CONSOLIDATED GUIDELINES ON DIFFERENTIATED HIV TESTING SERVICES 2024

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Consolidated guidelines on differentiated HIV testing services
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Presentation outline

1. **Global epidemiology – HIV**
2. Priority populations
3. Quality of HTS – prevention of misdiagnosis and the 3-test strategy
4. Summary of new and updated recommendations
5. HTS Approaches and DSD
6. Selfcare, HIVST, HCV and SST
7. Network-based testing
8. QMS

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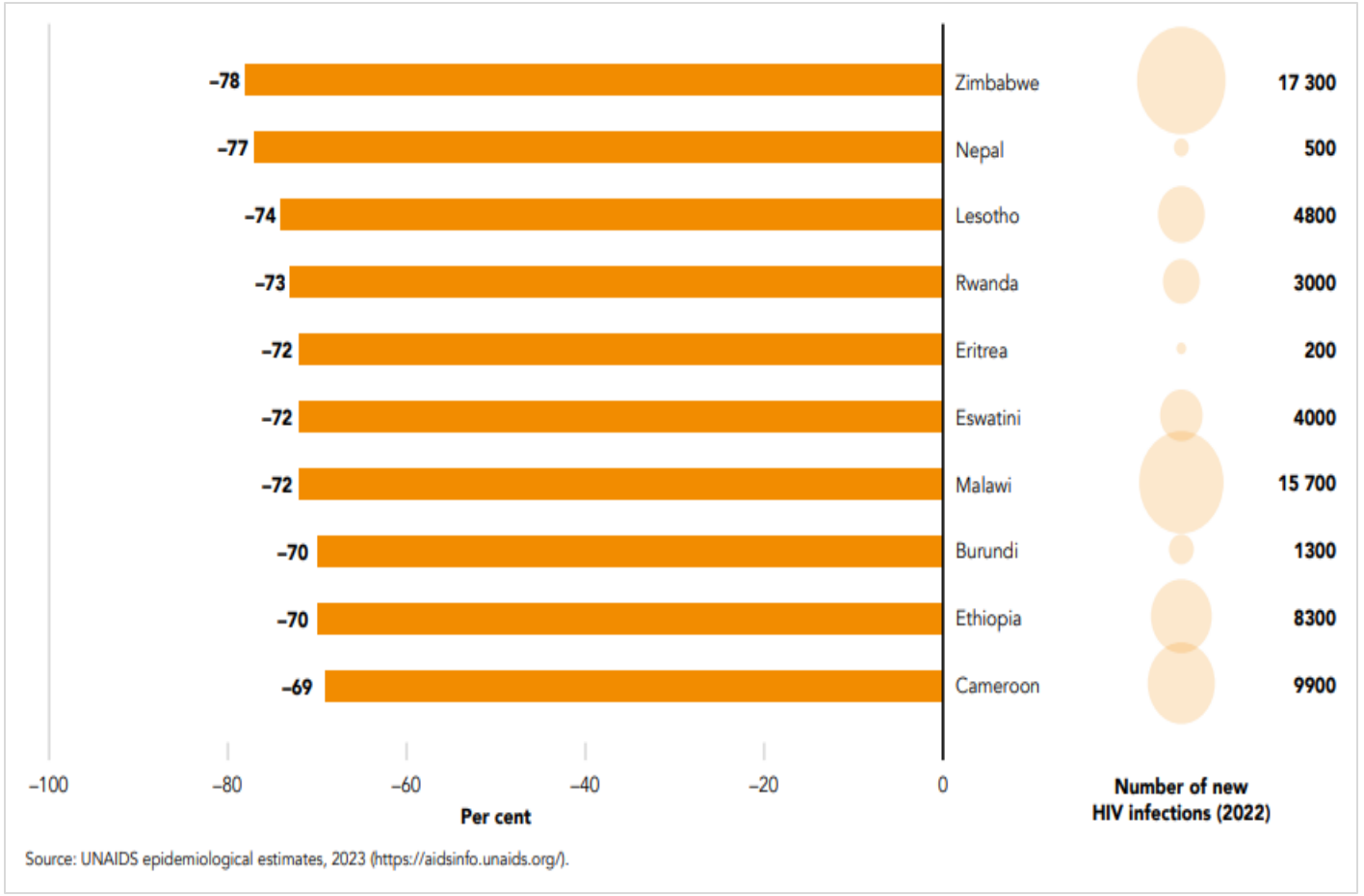
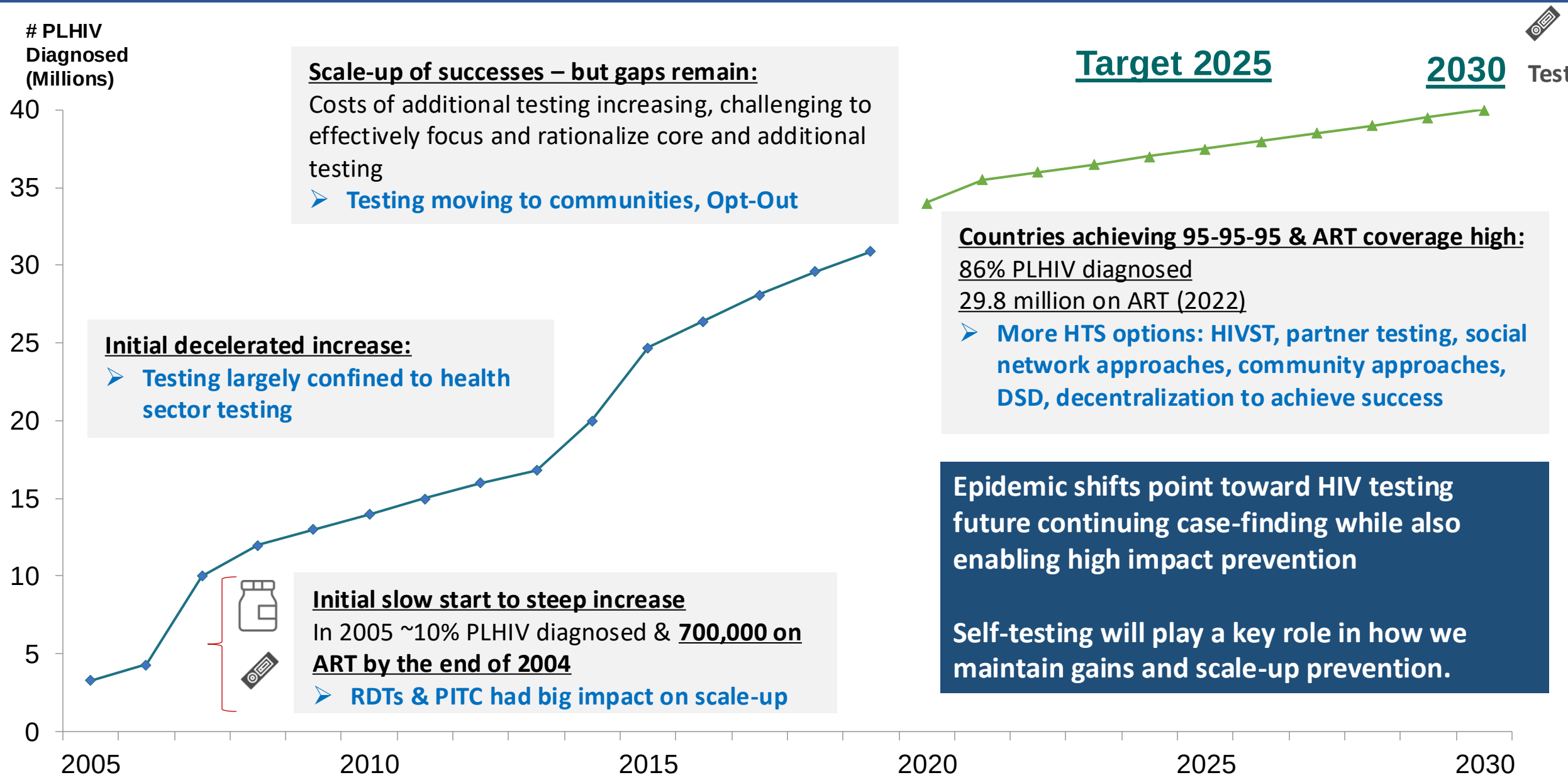
Testing shows decline in new infections, especially in ESA and WCA

Change in number of new HIV infections 2010–2022, and number of new HIV infections 2022, globally and by region
Source: UNAIDS epidemiological estimates, 2023 https://aidsinfo.unaids.org/



Progress toward Global targets: HIV testing innovations



Scale-up of successes – but gaps remain:
Costs of additional testing increasing, challenging to effectively focus and rationalize core and additional testing

- **Testing moving to communities, Opt-Out**

Initial decelerated increase:

- **Testing largely confined to health sector testing**

Initial slow start to steep increase
In 2005 ~10% PLHIV diagnosed & **700,000 on ART by the end of 2004**

- **RDTs & PITC had big impact on scale-up**

Countries achieving 95-95-95 & ART coverage high:
86% PLHIV diagnosed
29.8 million on ART (2022)

- **More HTS options: HIVST, partner testing, social network approaches, community approaches, DSD, decentralization to achieve success**

Epidemic shifts point toward HIV testing future continuing case-finding while also enabling high impact prevention

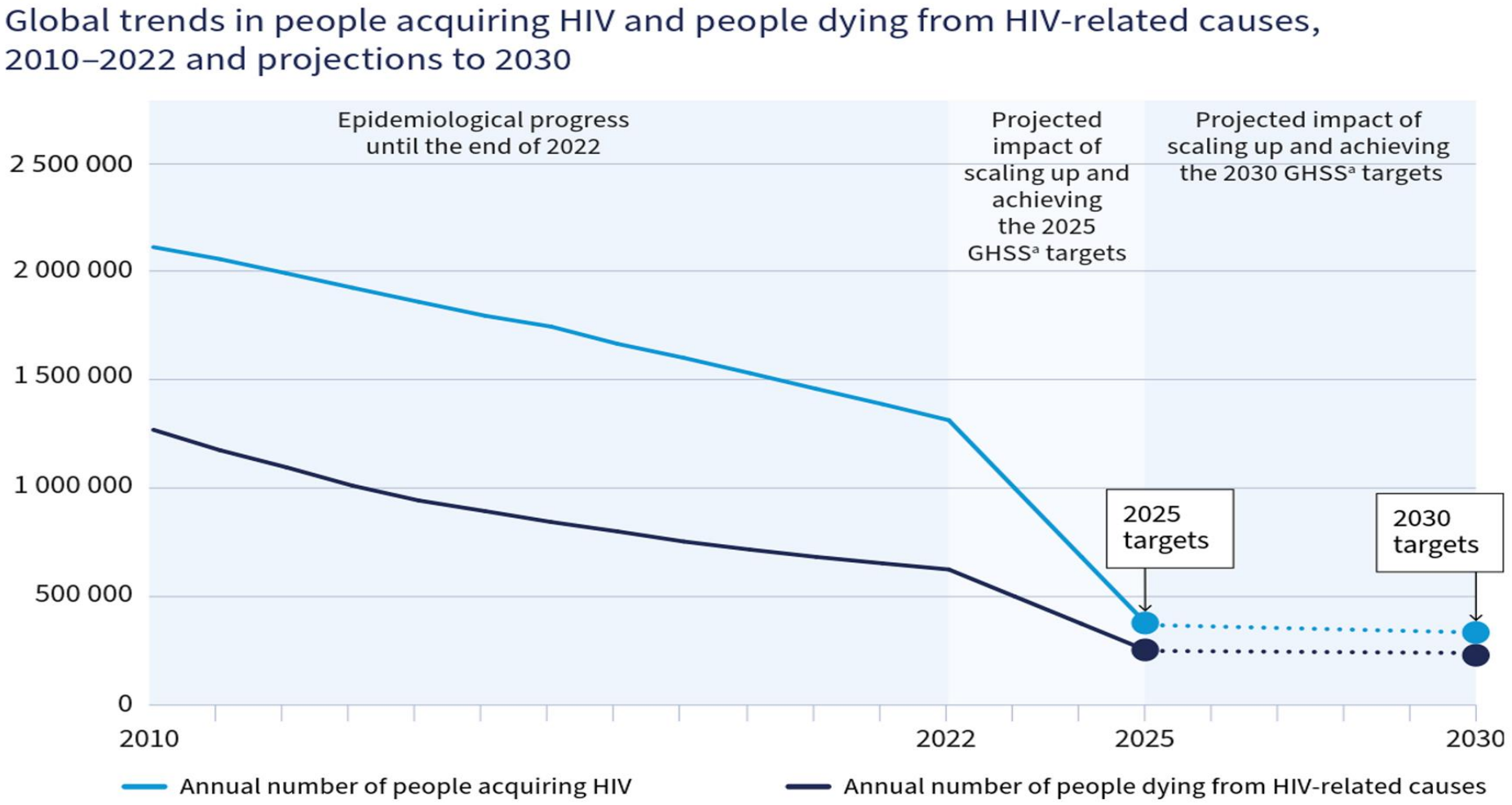
Self-testing will play a key role in how we maintain gains and scale-up prevention.

