Operationalizing Facility-Based HIV Self-Testing

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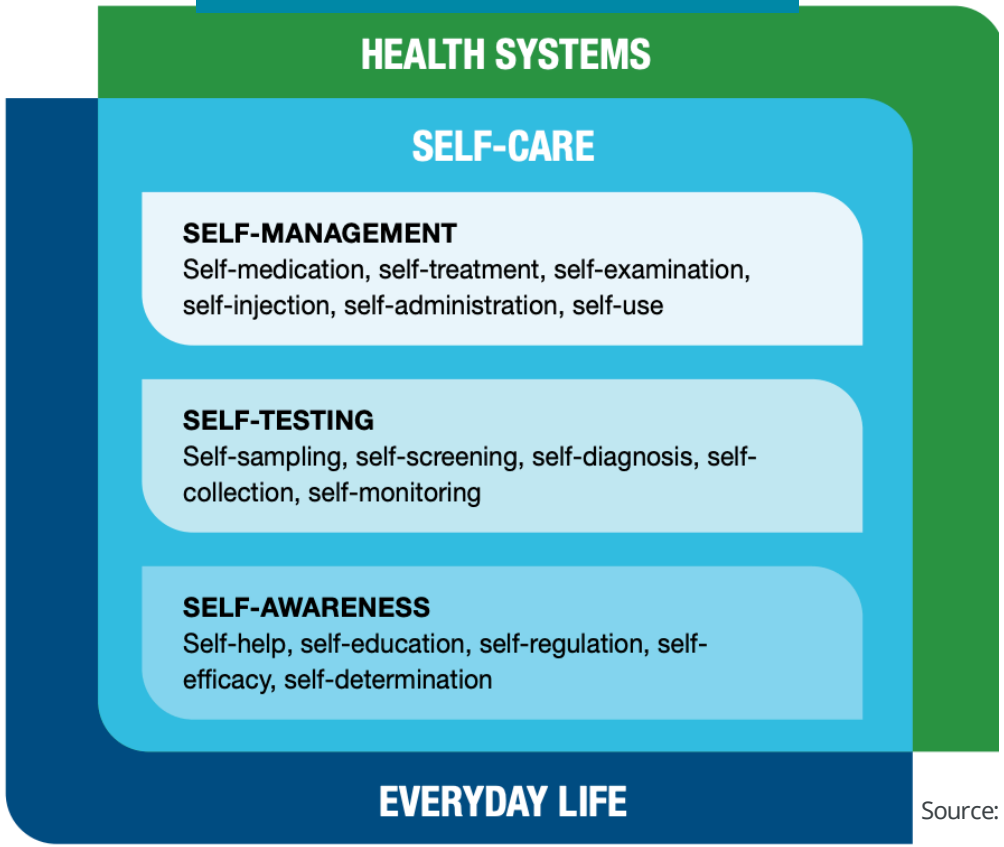
The self-care revolution: Why self-care?

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-care is not new – but there are new opportunities



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.

- Increase engagement and autonomy
- Increase access and equity
- Improve quality of care
- Increase efficiency
- Reduce costs to health system and individuals
- Expand UHC efforts

