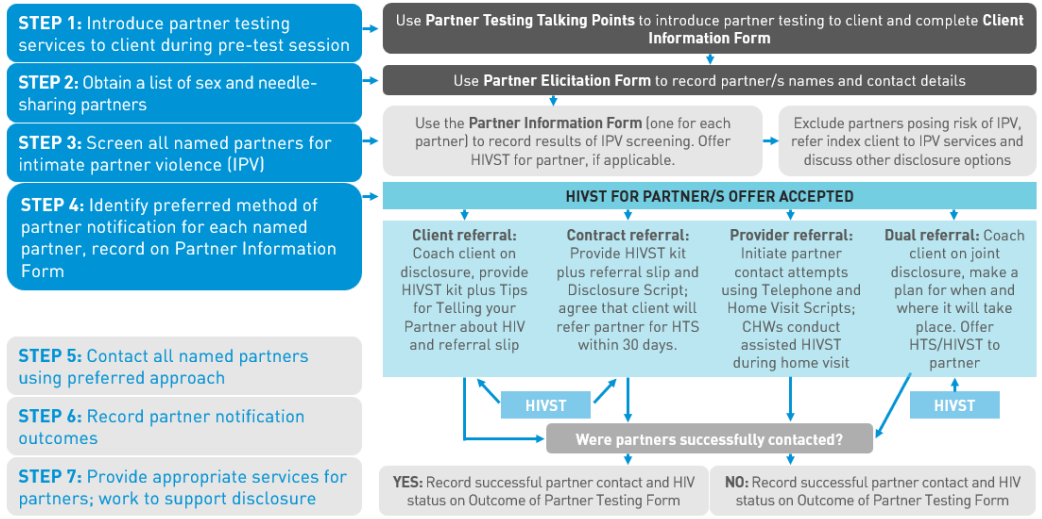
5

Overview of Facility-Based HIVST Distribution Approaches



5

Example for Steps in Provision of Partner Services



Source: HIV Self-Testing Operational Guide – For the planning, implementation, monitoring and reporting of HIV self-testing. PEPFAR, USAID, EpiC, 2021

🟦 Module 6

➡️ Objectives

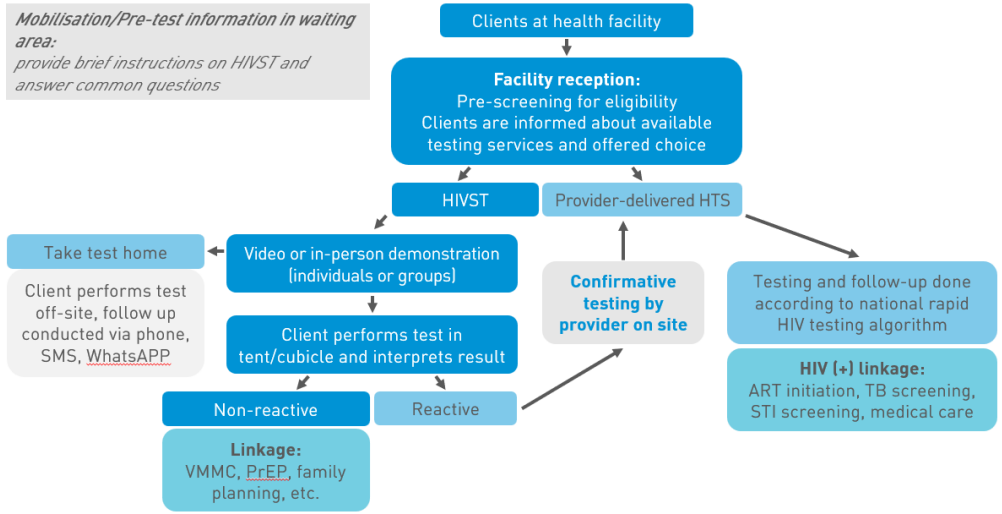
To support the design and setup of effective HIVST service delivery through flowcharts, layout planning, and job aids

✅ Content

- ✓ Design patient flow charts for HIVST in facilities
- ✓ Understand the various available options for HIVST stations
- ✓ Know the various digital and print resources available to clients in facilities

6

Flowchart: Facility Based Primary Distribution



6

Operational Aspects (1) – HIVST stations: Indoor Spaces within Facilities

Private Rooms or Partitioned Areas:

- **Room setup:** Use designated private rooms with ventilation and comfortable seating
- **Partitions and cubicles:** Use portable partitions OR tents to create testing spaces in larger rooms or waiting areas
- **Signage for privacy:** Clearly mark areas with signs like "Testing in Progress" to maintain confidentiality

Dedicated HIVST Stations:

- **Centralized kiosk or desk:** Place an HIVST station in high-traffic areas to increase accessibility
- **Information desk:** Provide staff to answer questions, distribute kits, and clarify the testing process

Separate Entry and Exit Points:

- Where possible, create separate entrances and exits for discreet client flow

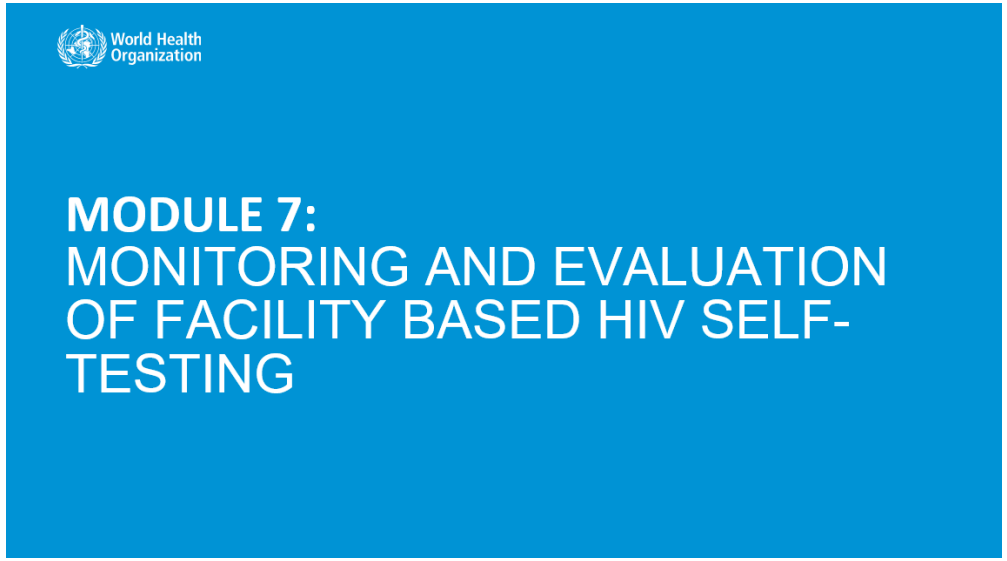
🟦 Module 7

➡️ **Objectives**

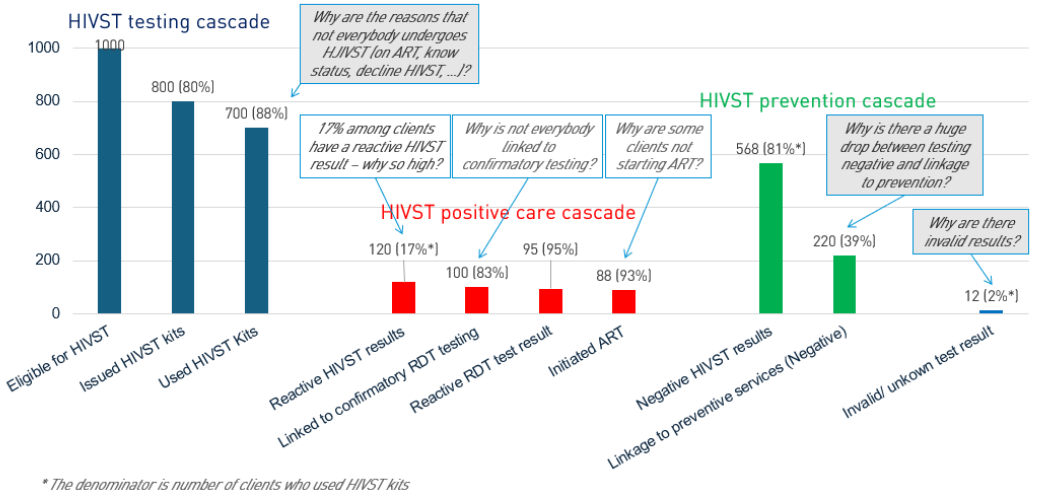
To introduce monitoring and evaluation concepts for HIVST, focusing on key indicators and the use of data to strengthen service quality

✅ **Content**

- ✓ Understand the Basics of Monitoring & Evaluation (M&E) in Facility-Based HIV Self-Testing (HIVST)
- ✓ Identify and Apply Key Indicators for Facility-Based HIVST
- ✓ Use Data to Enhance Program Quality and Identify Areas for Improvement



How to Identify Bottlenecks and Areas for Improvement? Cascade Analysis (2)



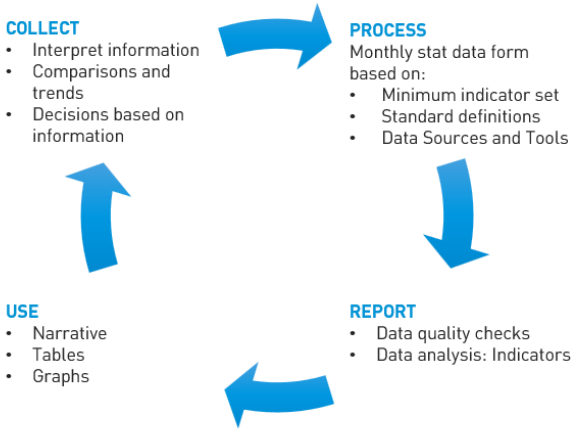
** The denominator is number of clients who used HIVST kits*

Data Feedback Loops for Program Monitoring

Use data and data feedback loops for monitoring and quality improvement at facility level and higher levels (e.g. program, national)

Feedback loop process:

- **Data collection:** gather data on key indicators (e.g. linkage rates, client satisfaction)
- **Analysis and review:** regularly review data to identify patterns and trends (e.g. monthly, quarterly, annually)
- **Feedback to staff:** share findings with staff to highlight successes and areas needing improvement
- **Action and adjustments:** implement improvements plans based on feedback to address service gaps or challenges



🟩 Accessing the Training Toolkit

💡 You can explore and download the full Facility-Based HIV Self-Testing Implementation Toolkit and Training Modules following the link:

🔗 https://drive.google.com/drive/folders/1QSvhUk5O5DPfPPkgoAE5Cwl32kmlAGrS?usp=sharing

Feel free to share this link with colleagues and partners.