Source: WHO forecast 2020; UNAIDS 2021; WHO 2005; CHAI 2015; WHO, UNICEF, PEPFAR, GFTAM 2018; GAM reporting 14 October 2020

Progress toward Global targets – testing to help bend the curve

Even though new infections declined since 2010, the 2025 target (<370 000) of new infections may not be realized with the current trajectory

There are still HIV-negative individuals at high ongoing HIV risk who remain unreached by high-impact HIV prevention services



Note: The United Nations global targets for 2025 are twinfold: reducing the number of people acquiring HIV to less than 370 000 and reducing the number of HIV-related deaths to less than 250 000. To end AIDS as a public health threat by 2030, the targets are a 90% reduction of the number of people acquiring HIV and dying from HIV using 2010 as the baseline.

Sources: Avenir Health using 2025 targets and UNAIDS/WHO epidemiological estimates, 2023.

[a] Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030. Geneva: World Health Organization; 2022 (https://apps.who.int/iris/handle/10665/360348, accessed 7 July 2023).

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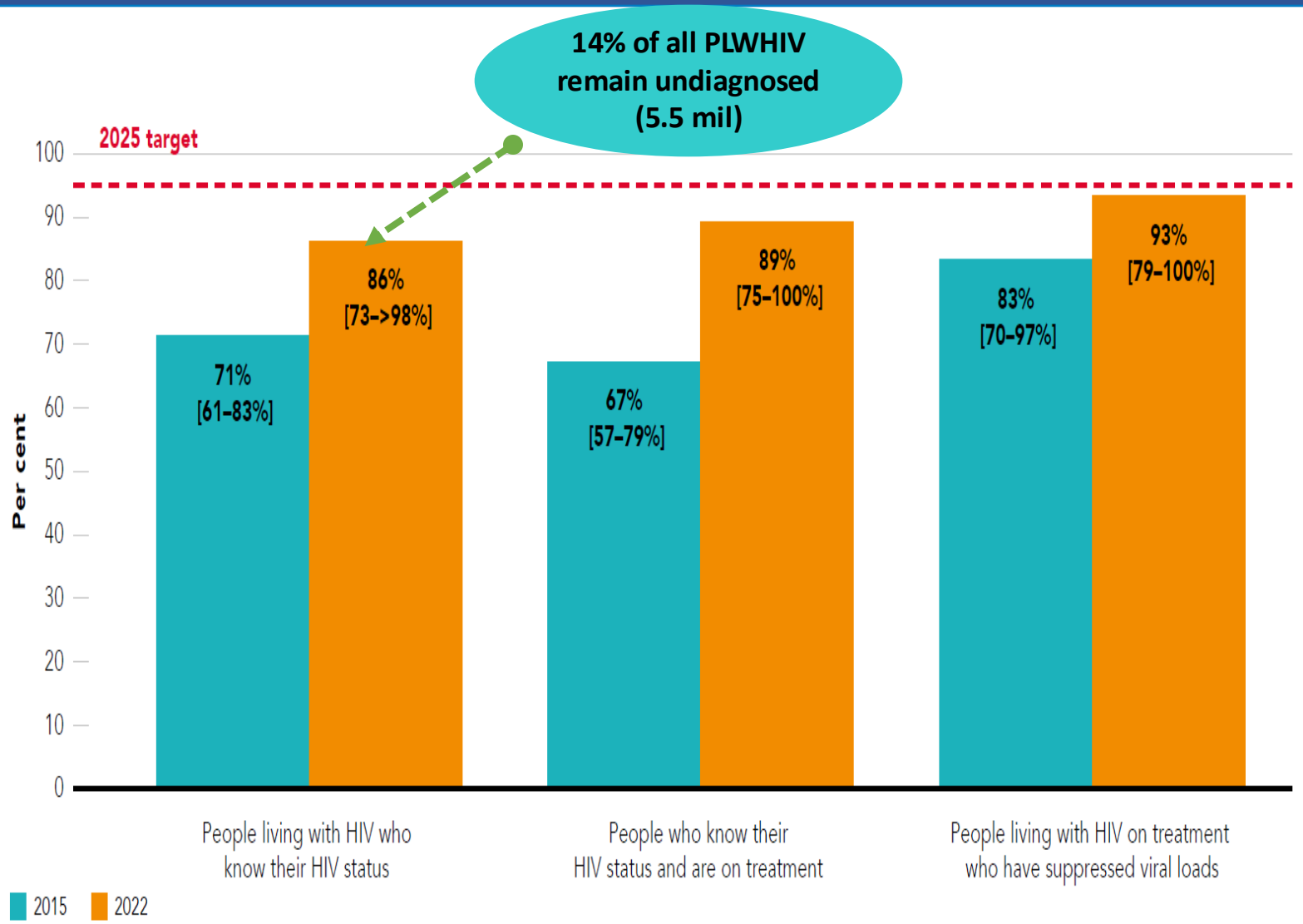
Global Progress towards the 95–95–95: Testing, Treatment and Viral load suppression targets 2015 and 2022

- Despite achievements, many at higher and ongoing risk remain unreached
- Most unreached by HTS globally are **KP**, **partners of PLHIV**, and people with co-infections including **STIs**, and viral hepatitis
- In Sub-Saharan Africa, **men** and **young people** remain a priority



Source: UNAIDS special analysis of epidemiological estimates, 2023.

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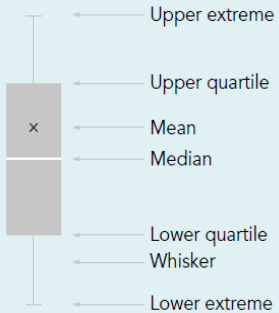
Gaps in testing for Key Populations

HIV prevalence among key populations compared with adults (15–49 years), reporting countries in eastern and southern Africa, 2018–2022

How to read



The median HIV prevalence among countries that reported these data in eastern and southern Africa was:

29.9% among sex workers.
12.9% among gay men and other men who have sex with men.
21.8% among people who inject drugs.
42.8% among transgender people.
5.5% among people in prisons.

The estimated HIV prevalence among adults (aged 15–49 years) is **5.9% [4.9–6.9%]**.

Sources: UNAIDS Global AIDS Monitoring, 2023; UNAIDS epidemiological estimates, 2023 (https://aidsinfo.unaids.org/).
Notes: *n* = number of countries. Total number of reporting countries = 21.
The adult prevalence uncertainty bounds define the range within which the true value lies (if it can be measured). Narrow bounds indicate that an estimate is precise, while wide bounds indicate greater uncertainty regarding the estimate.

HIV testing gaps for key populations (n= number of countries reporting)

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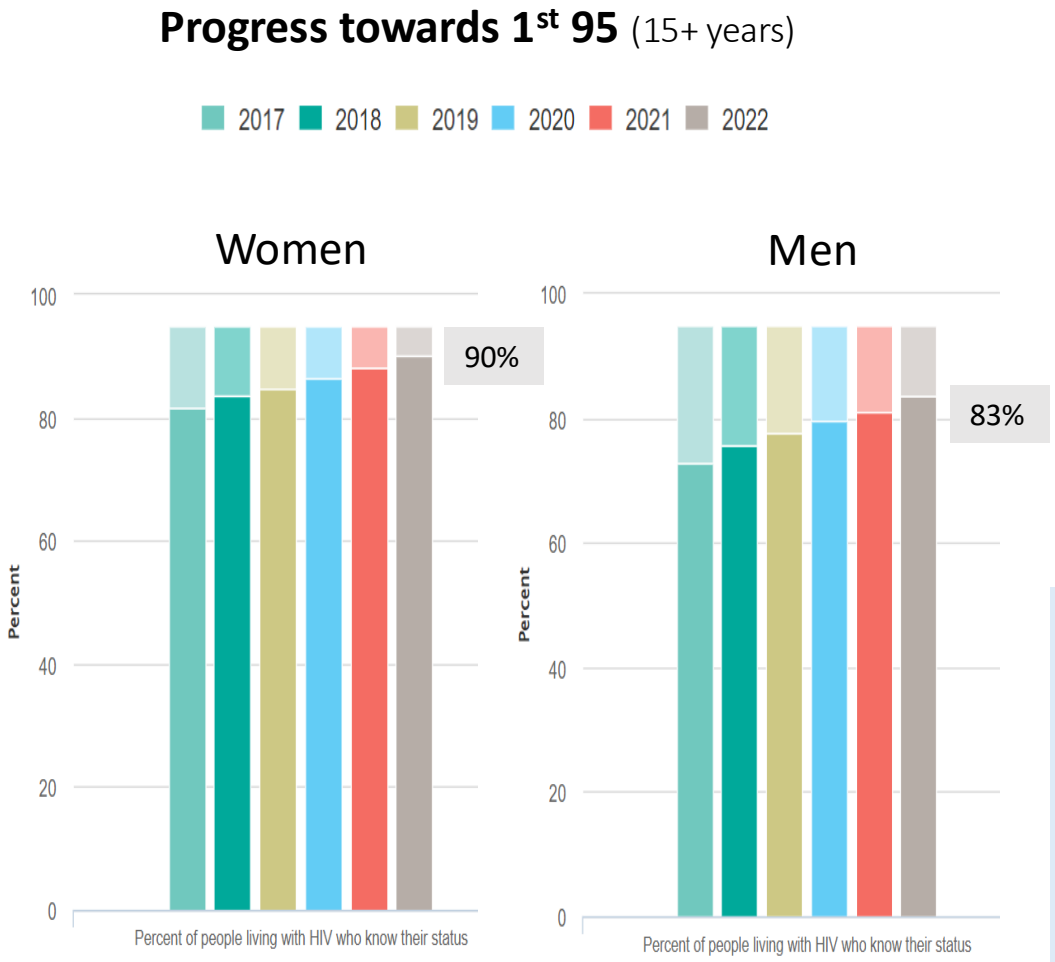
Men continue to lag in knowledge of HIV status