Self-Care and Self-Testing: Critical to Health Systems

Source: WHO guideline on self-care interventions for health and well-being, 2022

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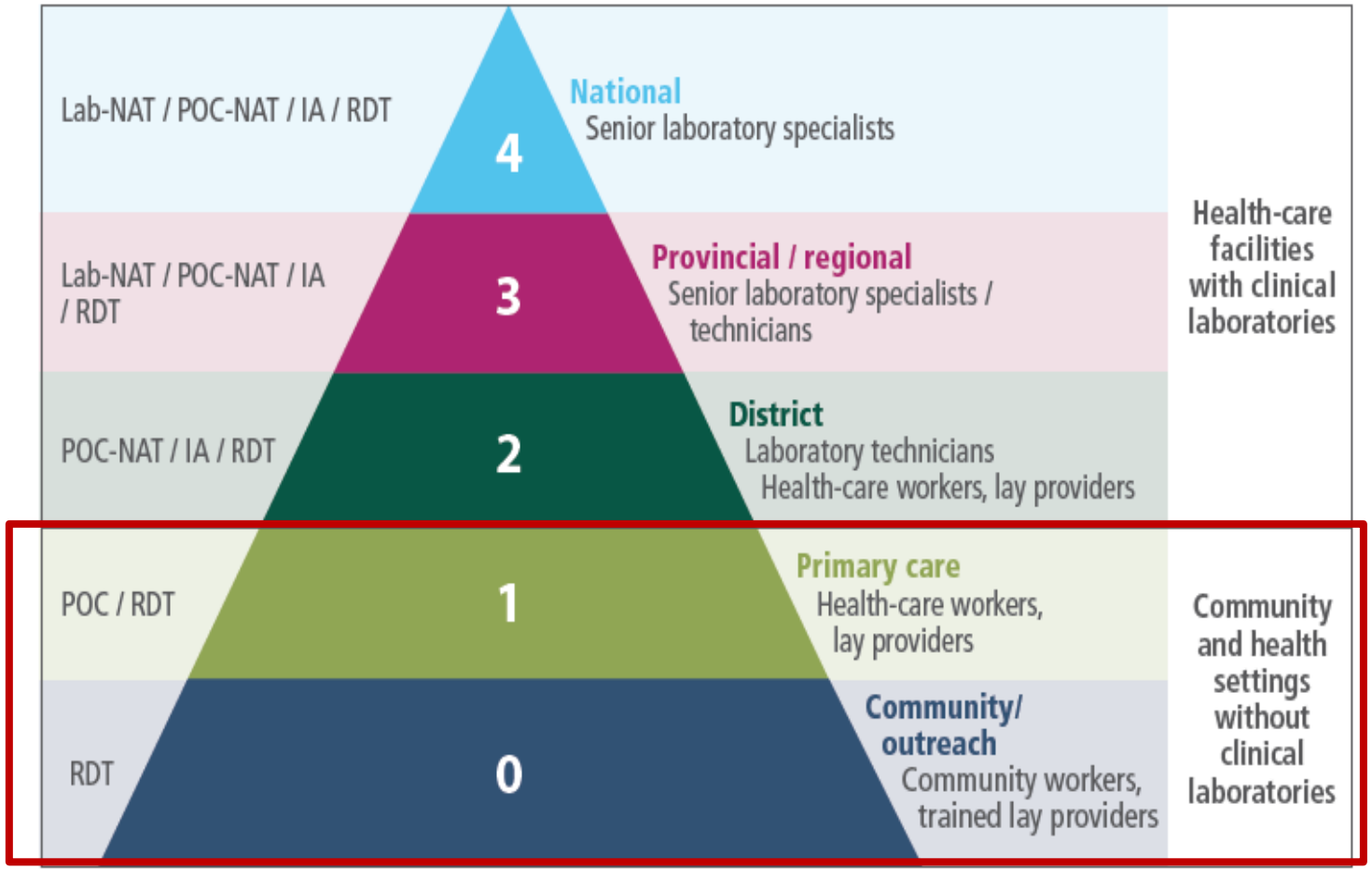
HIV testing – Majority conducted at primary and community level



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.

- Self-testing has been growing over time (102+ countries)
- With reduced funding and policy shifts, many are adopting '*integration of HIV into PHC*'
- Facility-based HIV tests contributed to almost 90% of all tests conducted in the African region
- Optimizing facility-based HTS is critical in reaching missing priority populations not routinely offered HTS when presenting at the facilities
- Facility-based self-testing – means the individual tests themselves