THANK YOU

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Celine Lastrucci, WHO
Anne Bekelyncka, WHO

Karin Hatzold, PSI

Leveraging Facility-Based HIV Self-Testing to Drive Access and Efficiencies

WHO Webinar Operationalizing Facility-Based HIV Self-Testing
12 June 2025

Christian Stillson
Clinton Health Access Initiative

As the entry point for all HIV services, it is critical to consider strategic shifts to sustain HTS to meet prevention and treatment goals, and reach priority populations amid constrained service delivery and a shifting funding landscape

"Offering **HIV self-testing at facilities** can **increase testing uptake** and **improve the efficiency of service delivery**, especially in settings where there are shortages of health workers and where HIV testing is not readily available otherwise"

– World Health Organization, 2023

- HIVST does not replace the need for professional use testing, but we should **maximize its potential**
- The presentation will highlight evidence on **facility-based primary distribution of HIVST** as a strategy to **expand access and drive efficiencies** in service delivery.
- Further efficiencies can be gained by leveraging the availability of **lower-priced, WHO prequalified HIVST** kits.

Evidence from studies in Malawi and Uganda on facility-based HIVST

INCREASE ACCESS:
Under-reached populations, like men and young people, **visit facilities but are not regularly offered HTS**

EFFICIENT:
HIVST offered to clients at OPD **reduced HCW time per test by 53%**

INCREASES TESTING:
FB HIVST **increases testing by 3x,** including among priority pops, **with similar linkage rates as conventional testing**

SUSTAINABLE:
Using $1 kit, **HIVST has lower cost per PLHIV identified** compared to standard HIV testing models

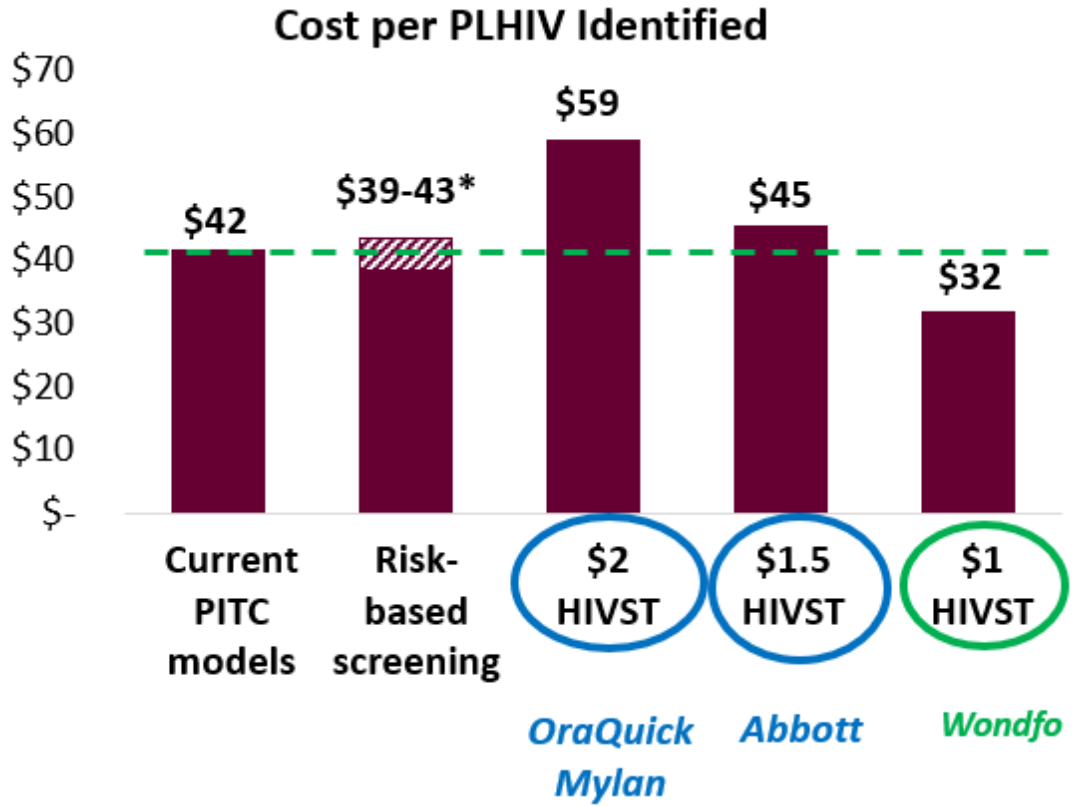
Background | Previously, prohibitively high costs of HIVST affected the scale up of HIVST. With the introduction of the lower-priced HIVST, scale-up is now more achievable

- Lower-cost kits can **generate savings and efficiencies**, enabling greater procurement volumes and **expanding testing coverage** through strategies like facility-based HIVST
- Early HIVSTs **cost ≥ $2 EXW** compared to **$0.80 for professional-use** HIV RDTs
- Since 2022, **two blood-based WHO prequalified HIVSTs** available for **≤ $1.50 EXW**

Abbott CheckNOW
$1.50 EXW
$1.79 landed

Wondfo HIVST
$1.00 EXW
$1.21-1.46 landed

Modeling using data from both Malawi and Uganda shows that with a $1 HIVST, the **cost per PLHIV identified is lower** when compared to existing testing service delivery and paper-based risk screening tools.



Evaluating risk-based screening tools vs HIVST as A0 | Paper-based screening tools are time-intensive and often have low sensitivity and specificity, leading to inefficient use of healthcare worker time and missed opportunities to identify people living with HIV.

Client Pathway with Risk-Based Screening Tool Implemented – *based off implementation in Uganda*

Outpatient department (OPD)

HIV testing point

Health education sessions

Pre-test messages provided to all clients, briefly describing the screening process.

Screening

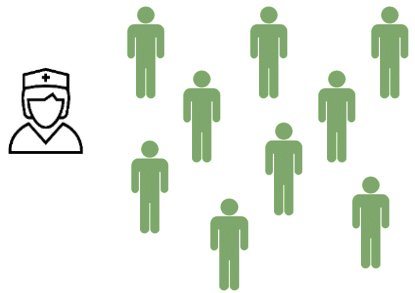
Administered to clients one-on-one, either at triage or in the clinical room. Being integrated with TB screening.

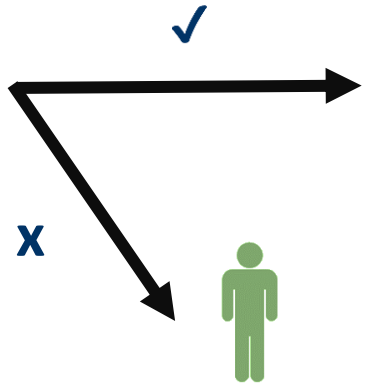
Risk determination and referral

Healthcare worker refers eligible clients to HIV testing or prevention services, as appropriate.

Professional-Use Testing

Eligible clients tested and linked to treatment or prevention.





Require **5-8 minutes** to screen and document each client

Low specificity means many HIV-negative clients are still screened in

Low sensitivity means PLHIV will be screened out

Evaluating risk-based screening tools vs HIVST as A0 | An evaluation of a risk-based screening tool in Uganda found that screening did not significantly increase yield rate and would miss nearly 10% of PLHIV

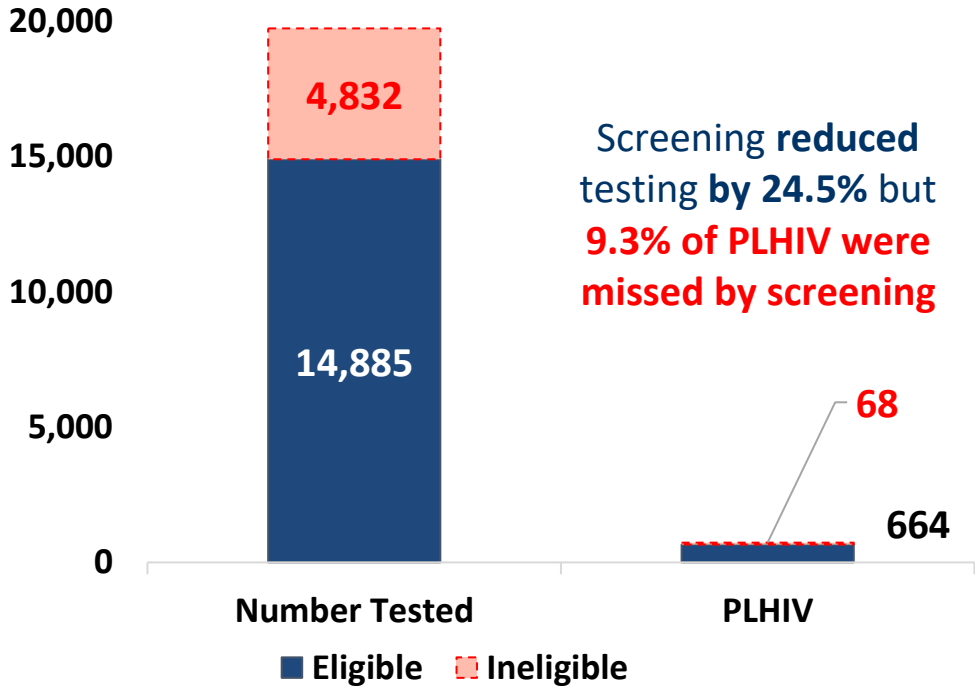
Analysis modeled the potential impact of scaling screening nationally in OPD, based on the sensitivity of the screening tool, current facility testing volumes, and HR and commodity costs in Uganda.