Source: UNAIDS special analysis, 2023

- 90% of women & only 83% of men (15+) with HIV aware of their HIV status in 2022
- Of these, 93% of women and only 86% of men (15+) had access to treatment
- AIDS-related mortality declined by 55% among women and girls and by only 47% among men between 2010-22
- **We need a strategic mix of differentiated HTS approaches to reach more men and link them to appropriate prevention and treatment services**

Reaching men with testing has huge impact on men <u>& women</u>

Had additional efforts to reach, test & maintain men in ART at levels equal to women, 50% new infections in AGYW could have been averted, bringing gender equality in the HIV burden

Growing gender disparity in HIV infection in Africa: sources and policy implications, Monod, 2023 doi: https://doi.org/10.1101/2023.03.16.23287351

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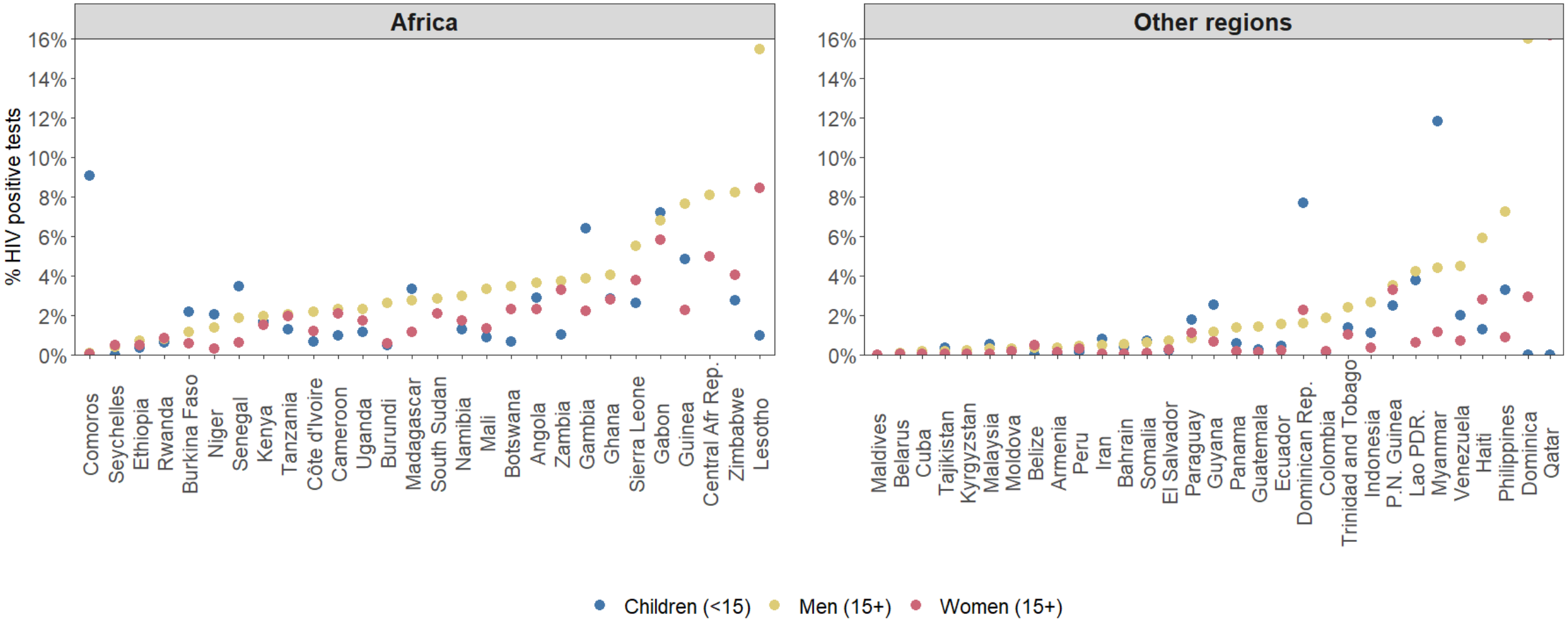
Positivity higher among men in most countries



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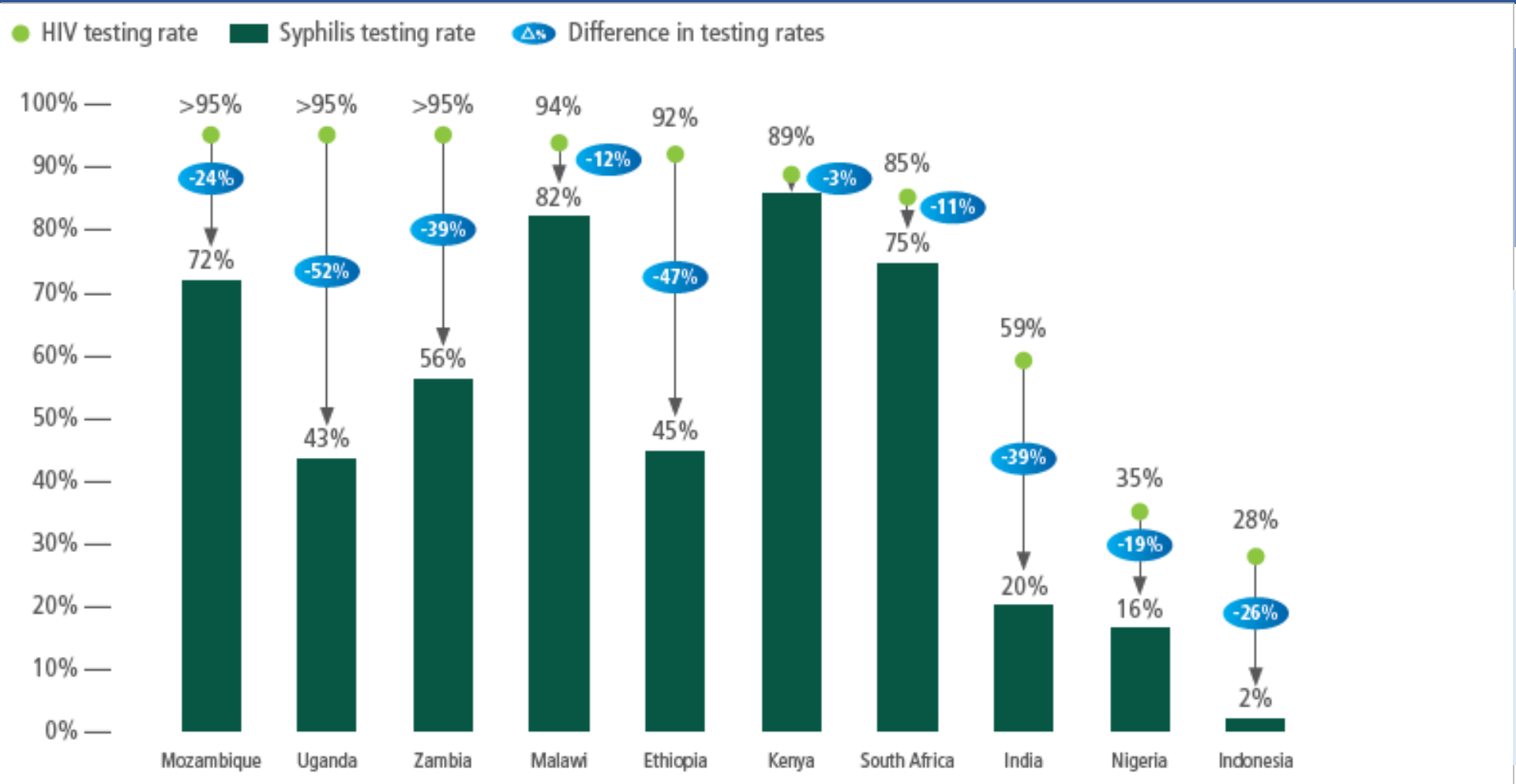
Source: WHO July 2024, Lanre Edun

Differences in coverage of testing for HIV and syphilis in pregnant women visiting ANC in 10 countries, 2016–2018



Prevalence	Mozambique	Uganda	Zambia	Malawi	Ethiopia	Kenya	South Africa	India	Nigeria	Indonesia	
HIV	15.0%	7.3%	14.3%	11.7%	1.2%	6.2%	23.7%	0.2%	3.0%	0.3%	Women between 15–49 years
Syphilis	4.6%	2.9%	3.5%	1.0%	1.1%	1.4%	2.0%	0.38%	0.8%	3.2%	% ANC attendees positive for syphilis

ANC = antenatal care

Source: Storey A, Seghers S, Pyne-Mercier L, Peeling R, Newman Owiredu M, Taylor M. Syphilis diagnosis and treatment during antenatal care: the potential catalytic impact of the dual HIV and syphilis rapid diagnostic test. Lancet Glob Health. 2019; 7(8): e1006-e1008.

Syphilis testing rates in ANC suboptimal and lagging behind

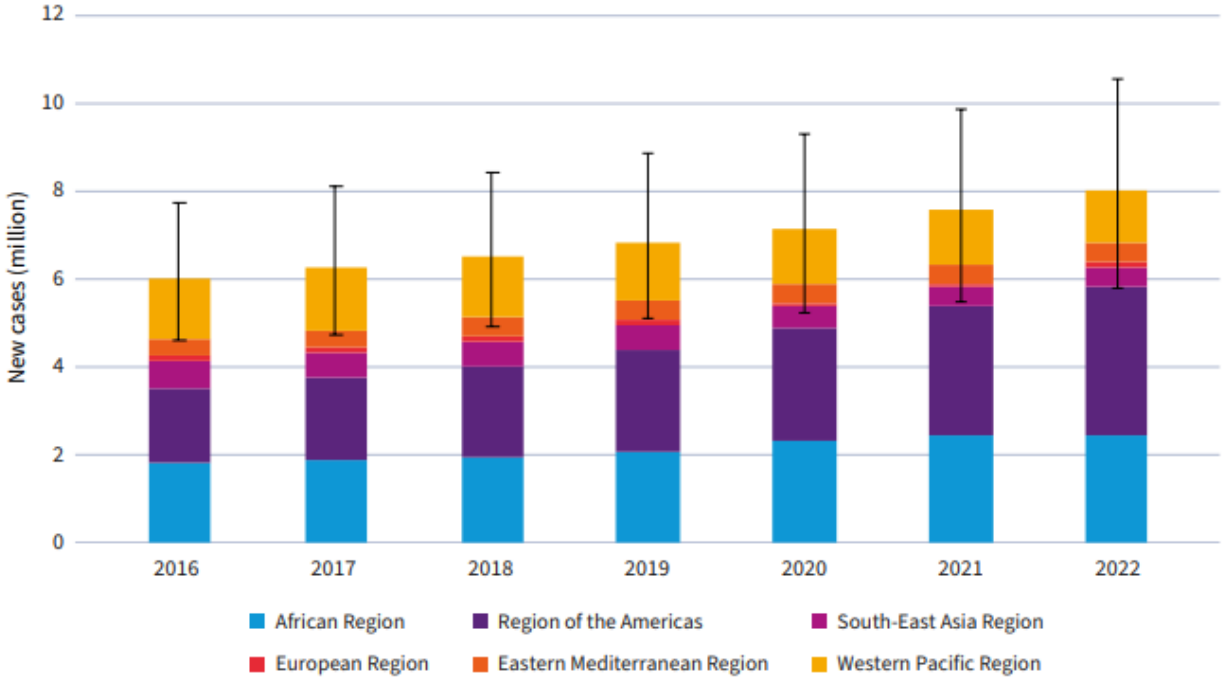
Introducing dual HIV/syphilis rapid tests as the first test in ANC is a cost-saving approach to reducing mother-to-child-transmission in all settings

Dual HIV/syphilis RDs can help close the gap!