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

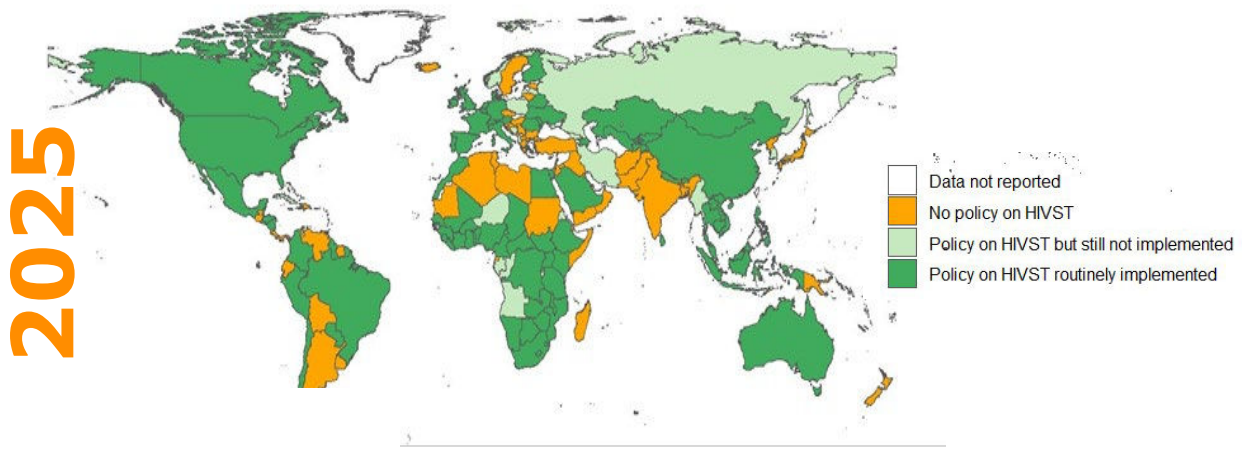
HIVST progress over a decade

2012-2025: 5000% increase in HIVST policy over 13 years

2012

- **Policies:** 2 countries
- **Implementation:** 1 country, only private sector
- **Quality-assured products:** 1, no WHO PQ
- **Procurement:** ~1 million HIVST kits annually (high-income and research only)
- **Cost:** High cost, wide variability ($5-40)

2025



- **Policies:** 109 countries
- **Implementation:** +100 countries, range of models
- **Quality-assured products:** 10 (8 PQ, 2 ERPD)
- **Procurement:** > 30 million HIVST kits annually (domestic, donor and private sector)
- **Cost:** Moderate to low in LMICs ($1-3), wide variability, high costs remain in some settings

Source: WHO/Unitaid landscape, Global AIDS Monitoring and ARV Survey, AMDS report

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HIV self-testing continues to be a critical approach and adaptation

Key evidence shows HIVST:

- **Blood, oral and urine, all safe** and **accurate** (8 WHO PQ products ~$1-3)
- **Facilitates acceptability, feasibility, access & uptake**
- Increases programme **flexibility**
- Achieves **good case finding** and **linkage to ART**
- **Empowering** with **no social or clinical harm**
- **Fills HRH and testing gaps** when needed
- **Switching to lower-cost HIVST** can lead to substantial cost savings
- Research suggests that most people report accurately their HIVST results

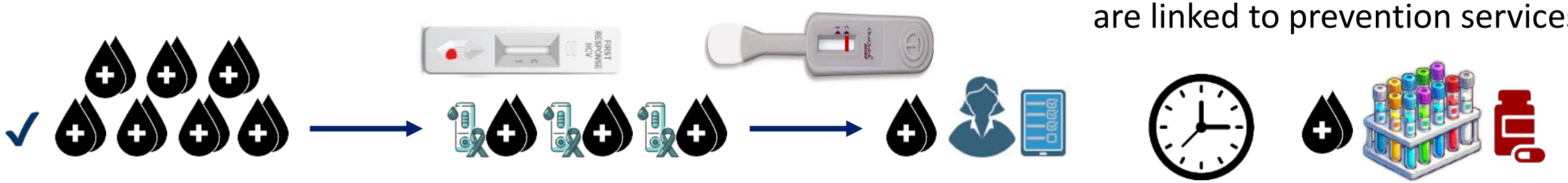
WHO recommendation:

- HIVST may be offered as an additional option for testing at facilities
- Complement existing testing capacity by increasing the use of HIVST in facilities per WHO guidance
- HIVST can be used to sustain essential services during stockouts
- Important to provide clear and simple prioritization of testing staff in facilities – to focus more on those needing further testing