- Screening could reduce the number of A1 tests by 2.2 million, with cost savings of approximately $1.5 million (~6%)
  - Costing accounted for HR and commodities
  - Does not reflect the full costs of implementing screening (training, printing and dissemination of tools, M&E, etc.)

- **If scaled nationally 22,131 PLHIV would be screened out in OPD**
  - There are significant costs to missing PLHIV, delaying diagnoses and initiation onto treatment
  - PLHIV screened out at the facility will likely need to be identified through other strategies that are more expensive than facility-based testing

Evaluation of Uganda national screening tool

2019

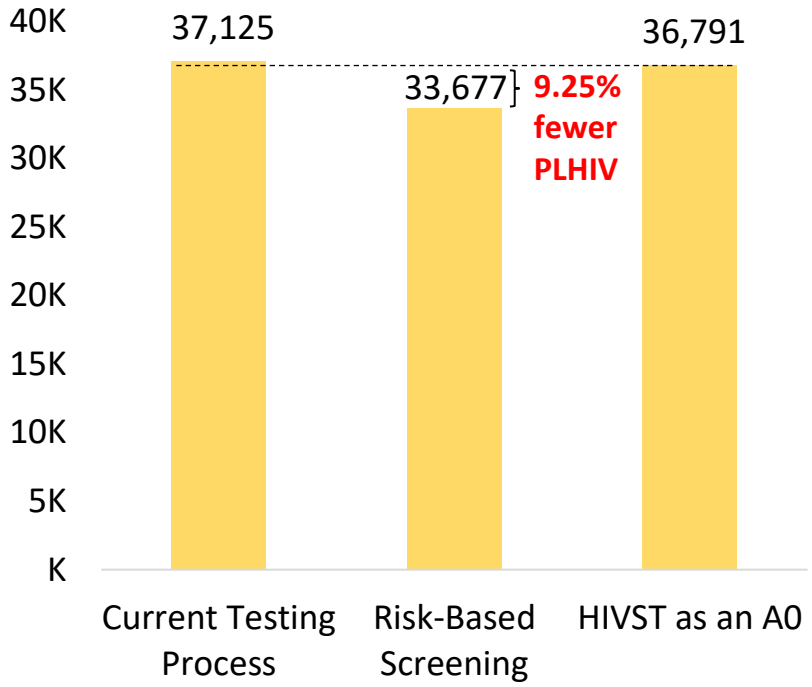


Screening **reduced** testing **by 24.5%** but **9.3% of PLHIV were missed by screening**

Yield rate increased from **3.71% to 4.46%,** but this change was **not statistically significant.**

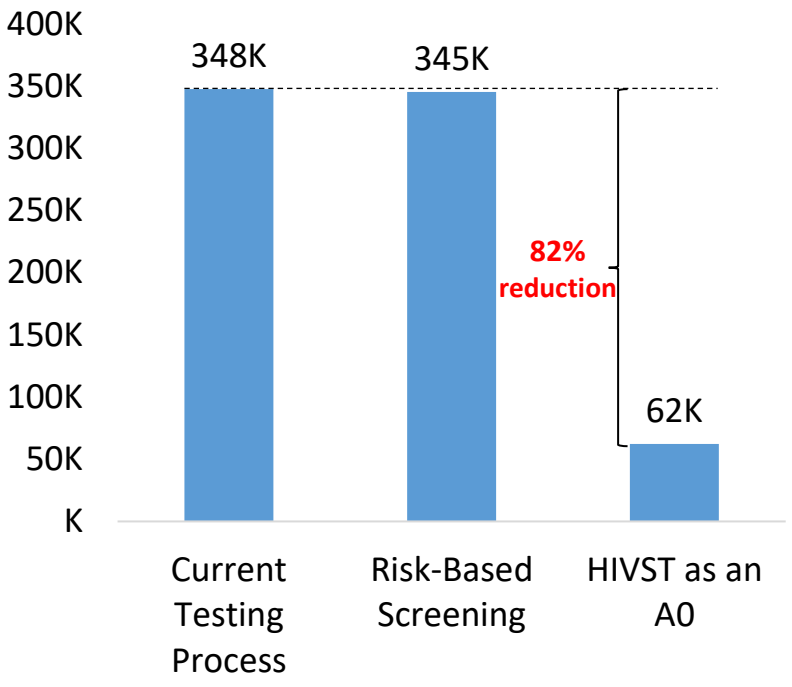
Evaluating risk-based screening tools vs HIVST as A0 | Using HIVST as an A0 in OPD at facilities could identify 9% more PLHIV than using a risk-based paper screening tool while reducing healthcare worker time spent on testing by 82%

Number of PLHIV Identified by Testing Approach



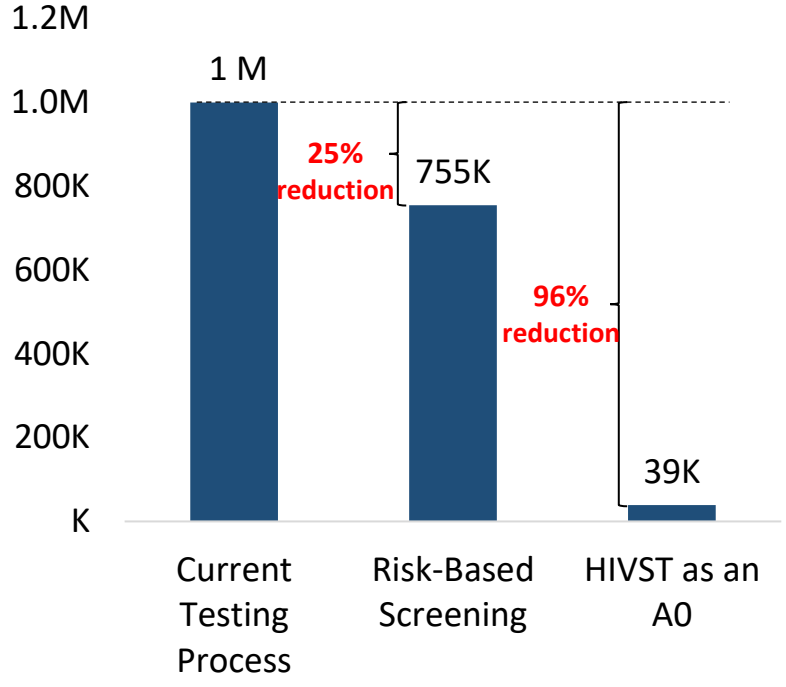
Implementing any sort of screening within the existing testing population will reduce the number of PLHIV identified, as no tool will be 100% sensitive

Total Hours Required by Testing Approach



Using HIVST as an A0 would decrease the total amount of HCW time required for testing by 82%.

Total Number of A1 Tests Required by Testing Approach



The major driver of the HCW time savings is **a 96% decrease in number of A1 tests required** as only those that screen A0-positive would be referred for professional-use testing

HIVST As A0 Efficiencies | Further evidence from studies in Malawi shows facility-based HIVST is a cost-effective, efficient, and sustainable approach to increase access to HTS

1

Reaching Priority Populations

In collaboration, PIH and CHAI sought to examine under-reached populations' use of facility-based health services.

The survey found that, contrary to popular belief, under-reached populations visit facilities, but are not regularly offered HTS

42% of youths and men surveyed had either never been tested or had not tested in the last two years

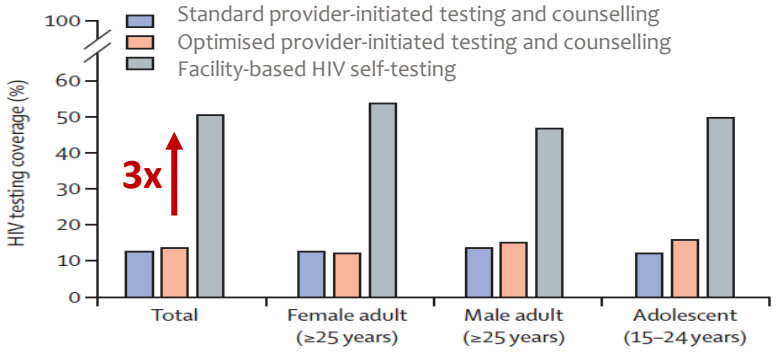
Even though 80% of those youth and men reported attending a health facility in the last two years

2

Testing Uptake

PIH's initial study found that HIVST in facilities is acceptable, increases testing uptake, results in similar positivity rates to standard HTS, and increases new identifications.

HIV testing coverage by sex and age across trial groups *(n=5,885)*



HIVST lead to a 3x increase in overall testing uptake among priority populations, including men & young people

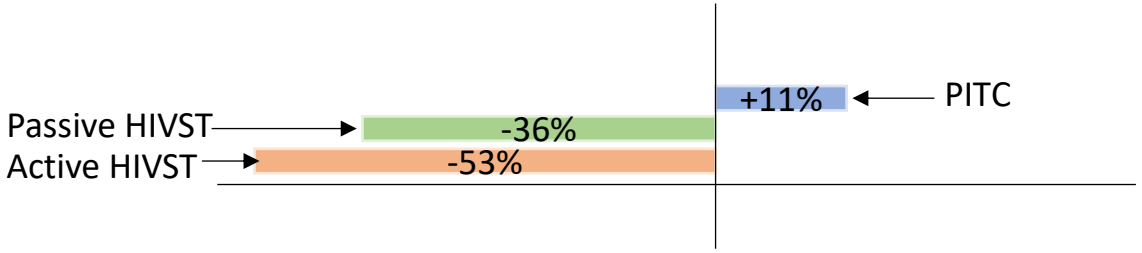
3

Program Efficiency

PIH recently conducted a second study on HIVST distribution in facilities, which had a secondary outcome focused on HCW time required per test completed.