Global STI situation

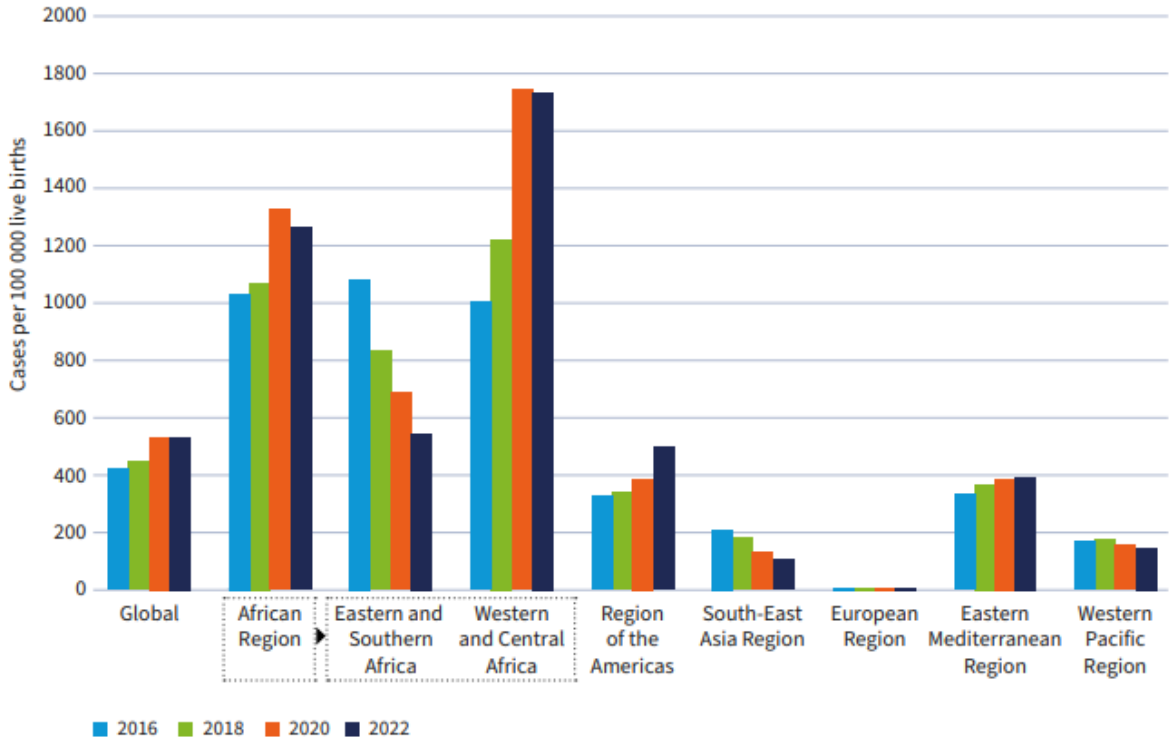
Syphilis and congenital syphilis case rates increasing in some Regions

Fig. 6.2 Estimates of the total number of new cases of syphilis among people aged 15–49 years by WHO region, 2016–2022



Source: Global HIV, Hepatitis and STIs Programmes (HHS), WHO, 2024.

Fig. 6.3 Estimates of congenital syphilis case rates per 100 000 live births, global and by WHO region, 2016–2022



Source: Global HIV, Hepatitis and STIs Programmes (HHS), WHO, 2024.

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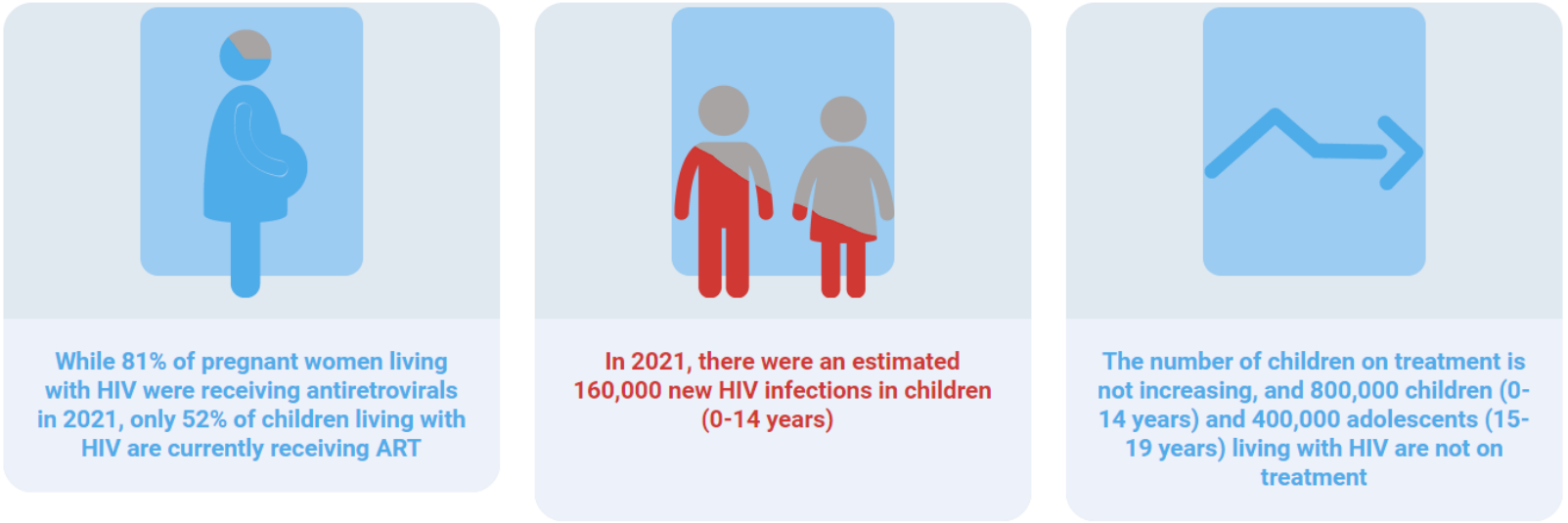
Case finding and equity priorities for HTS

Vision to end paedatric AIDS by 2030 focuses on addressing key gaps:

1. Missed opportunities for testing and late testing;
2. Ineffective linkage and lack of support on re-engagement in care where needed; transmission;
3. Suboptimal testing frequency and offer of prevention
4. Lack of low-barrier service delivery and restrictive policies (e.g. age of consent for testing)



Children and adolescents being left behind and need focused effort

https://www.childrenandaids.org/global-alliance

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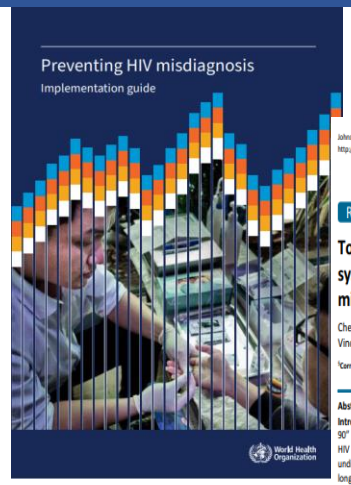
Prioritize quality testing to prevent misdiagnosis

- Maintaining good quality of testing essential for the prevention of misdiagnosis
- Priority to transition to 3-test strategy
  - WHO recommends **that an HIV-positive diagnosis be made based on three consecutive HIV-reactive results**. This is increasingly important as treatment-adjusted HIV prevalence and national HTS positivity continue to decline over time. The use of 3 tests, in the right order, can increase the PPV.

- **Testing quality is critical: Avoid misdiagnoses**
  - Using the **serial 3 test strategy in all epidemic settings**
  - Re-testing before ART initiation
  - Conducting verification studies to determine the most suitable HIV testing algorithm
  - Instituting strong quality management systems

- **Retesting is recommended for the following people**
  - With HIV-inconclusive status, after 14 days
  - Prior to ART initiation (rule out human errors and prevent misdiagnosis).
  - For monitoring in HIV prevention programmes – PrEP, PEP, ANC, VMMC,



Johnson CC et al. Journal of the International AIDS Society 2017, 20(Suppl 6):21755
http://www.jiasociety.org/index.php/jias/article/view/21755 | http://dx.doi.org/10.7448/IAS.20.7.21755

JIAS Journal of the International AIDS Society

Review article

To err is human, to correct is public health: a systematic review examining poor quality testing and misdiagnosis of HIV status

Cheryl C. Johnson[1,2§], Virginia Fonner[3], Anita Sands[4], Nathan Ford[1], Carla Mahklouf Obermeyer[5], Sharon Tsui[6], Vincent Wong[7] and Rachel Baggaley[1]

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Abstract

Introduction: In accordance with global testing and treatment targets, many countries are seeking ways to reach the "90-90-90" goals, starting with diagnosing 90% of all people with HIV. Quality HIV testing services are needed to enable people with HIV to be diagnosed and linked to treatment as early as possible. It is essential that opportunities to reach people with undiagnosed HIV are not missed, diagnoses are correct and HIV-negative individuals are not inadvertently initiated on life-long treatment. We conducted this systematic review to assess the magnitude of misdiagnosis and to describe poor HIV testing practices using rapid diagnostic tests.

Methods: We systematically searched peer-reviewed articles, abstracts and grey literature published from 1 January 1990 to 19 April 2017. Studies were included if they used at least two rapid diagnostic tests and reported on HIV misdiagnosis, factors related to potential misdiagnosis or described quality issues and errors related to HIV testing.

Results: Sixty-four studies were included in this review. A small proportion of false positive (median 3.1%, interquartile range (IQR): 0.4-5.2%) and false negative (median: 0.4%, IQR: 0-3.9%) diagnoses were identified. Suboptimal testing strategies were the most common factor in studies reporting misdiagnoses, particularly false positive diagnoses due to using a "tiebreaker" test to resolve discrepant test results. A substantial proportion of false negative diagnoses were related to retesting among people on antiretroviral therapy.