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

HIV self-testing replacing screening-in tools in facilities

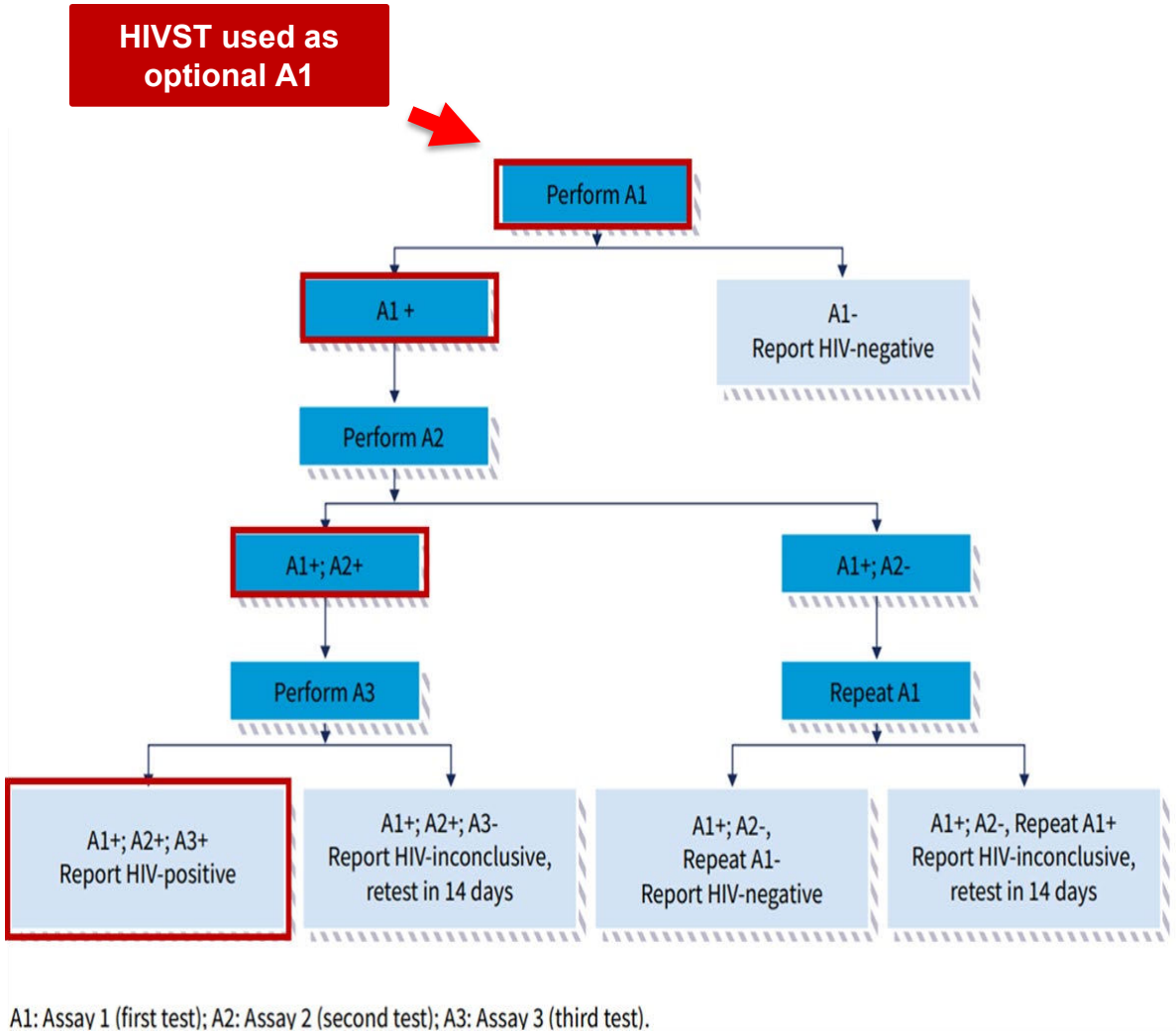
Health Education Sessions	Screening	Referral Based on Results
Pre-test messages provided to all clients in OPD, describing the HIV self-testing process, offering HIV self-testing	HIVST kits are offered to clients who opt for HIVST and are eligible (not HIV positive, not on ART, and willing to test themselves)	• Clients who test HIV **reactive** with self-test receive confirmative testing using national algorithm and initiate treatment. • Those with **non-reactive** results are linked to prevention services



Clients test themselves while they are waiting for the health care provider consultation, HIV self-testing replacing screening tools.