Both HIVST arms required significantly less HCW time than provider-initiated testing and counseling

Percentage time saved/gained per test completed, per arm



Source: Dovel, K, Shaba, F, et. al. Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: cluster randomized control trail, *Lancet Global Health.* 2020; Dovel, Balakasi, et al. Missing men or missed opportunity? Men's frequent use of health services in Malawi. IAS. 2020

**Active HIVST differed from Passive HIVST in that providers initiated the distribution of HIVST 1:1 in a private area, not in a group.*

While there is no “one-size-fits-all” model for facility-based primary HIVST, there is a need and opportunities for countries to be creative with models that maximize access to HTS

Barriers

Space: availability of private space to test at the facility that protects confidentiality and risk of stigma.

Integration into patient flow: no ‘one-size-fits-all’ approach to operationalization.

Funding: Many countries lack funding for evaluation, adoption, and scale-up of new approaches or products.

Institutional resistance: some programs prefer clients presenting at facilities be prioritized for professional-use testing.

Opportunities

Begin phased implementation across diverse facility settings to **address service delivery gaps caused by funding disruptions** and **generate operational evidence** for the introduction of primary HIVST in facilities addressing:

- **Profile facilities and service points** (e.g. OPD, ANC, STI clinics) to identify where HIVST can most be feasibly and sustainably introduced.
- **Prioritize adoption of lower-cost HIVST** to maximize distribution and scale-up
- **Test low-cost privacy adaptations** such as makeshift booths or, where feasible, designated spaces to ensure confidentiality and reduce stigma.
- **Train lay cadres** in HIVST distribution and M&E.

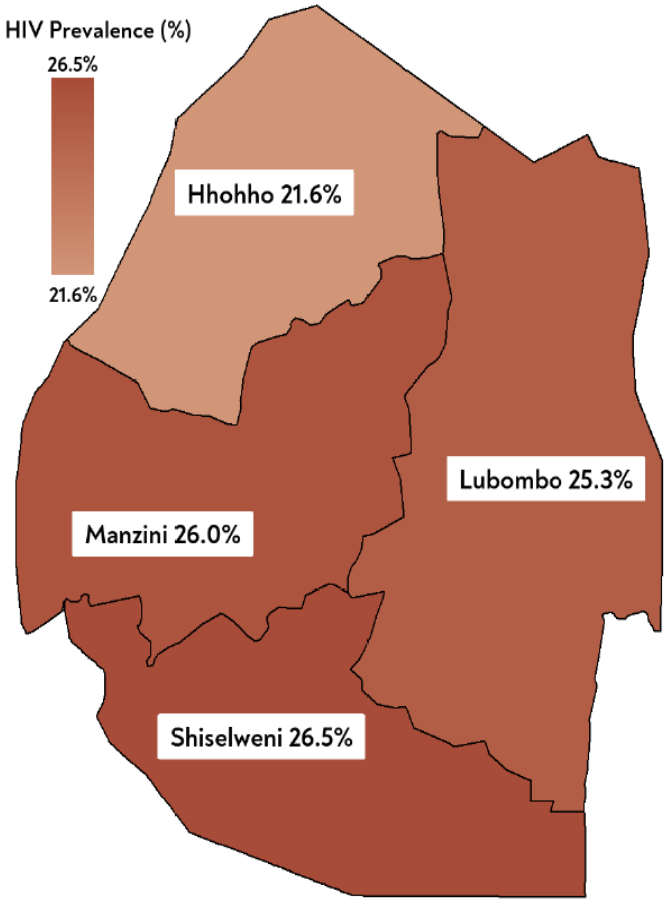
Screen, Test, Treat: Eswatini's Experience with Facility-Based HIV Self-Testing

Increasing HIV Testing and case finding in OPD:
Using HIV Self testing as screening tool

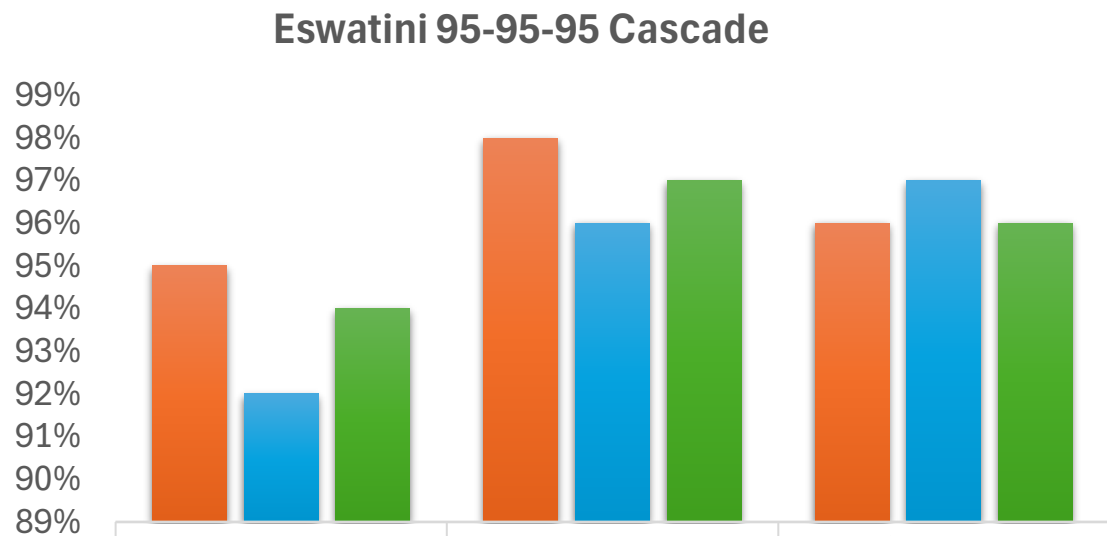
Lenhle Dube, National HIV Testing coordinator MOH Eswatini

World Health Organization

Country HIV Epi Context



- 24.8% national HIV prevalence
- Nearly twice as high in women as among men (30.4% vs. 18.7%).
- The overall HIV incidence rate is 0.62%, with a significantly higher incidence in women (1.11%) compared to men (0.17%). *2021 Data*



	Aware of status	On ART	Viral Load Suppression
Female	95%	98%	96%
Male	92%	96%	97%
Total	94%	97%	96%

Source: Third Swaziland/Eswatini HIV Incidence Measurement Survey 2021

Background

- Eswatini is nearing the achievement of the UNAIDS 95-95-95 HIV epidemic control targets across all population sub-groups.
- As the country progresses toward these goals, there is a growing need to identify cost-effective strategies and optimize the mix of HIV testing services (HTS), particularly for population segments where case detection gaps remain.
- In 2021, the Eswatini National AIDS Program introduced a risk-based HIV screening tool (HIVRST). However, program data revealed that the tool was inadvertently excluding individuals who were HIV-positive.
- To address this gap, the Ministry of Health, through the National AIDS Program, launched a quality improvement collaborative aimed at enhancing HTS eligibility screening.
- As part of this initiative, HIV self-testing (HIVST) was piloted as a screening tool in selected health facilities.
- Based on positive outcomes, the use of HIVST for screening has since been scaled up across all facilities nationwide.

Rationale

- **High client-to-provider ratio**: The number of clients eligible for HIV testing often exceeds the capacity of available HTS counselors, resulting in missed opportunities for testing. HIVST helps alleviate this burden by enabling self-screening.
- **Limited task-sharing**: HIV testing is often seen as the sole responsibility of trained HTS counselors. Introducing HIVST expands the scope for task-shifting to other clinical or lay staff, increasing overall coverage.
- **Delays in result turnaround**: When HIVST is offered without support, clients may experience delays in interpreting results. Structured HIVST integration, with minimal assistance or digital support, can reduce this delay.
- **Inefficient client flow**: Referring clients to a separate HTS room creates bottlenecks and prolongs wait times. Offering HIVST within the client flow, such as in waiting areas or triage points, streamlines service delivery and enhances client experience.

Introduction of facility based HIVST

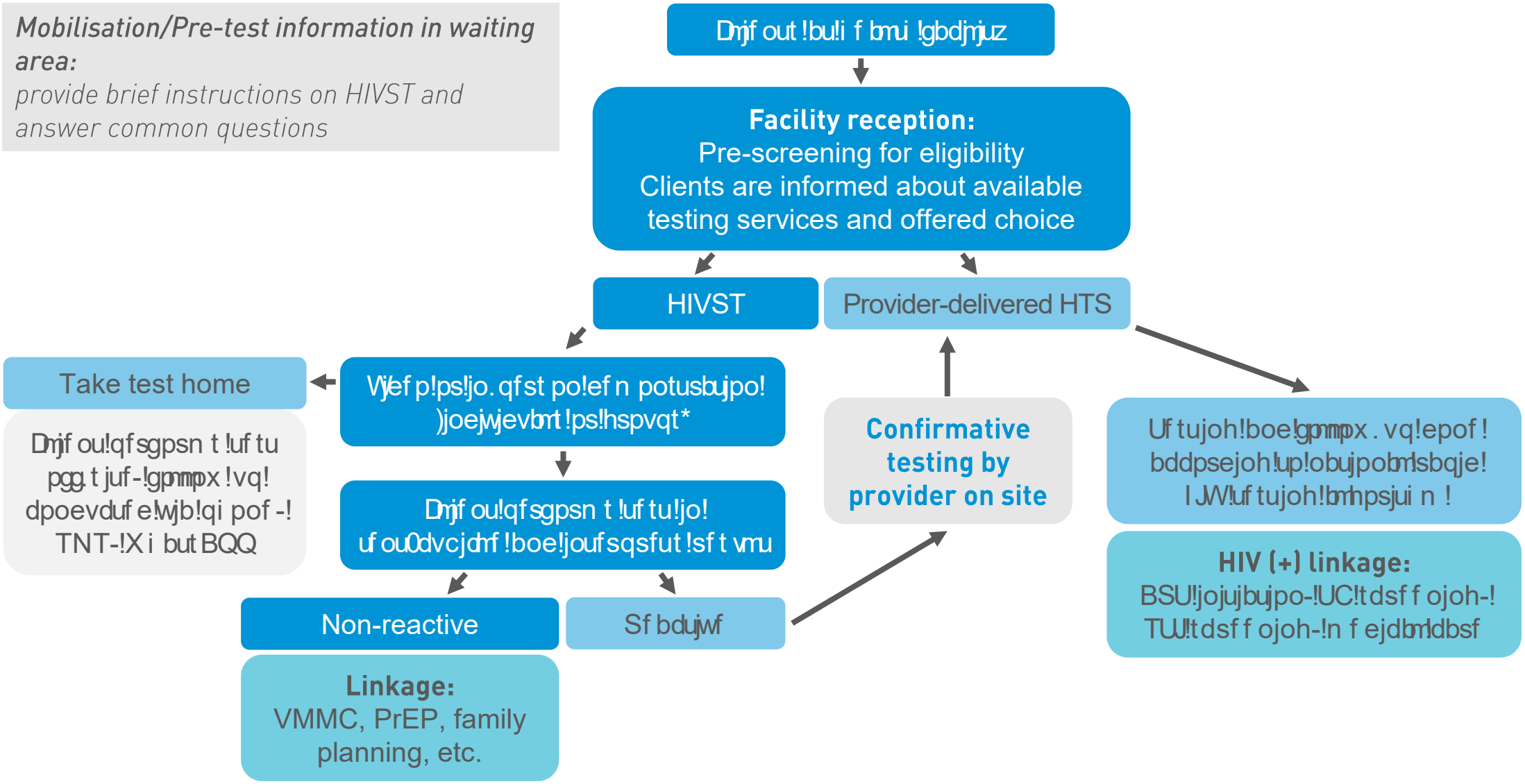
To Increase HTS coverage and case finding at all facilities out-patient departments (OPDs) using HIVST as a screening tool