Conclusions: HIV testing errors and poor practices, particularly those resulting in false positive or false negative diagnoses, do

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BRIEF REPORT

The Cost of Not Retesting: Human Immunodeficiency Virus Misdiagnosis in the Antiretroviral Therapy "Test-and-Offer" Era

Jeffrey W. Eaton,[1] Cheryl C. Johnson,[2] and Simon Gregson[1,3]

[1]Department of Infectious Disease Epidemiology, Imperial College London, United Kingdom; [2]HIV Department, World Health Organization, Geneva, Switzerland; and [3]Biomedical Research and Training Institute, Harare, Zimbabwe

We compared estimated costs of retesting human immunodeficiency virus (HIV)-positive persons before antiretroviral therapy (ART) initiation to the costs of ART provision to misdiagnosed HIV-negative persons. Savings from averted unnecessary ART costs were greater than retesting costs within 1 year using assumptions representative of HIV testing performance in programmatic settings. Countries should implement re-testing before ART initiation.

Keywords. HIV testing; misdiagnosis; antiretroviral treatment; cost-benefit analysis.

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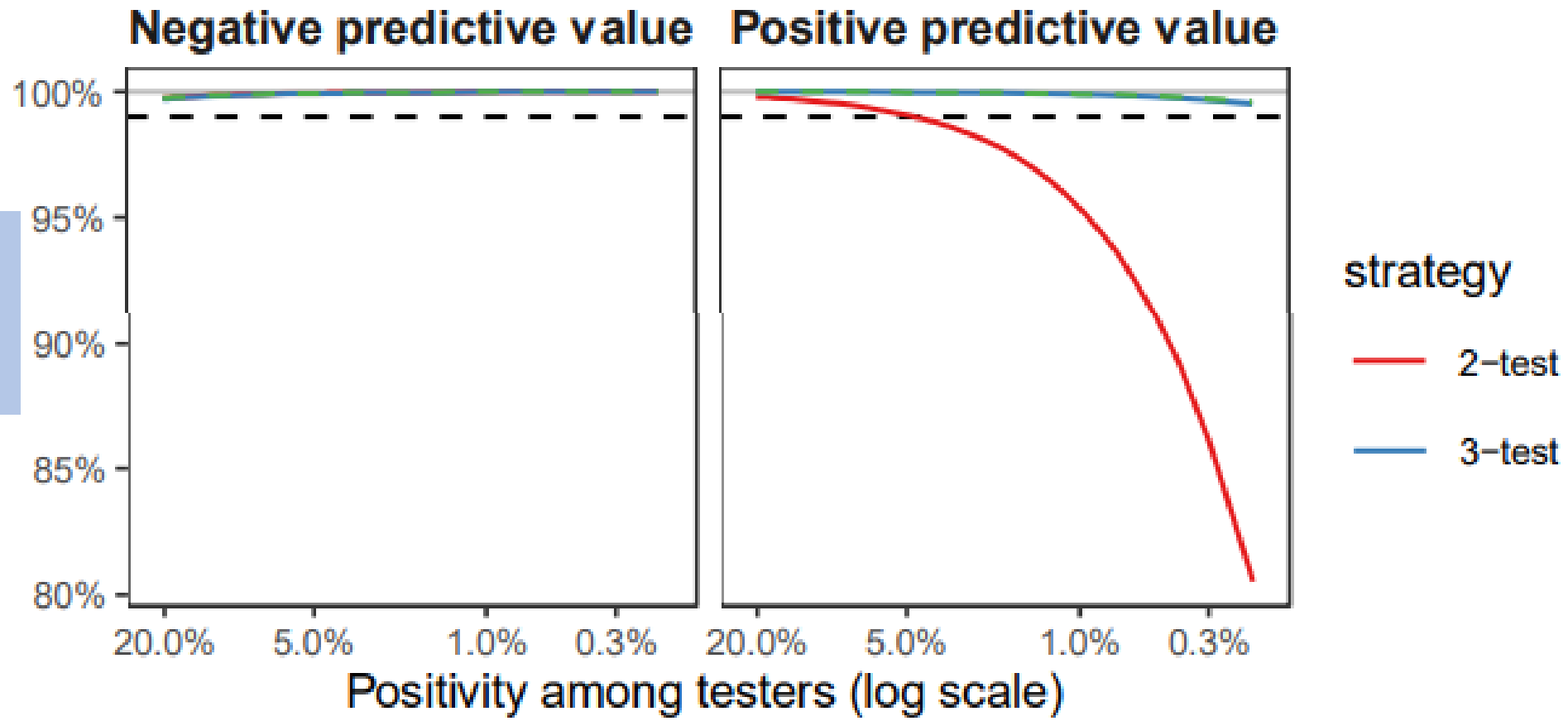
Negative predictive value and positive predictive value for 2 vs 3 test strategy

The NPV of both two-test and three-test strategies is similar at low and high positivity rates among testers.



Positive predictive value drops off substantially as HIV positivity in population being tested drops

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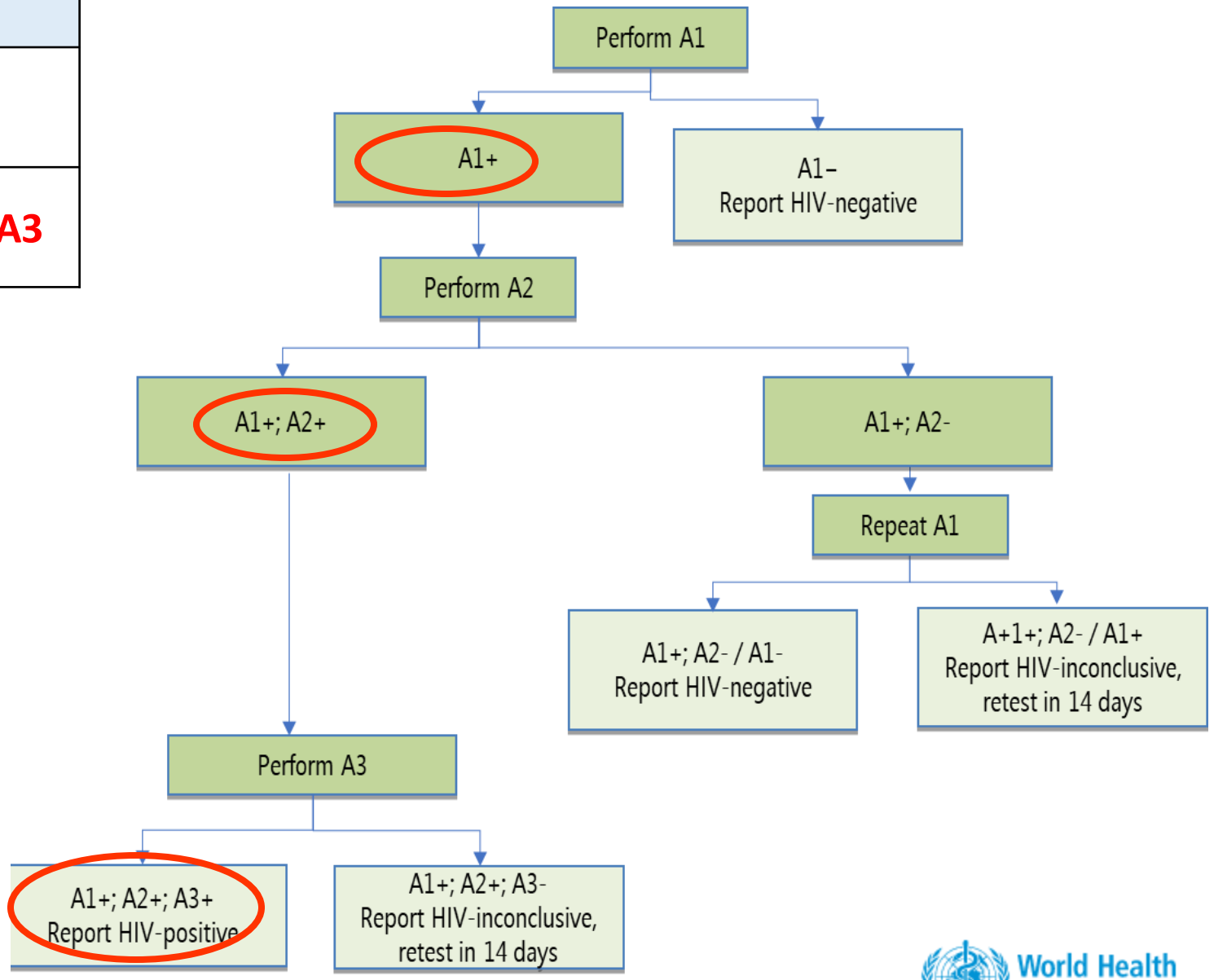
WHO recommended 3-test algorithm

Performance characteristics	
Highest sensitivity (to rule in all positives [true +false])	**A1**
Highest specificity (>A1) (to rule out all false positives)	**A2** and **A3**

To prevent misdiagnosis

WHO recommends **that an HIV-positive diagnosis be made based on three consecutive HIV-reactive results**.

The WHO three-test strategy should not be confused with a **tiebreaker strategy**:



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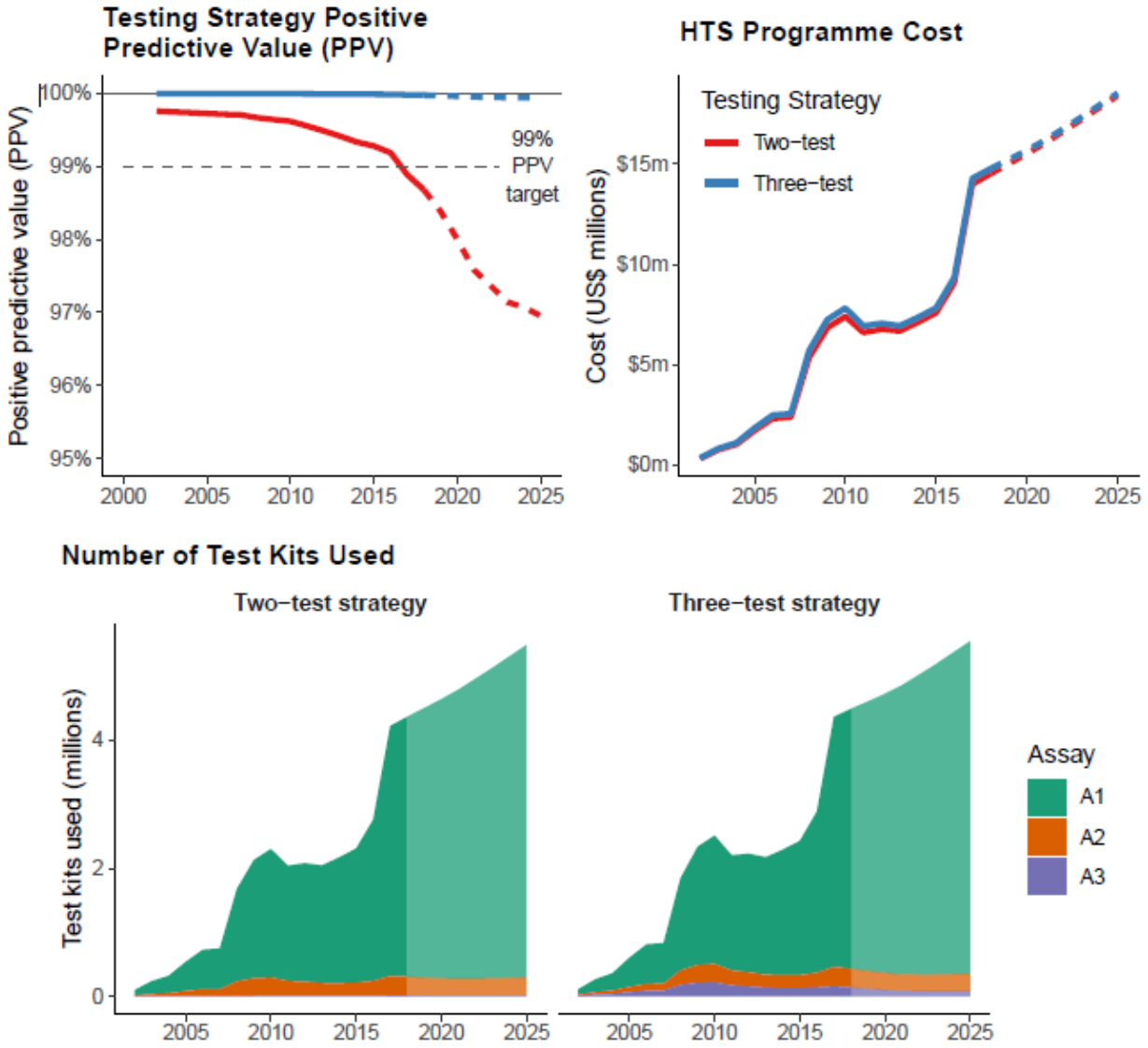
Implications for transitioning to the WHO standard 3-test strategy