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

Using HIVST in facilities to sustain HIV testing during stockouts



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

Adapted HIV testing strategy implementation considerations:

- HIVST is still recommended as a "test for triage"
- HIVST – flexibility needed
  - To mitigate HRH constraints
  - During stockouts
- When awaiting stock - use HIVST as A1 and support policies that include HIVST as A1
- Prioritize quality-assured, lower-cost HIVST kits
- Prioritize confirming all reactive self-test results
- **Do not start ART based on a single HIV reactive test**

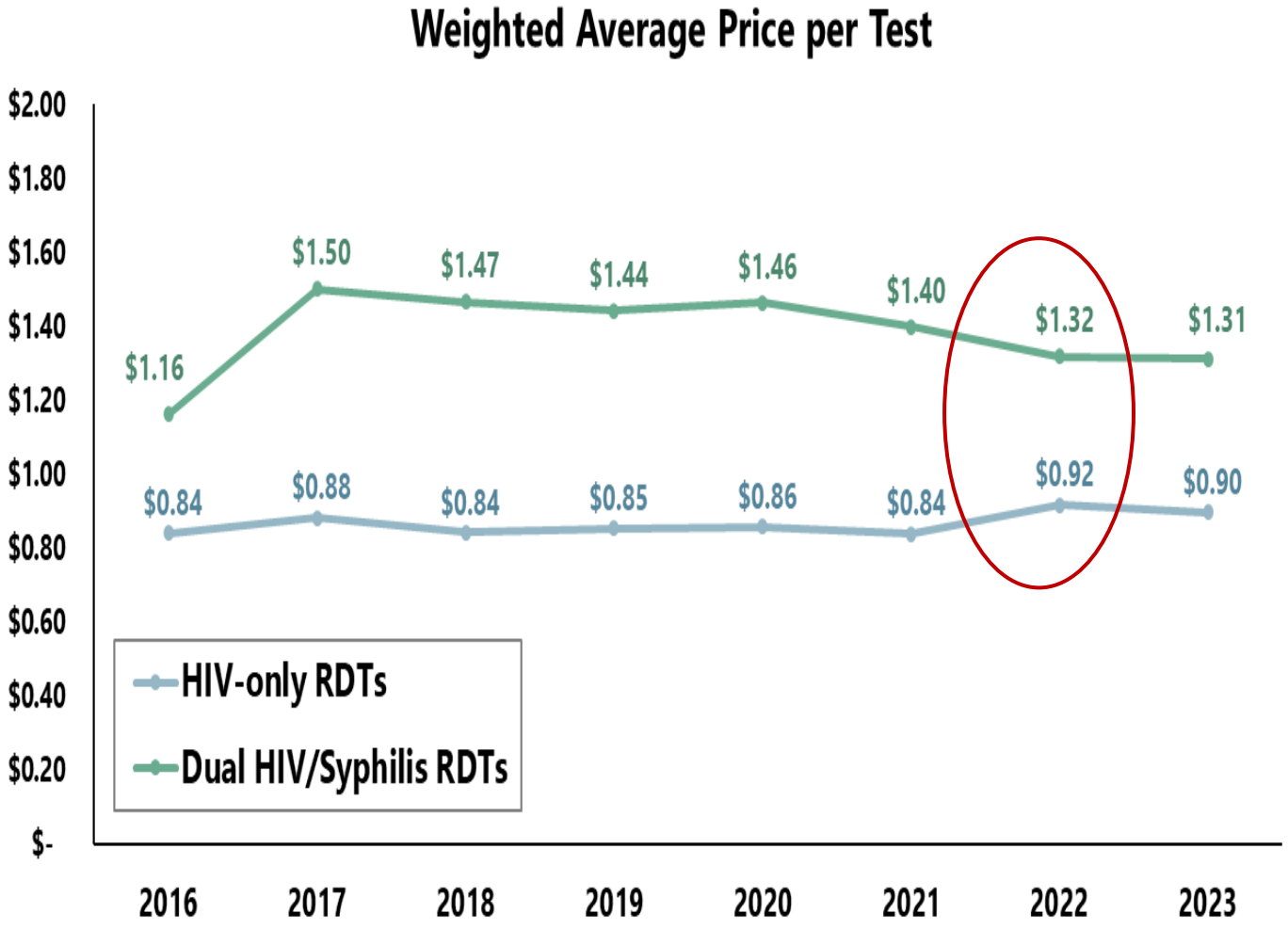
Source: WHO 2024, Consolidated guidelines on differentiated HIV testing services