Interventions;

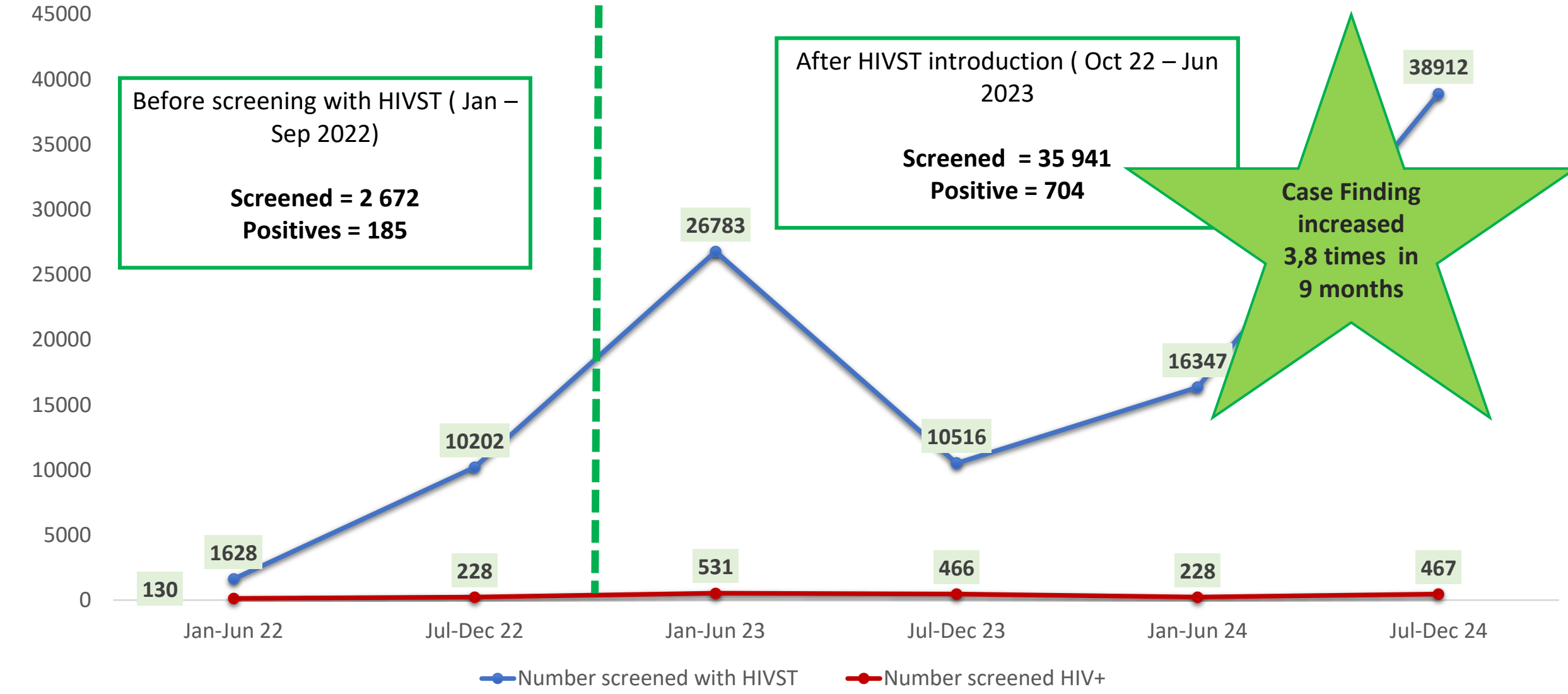
- Revised HTS Guidelines to include the guidance on using HIVST as a screening tool
- Developed facility process flow for using HIVST as a screening tool
- Revised HTS module in CMIS to include documentation of HIVST variable as a screening tool for eligibility
- Developed a change package
  - Refresher training of service providers
  - Conduct HTS eligibility screening together with TB and COVID-19 screening
  - Conduct HTS eligibility screening by nurses at triage for those missed at screening
  - Introduced use of assisted , multiple concurrent HIVST to assess for rapid diagnostic test (RDT) eligibility
  - Conduct HIVST at point of screening (do not refer to HTS room)

Process Flow

Mobilisation/Pre-test information in waiting area:
provide brief instructions on HIVST and answer common questions

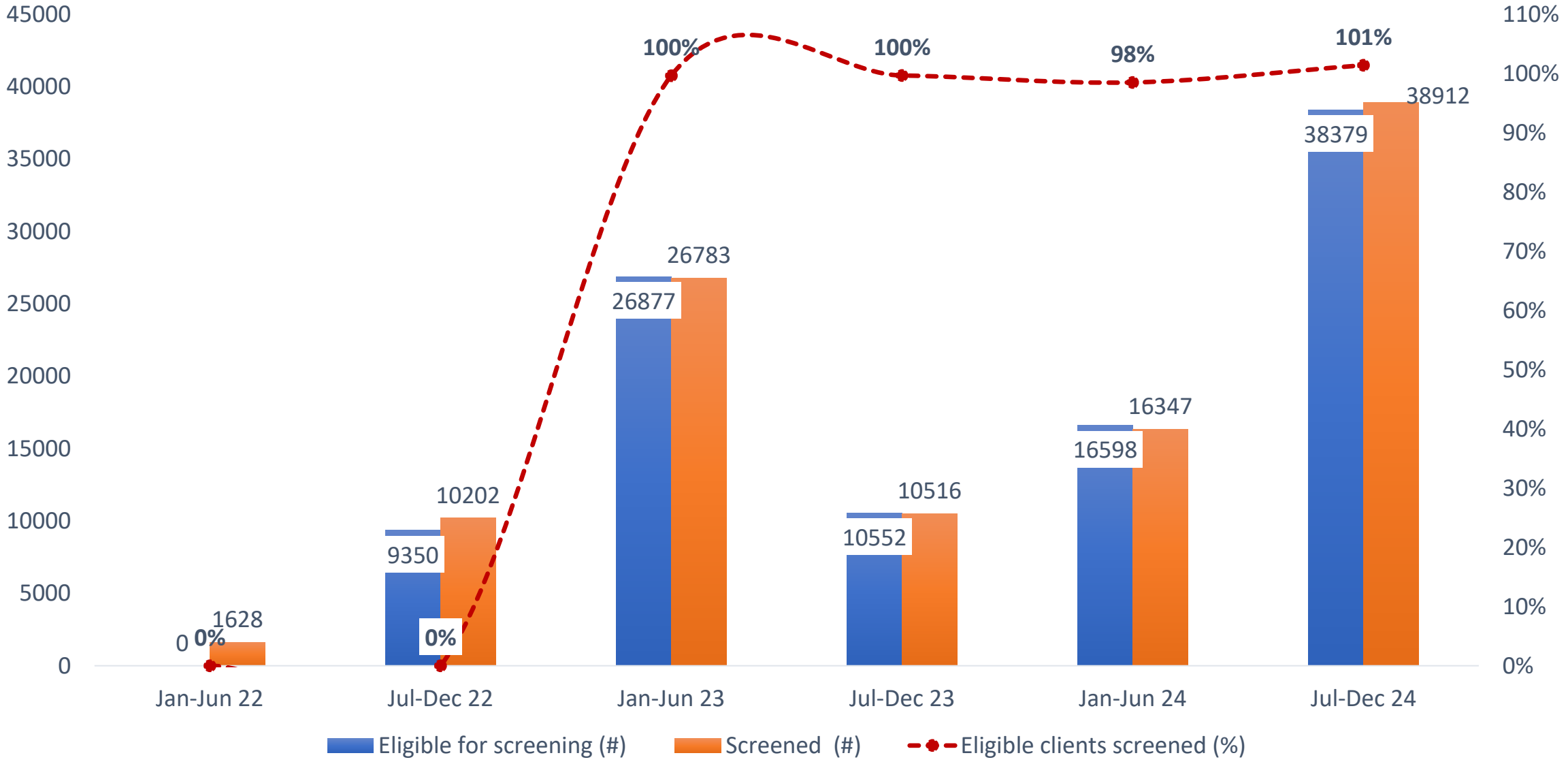


Use of HIV Self-Test as screening test for HTS in health facilities



An increase in case finding is noted throughout the trend to Dec 2024

Eligible Clients Screened with HIVST in Facilities



Lessons learned

- To optimize HIVST as a screening approach within facilities, client flow must be restructured to minimize missed opportunities and address gaps in service delivery.
- Previously, clients were bypassing the HIV screening station in the OPD or navigating around the paper-based risk screening process—resulting in missed testing opportunities.
- Engaging all hospital staff in routine data review fostered greater motivation and ownership of the HIVST initiative.
- HIVST helps address human resource constraints by reducing the workload on healthcare providers and optimizing staff time.
- Close coordination with the supply chain team is essential to maintain consistent availability of HTS commodities and avoid stockouts.