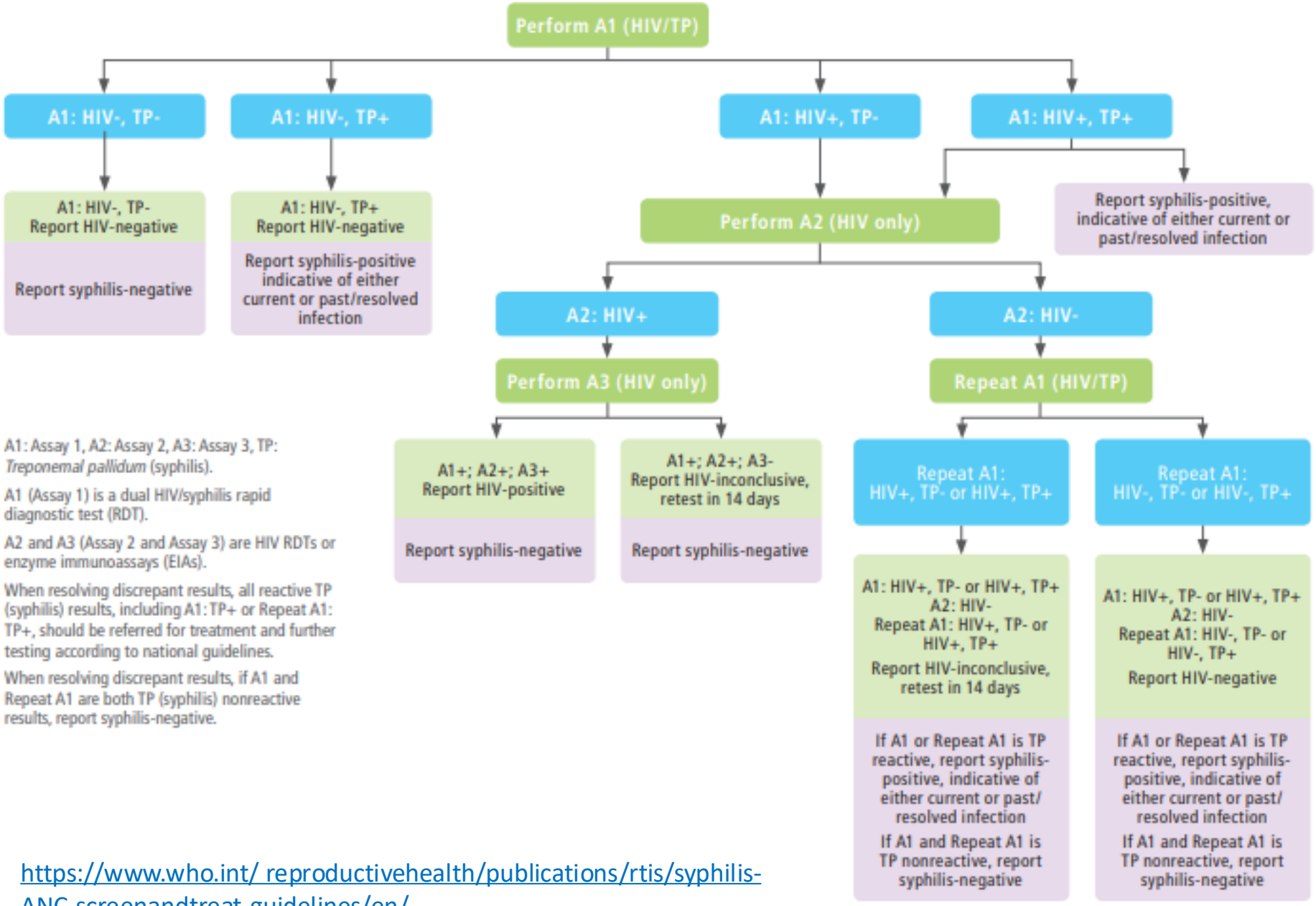
- **More accurate HIV+ diagnoses**
  - Increases **inconclusive** results:
    - A1+/A2+/A3- ruled inconclusive… but most will be confirmed negative at day 14 *(a good thing, otherwise, they would go on ART)*.
  - Important for treat all and rapid initiation
- **Cost-effective overall**
  - Without even considering cost of misdiagnosis and unnecessary ART initiation
- **HTS programme costs are comparable** – see Malawi example
  - Incremental cost of 3-test vs. 2-test algorithm <2.5% for positivity below 5%
  - Continued efforts to minimize costs are needed, by having good coordination and exploring ways to reduce cost of delivering first test
- **Need to consider ways to ease implementation**
  - Greater expansion of test for triage and HIV self-testing

Estimates and projections for HIV rapid test kit usage (2000-2025), Malawi, and implications for HIV testing



Source: WHO GL 2019; WHO/UNAIDS/Malawi Department of HIV/AIDS, 2019 derived from Maheu-Giroux M et al AIDS 2019. DOI: 10.1097/QAD.0000000000002386.

Testing strategy for dual detection of HIV and syphilis infection for ANC settings



A1: Assay 1, A2: Assay 2, A3: Assay 3, TP: *Treponema pallidum* (syphilis).

A1 (Assay 1) is a dual HIV/syphilis rapid diagnostic test (RDT).

A2 and A3 (Assay 2 and Assay 3) are HIV RDTs or enzyme immunoassays (EIAs).

When resolving discrepant results, all reactive TP (syphilis) results, including A1: TP+ or Repeat A1: TP+, should be referred for treatment and further testing according to national guidelines.

When resolving discrepant results, if A1 and Repeat A1 are both TP (syphilis) nonreactive results, report syphilis-negative.

https://www.who.int/ reproductivehealth/publications/rtis/syphilis-ANC-screenandtreat-guidelines/en/

Penicillin is prevention: all women whose dual HIV/syphilis test results include a reactive TP (syphilis) result should be treated using benzathine penicillin and referred for further testing to provide final diagnosis of active syphilis

Rapid dual HIV/syphilis test cannot be used for:

- women with HIV on ART
- women already diagnosed with and treated for syphilis during their current pregnancy
- retesting for HIV before ART initiation.

Principles for the selection of HIV products
–Verification study–

Performance characteristics	
Highest sensitivity (to rule in all positives [true + false])	**A1**
Highest specificity (to rule out all false positives)	**A2** and **A3**

Correctness of the final HIV status is dependent on:

- Specificity of the individual products used (for A1, A2, A3), and
- Probability that any specimen that is falsely-reactive on the first assay (A1) is not also falsely-reactive on the second assay (A2) and third assay (A3)

It is suggested to conduct a **verification study of the new testing algorithms** in order to:

1. Identify the **combination of products which have minimum possible common cross-reactivity** to reduce the risk of false HIV-positive diagnosis. (**Note**: *Products from the same manufacturer should not be used as part of the testing algorithm to minimize common cross-reactivity*)

2. Not intended to reevaluate sensitivity and specificity of individual products!

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WHO supporting verification studies and developing country-facing QMS tool kit for non-lab settings to optimize limited resources and help pave the way for future sustainability and local production priorities

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Summary of new and updated recommendations

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Self-testing

NEW: HIV self-testing may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence).*

NEW: HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation *(conditional recommendation, low-certainty evidence).*

NEW: Syphilis self-testing is suggested as an additional approach to syphilis testing services *(conditional recommendation, low-certainty evidence).*

Network-based testing services

NEW: STI partner services should be offered to people with STIs as part of a range of options based on their needs and preferences and within a comprehensive package of voluntary STI testing, care and prevention *(strong recommendation, low-certainty evidence).*

UPDATED: Social network testing services may be offered as an additional HIV testing approach as part of a comprehensive package of care and prevention *(conditional recommendation, low-certainty evidence).*

HIV testing strategies

NEW: HIV recency testing is not recommended as part of routine HIV testing services *(conditional recommendation, low-certainty evidence).*

What do WHO guidelines say about recency?

In 2022, WHO issued guidance on the use of recency essays for HIV surveillance

Recency assays in surveillance

- are used in estimating HIV incidence in cross-sectional surveys and epidemiological studies
- help understand patterns and distributions of both new and long-standing HIV infections
- The utility of recency testing is demonstrated in population-based surveys to measure HIV incidence
- May be used for estimation of HIV incidence for population surveillance, evaluation of the impact of preventive interventions, and selection of a population for recruitment to a clinical trial on the efficacy of a new preventive intervention or early treatment.
- Uses an antibody-based algorithm that identifies infection less than a year ago versus more than a year ago using biomarkers.

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Source: *https://www.who.int/publications/i/item/978-92-4-155058-1*

New: **HIV recency testing is not recommended as part of routinely offered HIV testing services** *(conditional recommendation, low-certainty evidence)*

- Recency testing should not be incorporated into national diagnostic algorithms
- Use of recency assays not recommended for individual clinical use or management

Reasons why recency testing is not recommended:

- Currently no WHO-prequalified recency assays
- Recency assays do not identify acute HIV infection
- Recency assay is not a diagnostic test.
- The proposed use case for recency testing in routine testing to identify case clusters/hotspots is not supported by evidence.
- No diagnostic benefit of recency testing identified - everyone offered immediate ART, regardless of when HIV was acquired.
- Harms associated with recency testing are not well documented in the literature (may be significant)
- In routine HTS, not ethical to withhold results from clients.

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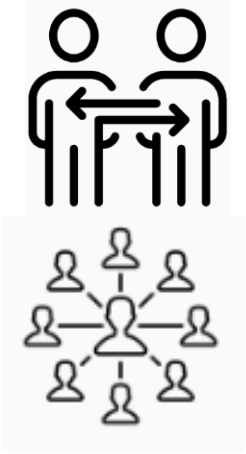
WHO recommends a strategic mix of differentiated HTS approaches

Facility-based HTS remains a priority and should be routinely offered to all clients of unknown or HIV-negative status. This includes offering HIV testing in a facility, identifying key entry points for both in-patient and out-patient clinics, **malnutrition clinics**, **ANC, TB, STI, family planning services**

Focused community-based (in addition to routine offering of facility-based testing): Offering HIV testing in natural setting of the community with linkage to prevention, care and treatment services, e.g. outreach, CBOs, workplace, clubs, bars.