HIV self-testing reducing burden on limited staff

- Before funding cuts, HRH was already limited
- HIVST could lead to savings if replacing provider testing in health facilities
- HIVST provides a flexible operational triage model where needed
- Can reduce cost and staff burden when there are health workforce shortages
- ROI more favourable with lower-cost HIVST
- HIVST could support maintaining KP services and still reduce total provider costs by 1%
- HIVST could lead to savings if replacing provider testing
- Country-facing calculator in development for local planning for optimal savings for HRH and HIVST

Source: Nichols, Edun, Imai-Eaton, Bernsteyn, Johnson IAS 2025

Average weighted price of HIV tests remains high, yet low-cost quality-assured options are available-1



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

**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

Average weighted price of HIV tests remains high, yet low-cost quality-assured options are available-2

Current opportunities in the WHO catalogue:

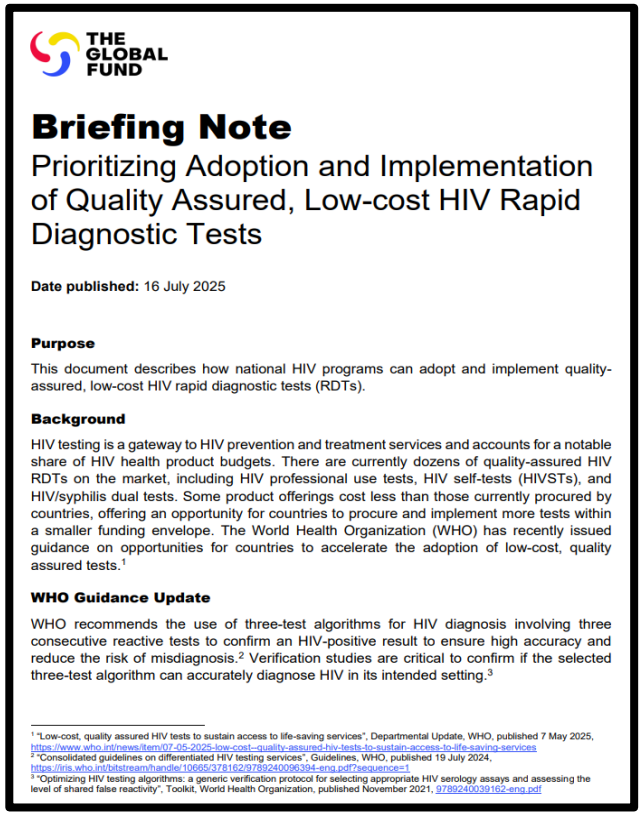
HIV RDT: +22 PQ'ed ($0.53-$2.79)

- 4 manufacturers have tests costing less than $0.70
- 5 manufacturers have tests costing $0.70 to $0.75
- All can be used as the first test

Dual HIV/Syph RDT: 3 PQ'ed costing $0.90 to $0.95

HIVST: 8 PQ'ed ($1-$3,29)

- 2 manufacturers have tests costing less than $1.50



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Briefing Note

Prioritizing Adoption and Implementation of Quality Assured, Low-cost HIV Rapid Diagnostic Tests

Date published: 16 July 2025

Purpose

This document describes how national HIV programs can adopt and implement quality-assured, low-cost HIV rapid diagnostic tests (RDTs).