Conclusions

- Integrating HIVST as a screening tool in OPD settings significantly increased the absolute number of new HIV diagnoses.
- HIVST improved HTS coverage among eligible clients in the OPD, offering a scalable approach to reach more individuals.
- While effective, screening all OPD clients remains resource-intensive, underscoring the need for streamlined client flow and strategic task-shifting to optimize human resource use.
- Overall, HIVST is a valuable addition to OPD services, enhancing case detection and coverage when integrated thoughtfully into routine workflows.

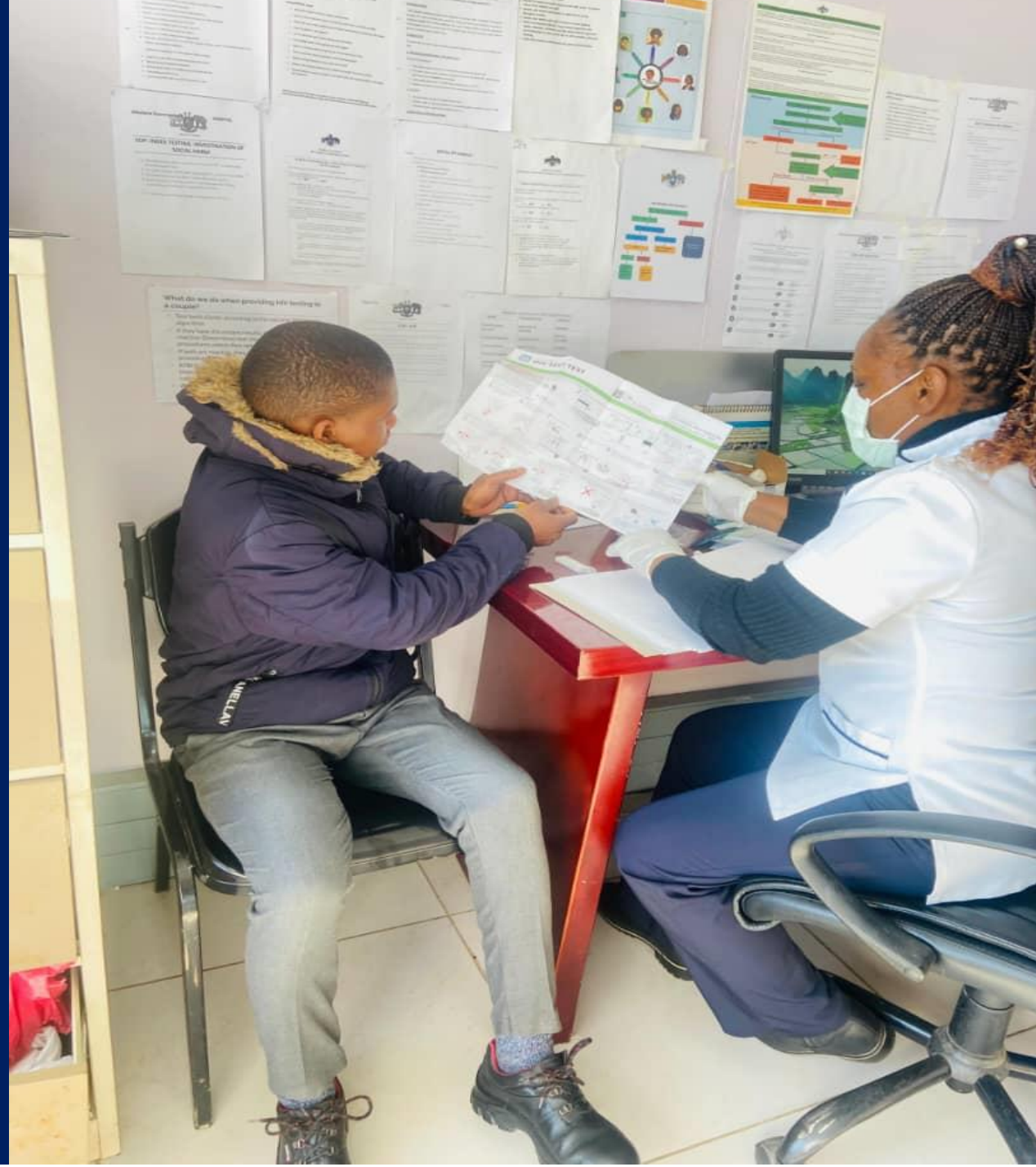
Recommendations and way forward

- Streamline facility workflows to effectively integrate HIVST into triage and routine service delivery.
- Implement task shifting by training nurses and other clinical staff to provide HIV testing services, including HIVST.
- Leverage digital tools to deliver video or app-based instructions for clients using HIVST, whether at home or in clinic waiting areas.

THANK YOU

Acknowledgements:

- Ministry of Health (Eswatini AIDS Program)
- PEPFAR for funding
- Regional Health management teams
- Facility Managers
- OPD health providers
- Implementing partners for TA and support
- WHO for guidance and TA support
- HTS TWG