Network-based testing includes a range of approaches (partner services, social network testing, family and household testing services) that can extend testing to partners, family members, and other members of social networks. Network-based testing can include distribution of self-tests and should always link to both prevention and care services.

Social network testing (part of network-based testing) is now recommended for everyone, and no longer limited to key populations

HIV Self-testing: Offering self-test kits for individual, and/or their partner, enabling them to collect their sample (oral or blood), perform tests, and interpret results privately. All reactive results need confirmation.

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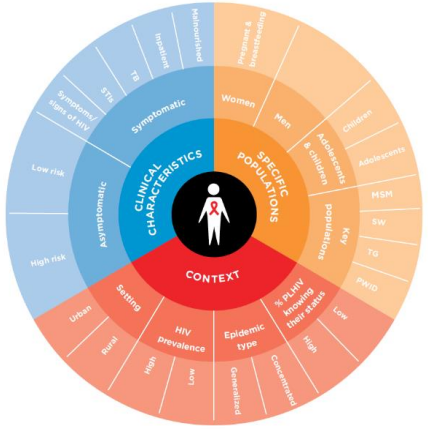
MOBILIZING | TESTING | LINKING

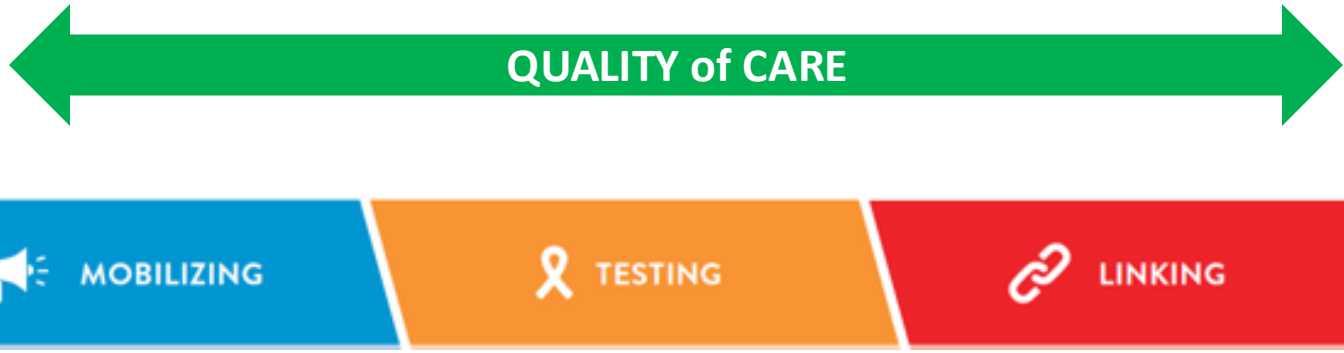
Strategic principles for differentiated testing services

Testing approaches need to consider three dimensions for implementation:

1. Mobilizing and creating demand for testing
2. Testing service delivery
3. Linkage to post-test services

Approaches are then adapted based on the context, population and epidemic





	Mobilizing and creating demand	Testing implementation	Linkage
When	Continuous, intermittent or focused	Time of day and frequency	Time period for linking and frequency of monitoring
Where	Location of mobilization activities	Health facility, other facility, community, homes	Location of linkage activities
Who	Who does the mobilizing?	Who does the HIV testing? Self-testing and/or health workers?	Who supports linkage to prevention or ART initiation/ re-initiation?
What	What package of services and demand creation interventions?	HIV testing alone or integrated with other services?	What linkage interventions?

Source: Adapted from IAS 2018 *(5)*.

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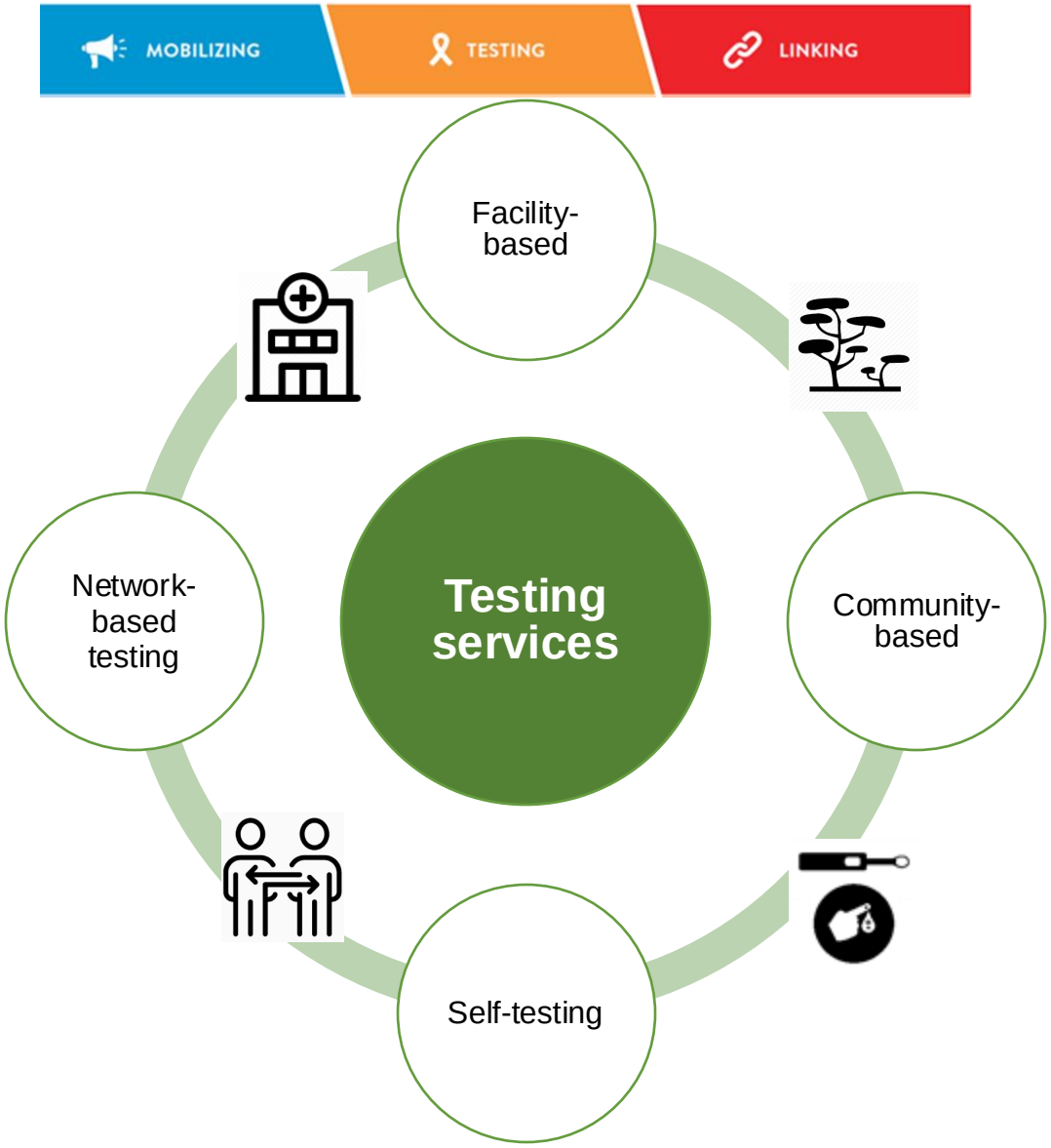
Source: WHO 2024; IAS 2018

Understanding testing services: a cross-cutting perspective



Different purposes for testing

- **Case-finding focused testing**: Implementation focused on reaching undiagnosed individuals and facilitating linkage to care. Generally, includes specific targeted testing outreach.
- **Prevention focused testing**: Ensuring those people stay negative and identifying new infections early in those with high ongoing risk. Core services e.g. PMTCT/ANC, KP etc
- Aim is to achieve a strategic mix that is person-centered and contributes to larger treatment and prevention goals.

Different scale and providers

- Diagnosis with rapid tests and includes range of cadres often lay providers, community workers as well as self-testing and self-sampling
- Testing providers have many tasks including mobilizing, testing, linking; often integrating work with other disease
- Testing sites vary widely (mobile & fixed, big & small, high & low throughput). In some settings testing in ANC/PHC settings and lower-level sites without clinical labs and limited staff capacity

World Health Organization

Some Integration priorities for consideration for HTS

Service delivery setting	HIV	HCV	HBV	STIs
Health facilities				
ANC	X	X	X	X
Contraception	X			X
Standalone VCT sites	X	X	X	X
Inpatient & outpatient department	X	X		X
Emergency departments	X	X	X	X
TB clinics	X			
STI clinics	X	X	X	X
Immunization clinics	X		X	
Malnutrition clinics	X	X	X	
Community testing approaches				
Community outreach (KP)	X	X	X	X
Community outreach (GP)	X		X	X
Workplaces	X	X		
Additional testing approaches				
Prisons and closed settings	X	X		X
PrEP/PEP programmes	X	X	X	X
VMMC sites	X			X
Network-based testing	X	X	X	X
Self-testing	X	X		X

* This table is not exhaustive. It is important to adapt integration priorities based on local context and resources, epidemiology, co-infections and populations being served.

World Health Organization

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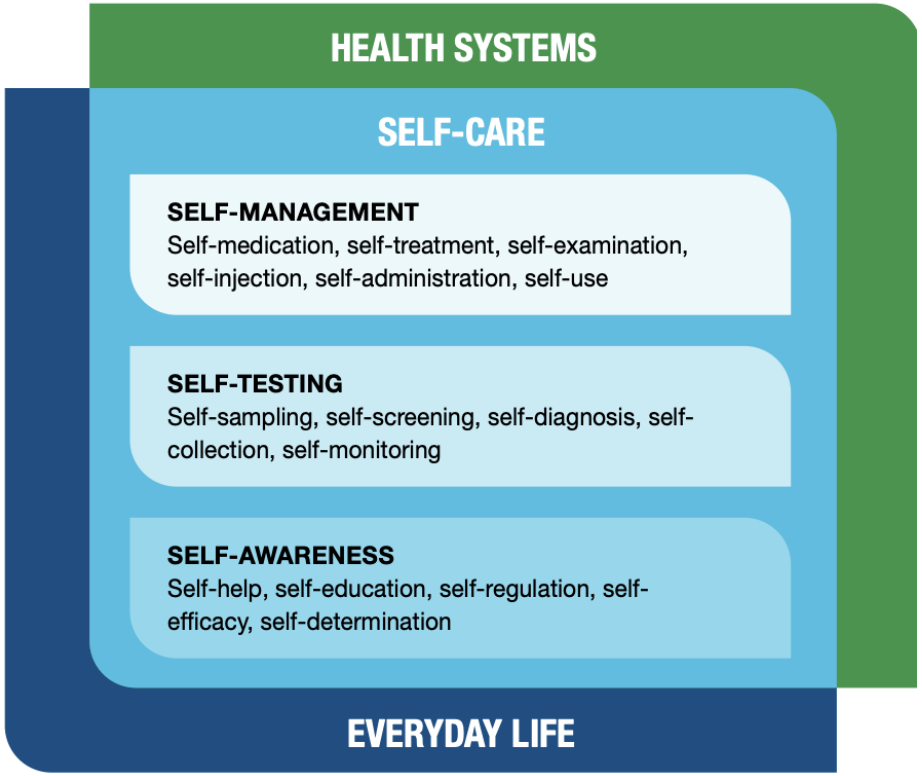
1. Global epidemiology – HIV
2. Priority populations
3. Quality of HTS – prevention of misdiagnosis and the 3-test strategy
4. Summary of new and updated recommendations
5. HTS Approaches and DSD
6. **Selfcare, HIVST, HCV and SST**
7. Network-based testing
8. QMS

World Health Organization

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.