Background

HIV testing is a gateway to HIV prevention and treatment services and accounts for a notable share of HIV health product budgets. There are currently dozens of quality-assured HIV RDTs on the market, including HIV professional use tests, HIV self-tests (HIVSTs), and HIV/syphilis dual tests. Some product offerings cost less than those currently procured by countries, offering an opportunity for countries to procure and implement more tests within a smaller funding envelope. The World Health Organization (WHO) has recently issued guidance on opportunities for countries to accelerate the adoption of low-cost, quality assured tests.[1]

WHO Guidance Update

WHO recommends the use of three-test algorithms for HIV diagnosis involving three consecutive reactive tests to confirm an HIV-positive result to ensure high accuracy and reduce the risk of misdiagnosis.[2] Verification studies are critical to confirm if the selected three-test algorithm can accurately diagnose HIV in its intended setting.[3]

[1] "Low-cost, quality assured HIV tests to sustain access to life-saving services", Departmental Update, WHO, published 7 May 2025, https://www.who.int/news/item/07-05-2025-low-cost--quality-assured-hiv-tests-to-sustain-access-to-life-saving-services
[2] "Consolidated guidelines on differentiated HIV testing services", Guidelines, WHO, published 19 July 2024, https://iris.who.int/bitstream/handle/10665/378162/9789240096394-eng.pdf?sequence=1
[3] "Optimizing HIV testing algorithms: a generic verification protocol for selecting appropriate HIV serology assays and assessing the level of shared false reactivity", Toolkit, World Health Organization, published November 2021, 9789240039162-eng.pdf

https://resources.theglobalfund.org/media/oa1hc4ss/cr_prioritizing-qa-low-cost-rdts_technical-briefing-note_en.pdf

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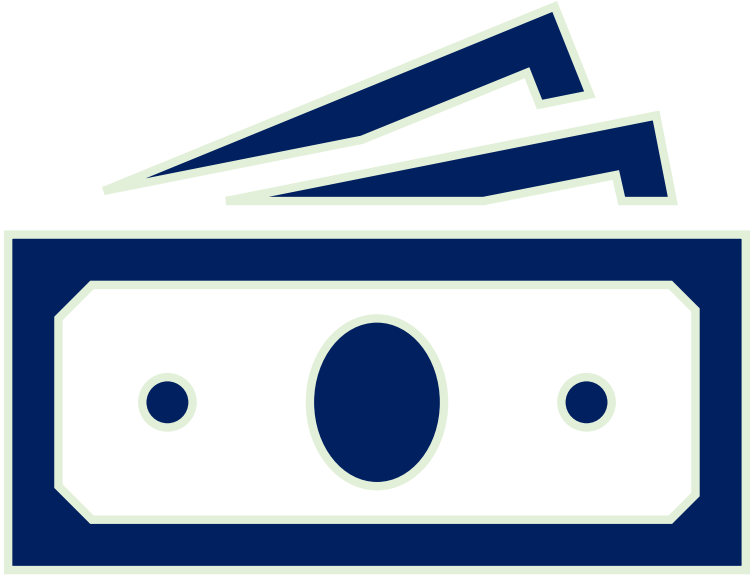
Example of savings: Procurement of 1 million HIVST annually



Switching to lower-cost, quality-assured A1, including HIVST, should be prioritized