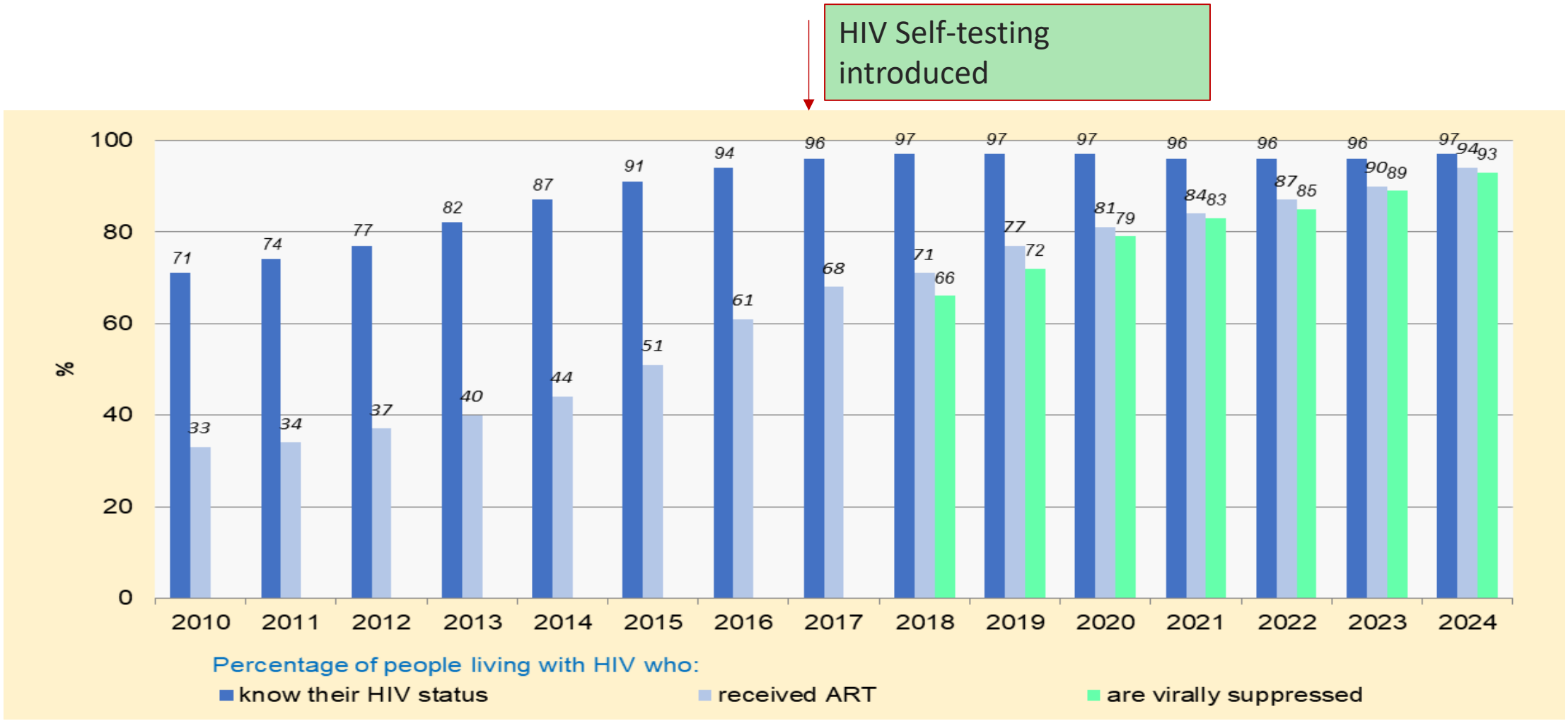


Facility-Based HIV Self-Testing in Lesotho from pilot to scale Up

Mphotleng Tlhomola, Ministry of Health Lesotho

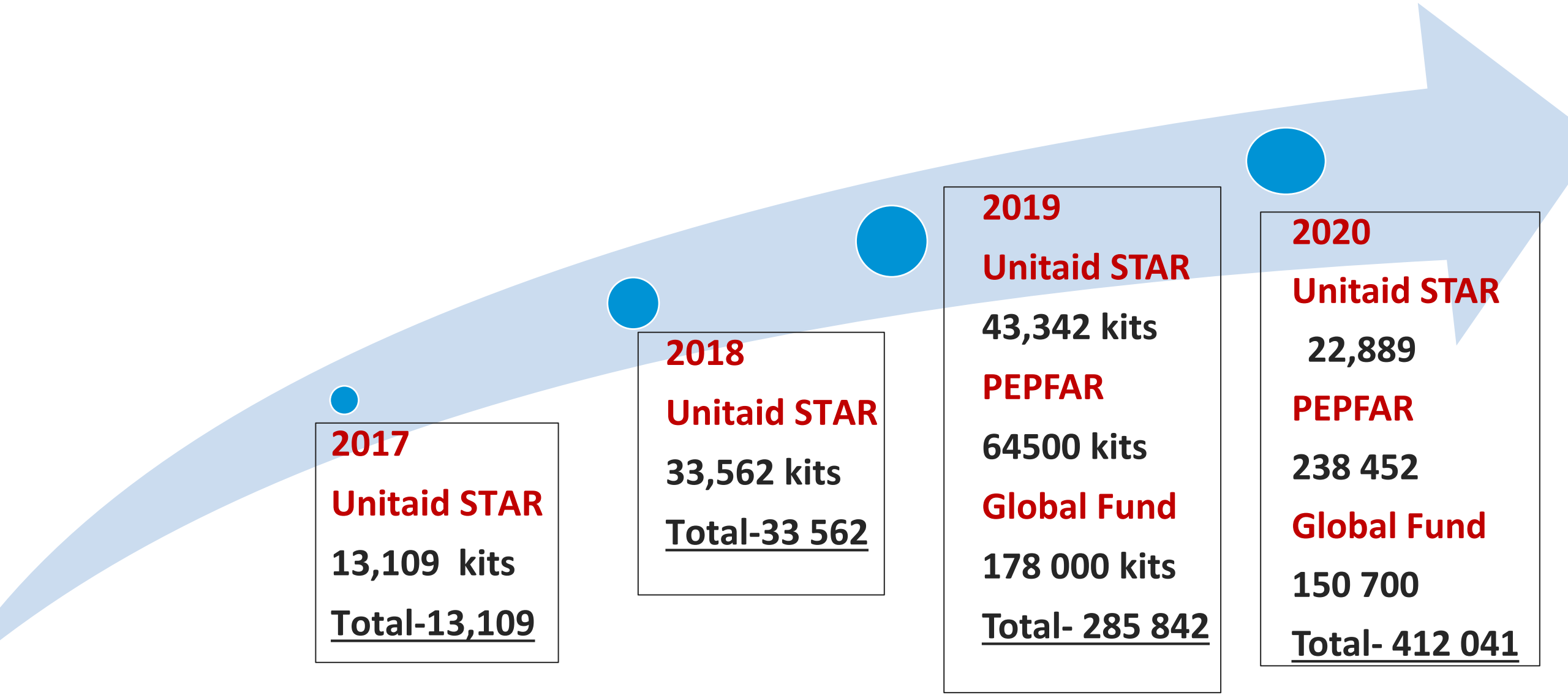
World Health Organization

HIV Treatment cascade Lesotho



HIV Self-Testing launched by His Majesty King Letsie III on 1st Dec 2017

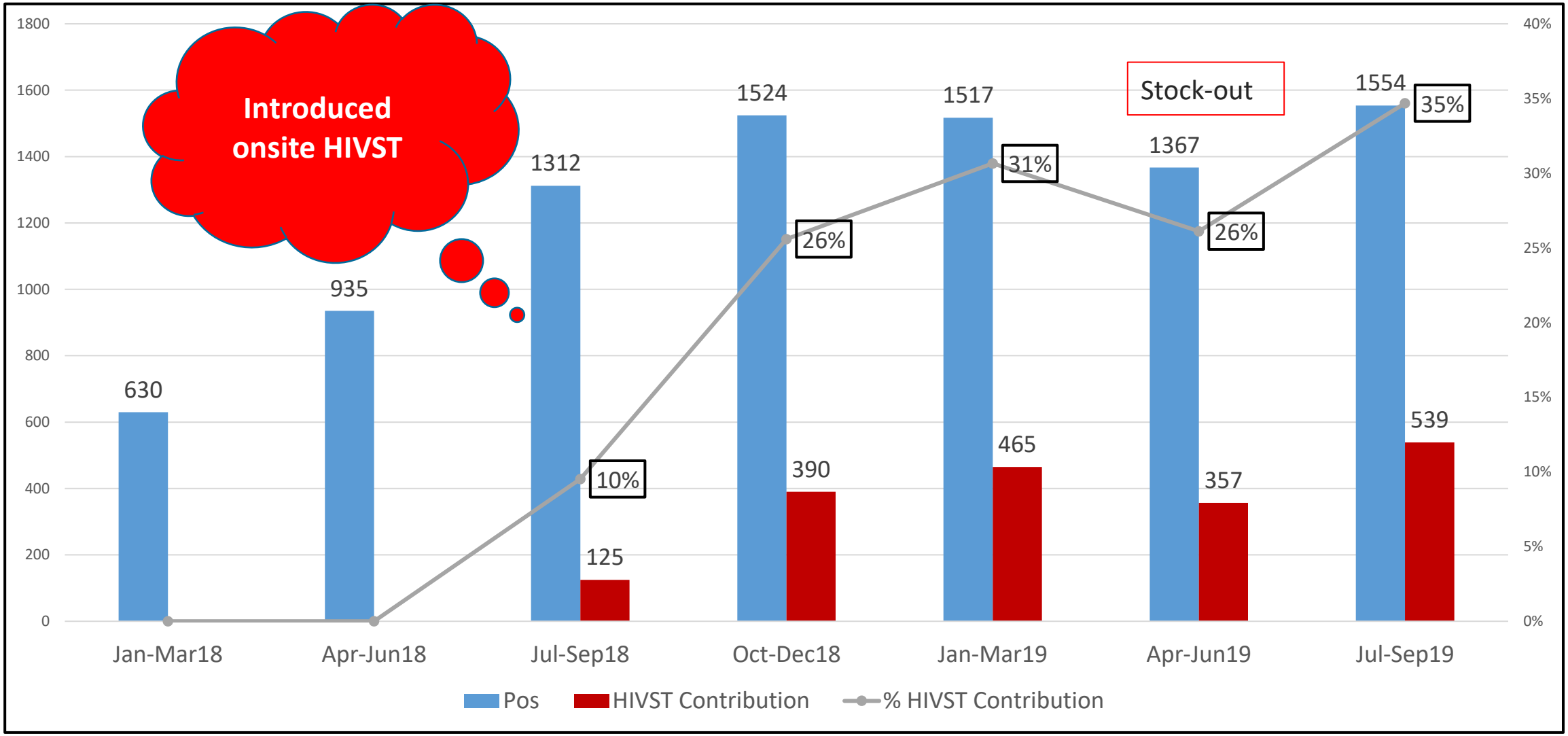
HIVST Catalytic Investment Lesotho



Initial phase: HIV self-test distribution models

- Distribution at workplaces including uniformed forces
- HIVST offered as an additional strategy during HIV testing services provision at New Start HIV testing clinics
- Secondary Distribution
  - Sexual partners of antenatal and post natal care attendees at 5 hospitals
  - Sexual partners of people living with HIV identified at HIV testing services sites
- Targeted community-based distribution through HIV Testing outreaches

Proof of concept: Increased case identification with on-site facility based HIVST in 2019



HIVST at Facility level

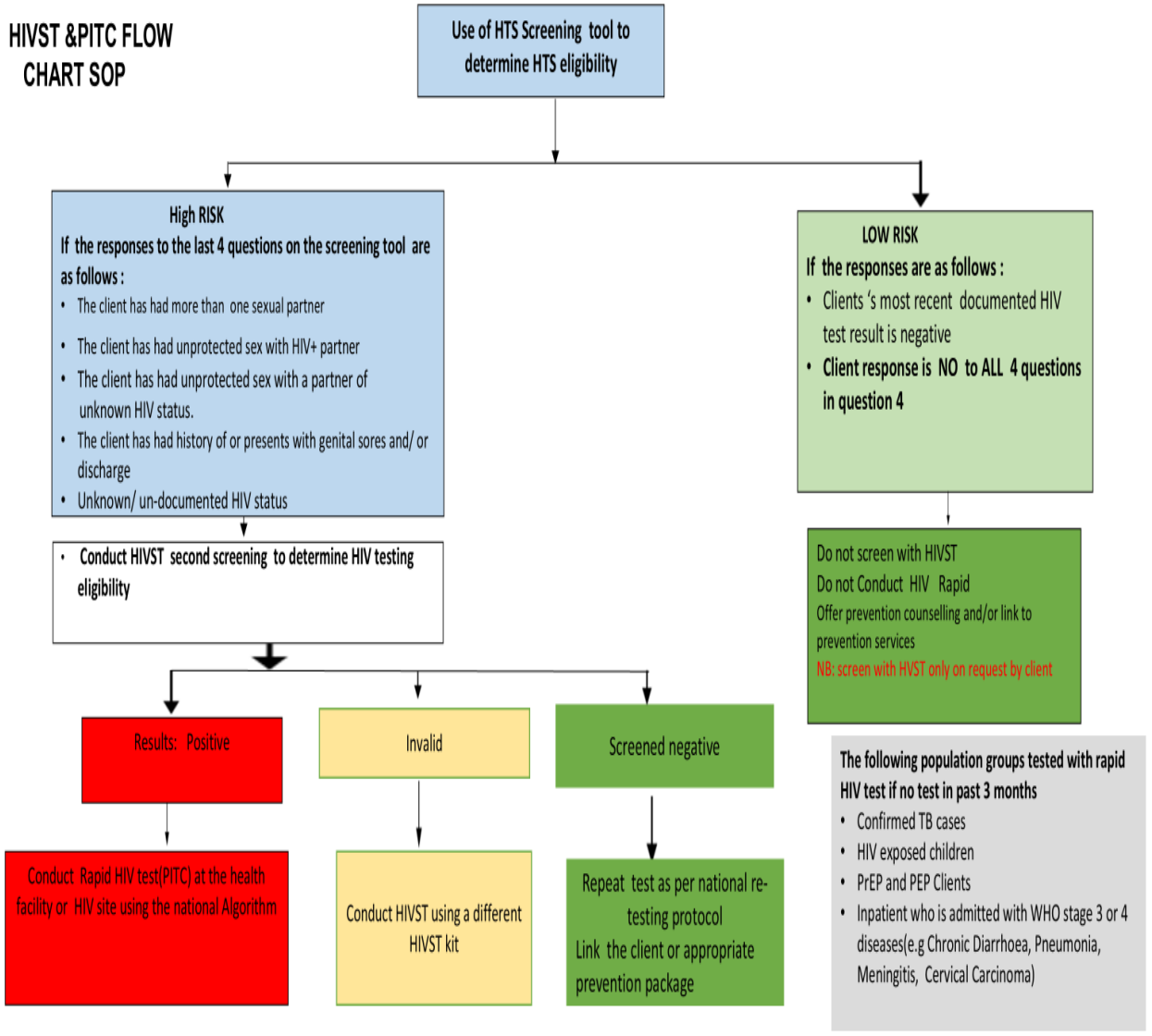
Tremendous progress over last decade:

- Achieving first 95 –but priority populations still missed.