Status quo HIVST RDT

- $3.00 costs US$3.0 million

Low-cost HIVST RDT

- $1.50* costs US$1.5 million

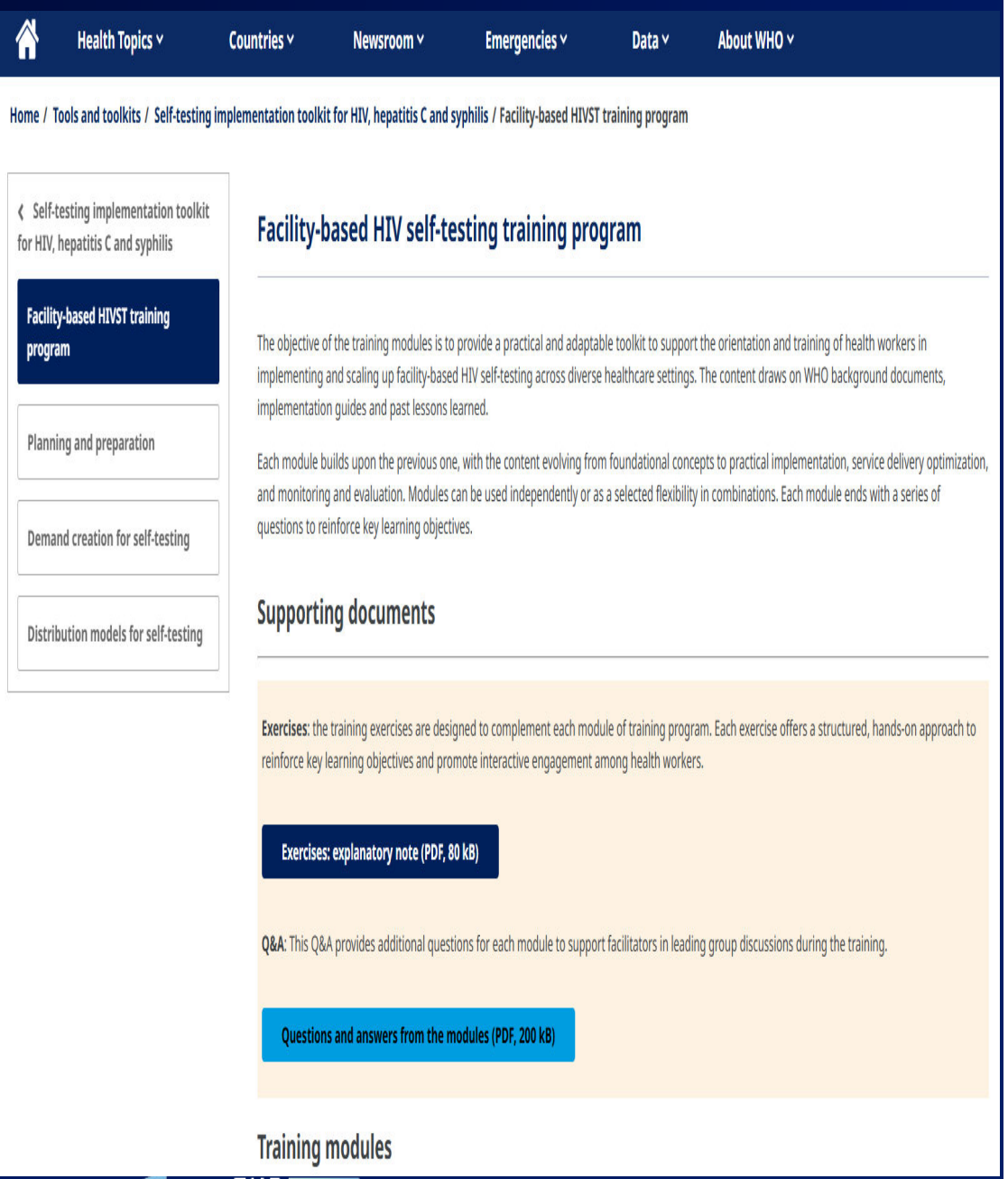
Savings gained

- US$1.5 million savings
- 50% instant decrease in annual costs

Could be used to maintain testing coverage and reinvest in lifesaving services

**Lowest cost RDTs with accessories as per May 2025 WHO catalogue*

Note this is a simplified and illustrative example based on costs in previous slides



Acknowledgements

WHO HIV Testing Team

Training program developed by WHO/PSI

https://www.who.int/tools/self-testing-implementation-toolkit-for-hiv-hcv-and-syphilis/facility-based-hivst-training-program

Self-testing implementation toolkit

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