Achieving high awareness of status is challenging:

- **Key populations** more likely to be undiagnosed and contribute to new infections
- **Men** and **AGYW**
- **Partners of PLHIV**, **STI patients** missed
- Populations and settings affected and missed due to **COVID-19 related disruptions**

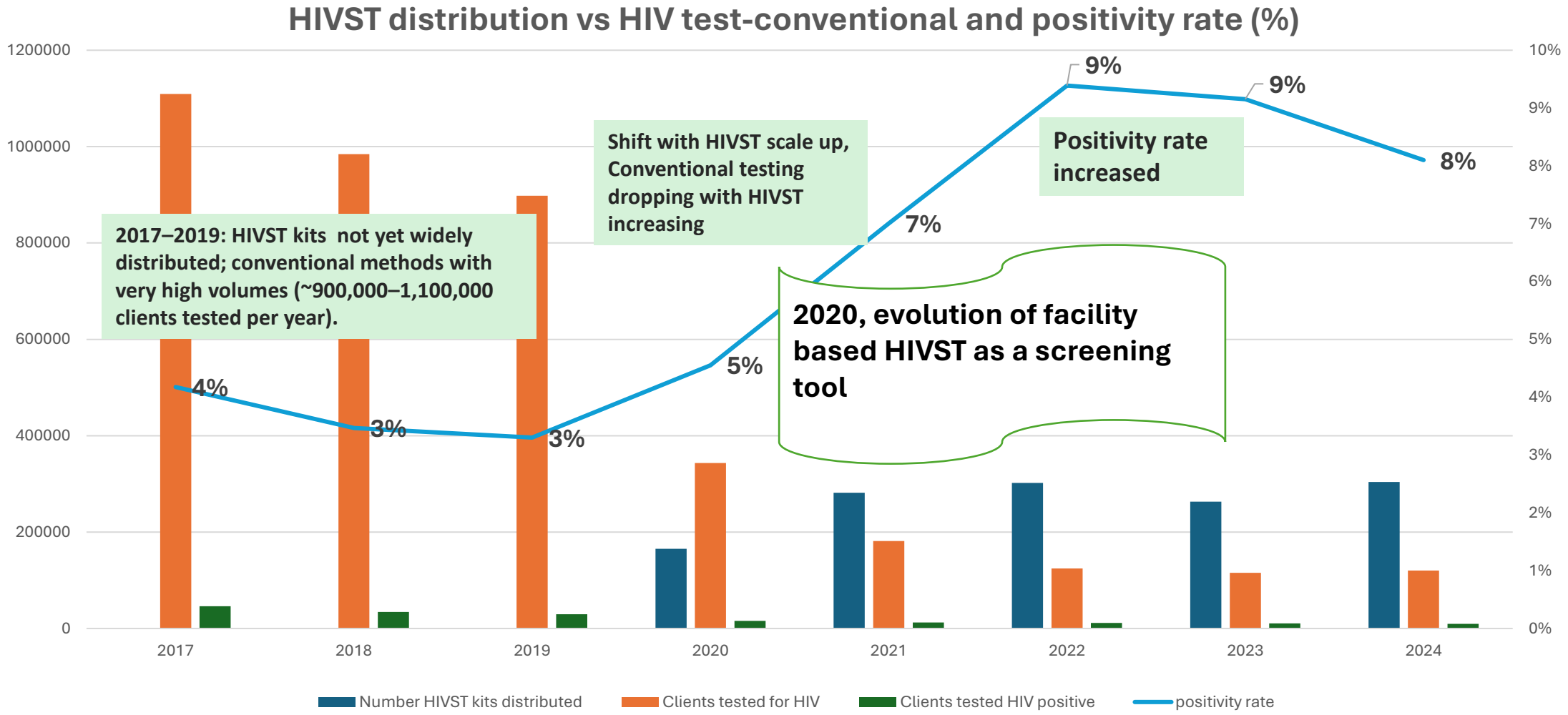
- Need to optimize HIV testing services, increased use of HIV Self-Testing focusing on priority populations.



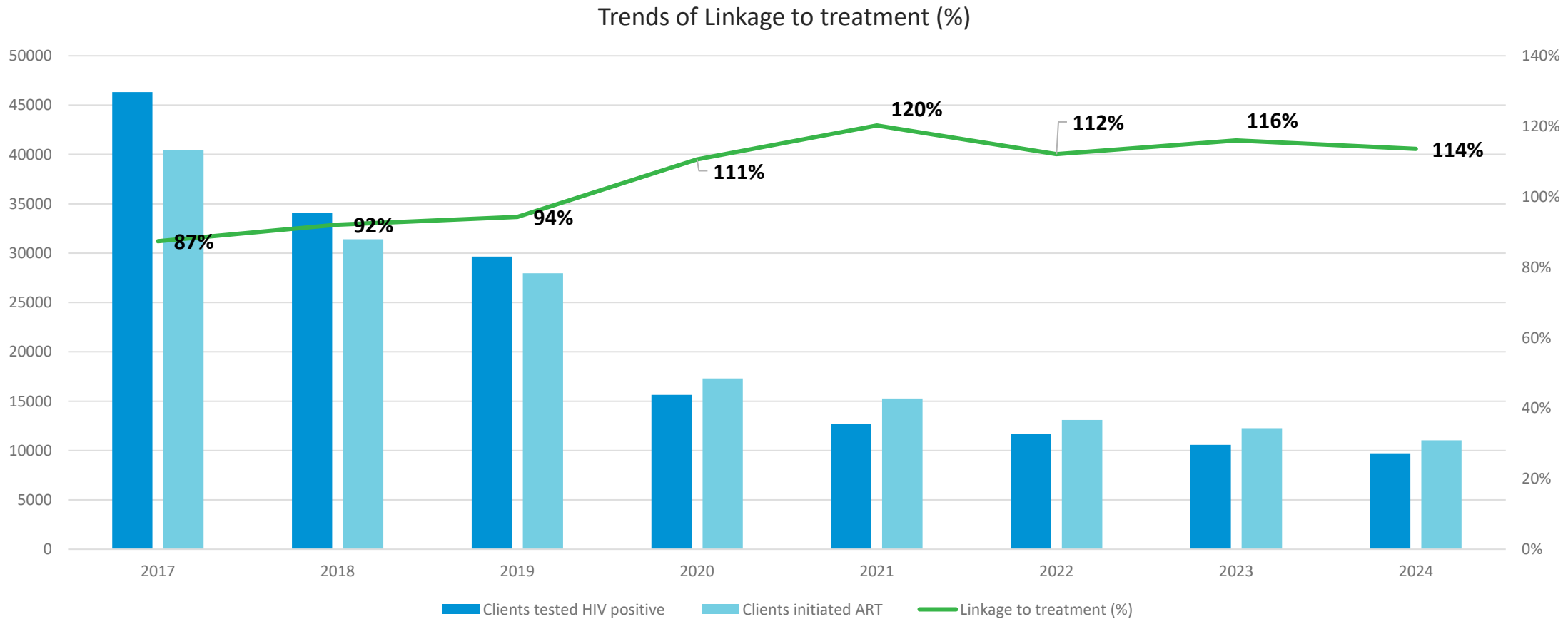
Facility based-HIVST Outpatients

- HIV testing information in waiting area; SESOTHO VERSION HIVST VIDEO PLAY
- Screening tool for eligibility followed by HIVST
- Registration
- HIV Self-testing in private booth
- Follow algorithm by 1st tester if self-test reactive
- Confirmative by 2nd tester
- Same day ART initiation

HIVST DISTRIBUTION V.S HIV TEST CONVENTIONAL AND POSITIVITY RATE %



Linkage rates may exceed 100% as individuals self-test privately and present later for confirmatory testing and ART, outside the initial reporting cohort.



Summary Observations

- High acceptability and uptake of HIV self-testing.
- Majority of HIVST users complete testing onsite.
- HIVST contributes to increased overall HIV testing coverage.
- Onsite HIVST facilitates higher case detection rates.
- HIVST under index testing modality identifies more HIV-positive men.
- Stock-outs of HIVST kits negatively impact testing yield and program performance.
- HIVST reaches populations with previously unmet testing needs, particularly adult men.
- Use of IEC materials supports self-reporting of reactive HIVST results and facilitates linkage to care.
- HIVST serves as an efficient triage tool within facility-based testing workflows.

Recommendation and way forward

- **Increased Uptake:** FB-HIVST expands testing coverage and case detection, especially in high-burden settings.
- **Optimized Integration:** Easily incorporated into routine facility services to strengthen testing strategies.
- **Streamlined Process:** Simplifies workflows and reduces time compared to conventional testing.
- **Cost-Effective:** Demonstrates good value, particularly in high-volume outpatient departments.
- **Enhanced Linkage:** Supports timely linkage to care for those who test positive.
- **PrEP Support:** Facilitates PrEP initiation and continuation.
- **Pregnant & Breastfeeding Women:** Enables HIV screening alongside syphilis testing during initial antenatal visits.

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