World Health Organization

SELF-TESTING

- **Self-testing recommended across conditions and diseases**

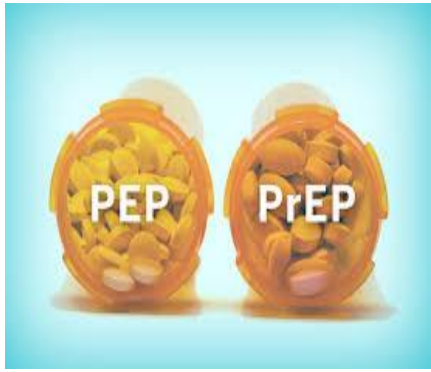
- **Self-testing and self-care** becoming standard of care across many different areas

- **No difference in blood vs oral self-tests**
  - 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



World Health Organization

HIVST recommended in health facilities

HIV self-testing may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence)*.

Challenges/Limitations with Facility-based HTS

- Suboptimal HIV testing for those with HIV-related risk (in family planning and STI clinics)
- Missed opportunities for priority populations not routinely offered HTS when presenting at the facilities (STI clients, TB patients, FP clients, men)
- Worsened by the use of risk-based screening tools
- Offering risk-based testing is inferior to HIV testing

World Health Organization

Facility-based HIV tests contributed to almost 90% of all tests conducted in the African region

Optimizing Facility-based HTS to be inclusive and accessible to missing populations is critical

Facility-based HIVST:

- replacing risk-screening-out tools
- compliments provider-administered testing (not replacing it)
- may increase testing uptake for specific populations, and increase positivity
- has the potential to reduce barriers to testing
- Should be routinely monitored and reported as part of the national HIV response

Facility-based HIVST: Case-finding focused or Prevention focused

Case-finding focused HIVST

- Helps diagnose PLHIV at high risk and initiate ART as soon as possible
- Increase routine offer of FB HTS in key entry points (PHC, OPD, FP, STI)
- Replace risk screening tools to simplify and streamline HTS in facilities
- Increase offer in KP settings (clinics and drop-in centers)
- Secondary distribution for SN, sexual partners, new HIV cases, and PWID partners

Prevention focused HIVST

HIVST part of implementing and monitoring prevention services

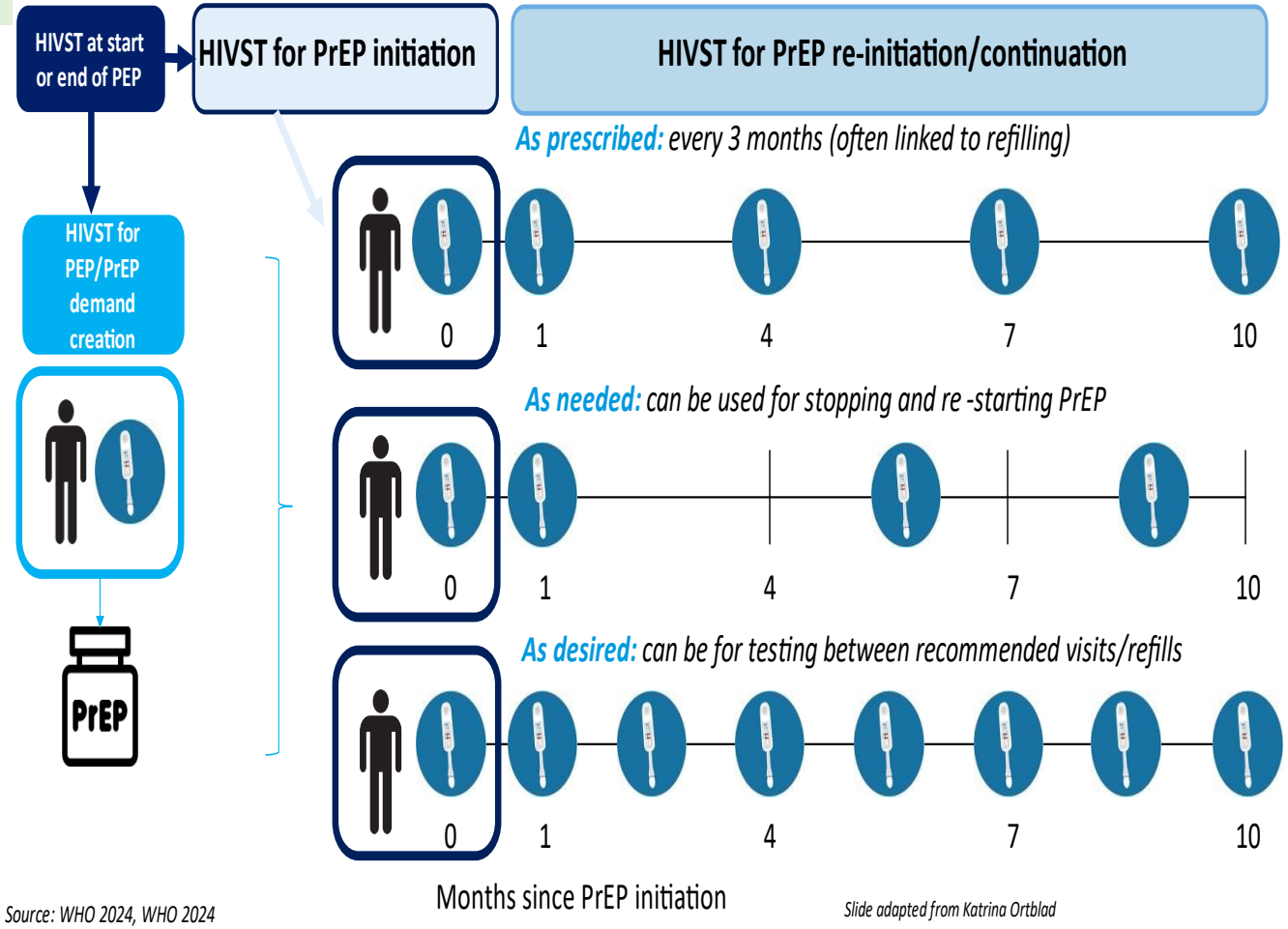
- helps support HIV-negative people to stay negative (monitoring)
- ANC – retesting & male partner testing
- VMMC – uptake and offering those accompanying VMMC clients
- PrEP – initiation, re-initiation, continuation
- PEP – beginning and end of course
- Dapivirine Ring – throughout usage
- Harm Reduction clinics

World Health Organization

HIV self-testing for PrEP and PEP

HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation *(conditional recommendation, low-certainty evidence).*

- HIVST may be considered for use in post-exposure prophylaxis (PEP)
- HIVST can be used for initiation, continuation, and re-initiation of PrEP
- Could simplify PrEP delivery by reducing the need for frequent clinic visits
- Should be driven by client needs and preferences
- HIVST in PrEP helps streamline HTS requirements for oral PrEP (daily and on-demand) and the dapivirine ring (DVR)
- No need for further testing to confirm negative results
- Ongoing research on the role of HIVST in the use of long-acting injectable PrEP (CAB-LA)



Source: WHO 2024, WHO 2024

Slide adapted from Katrina Ortblad

https://www.who.int/publications/i/item/9789240095137

https://www.who.int/tools/prep-implementation-tool

World Health Organization

Syphilis Self-testing

WHO suggests offering syphilis self-testing as an additional syphilis testing approach *(conditional recommendation, low certainty in evidence of effects)*

- Offer within broader programme and package of services - access and linkage to confirmatory testing (where available) and immediate treatment initiation
- **Use quality-assured products**
- **Epidemiology and context**: where to deliver self-testing to specific populations and in certain geographies.
- **Clear messages : confirmatory testing and treatment**

World Health Organization

- 5 studies reported on dual HIV/syphilis self-tests
- 2 reported on single syphilis self-tests
- None on T/NT RDT

- Greater testing uptake (p=0.03)
- No significant difference in test reactivity
- No significant difference in linkage to confirmatory testing

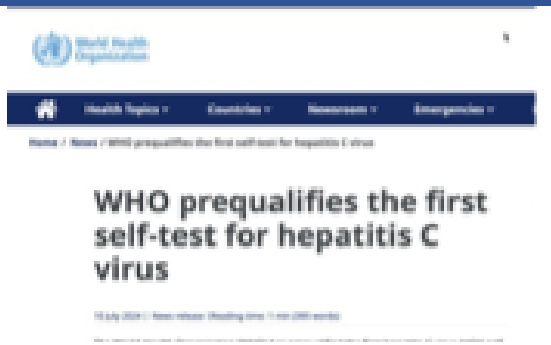
- No evidence of increased social harm or adverse event.

- High acceptability among MSM, TGW and FSW & providers in China, Zimbabwe and the US

- Lower cost per person tested than existing facility-based testing (China and Zimbabwe)

WHO recommendation on HCV self-testing

Hepatitis C virus (HCV) self-testing should be offered as an additional approach to HCV testing services
(strong recommendation, moderate-certainty evidence)

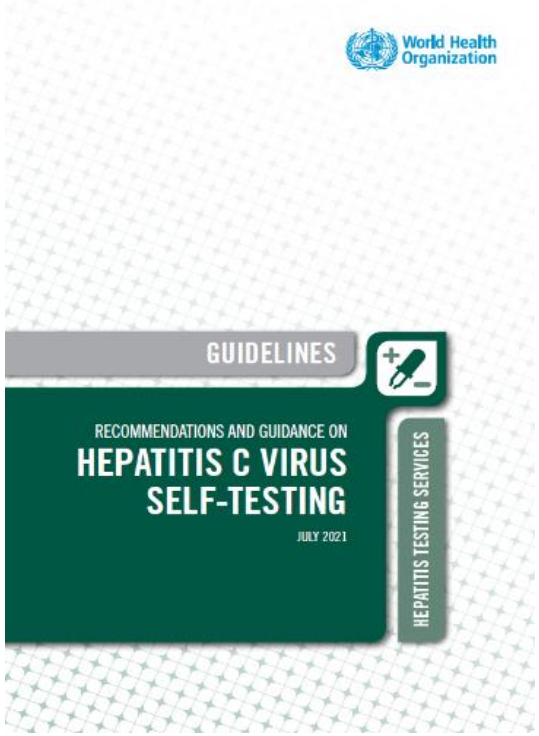


Remarks

- HCV self-testing needs to be followed by **linkage to appropriate post-test services**, including confirmation of viraemic infection, treatment, care and referral services, according to national standards.

- It is desirable to **adapt HCV self-testing service delivery and support options** to the national and local context, which includes community preferences.

- **Communities, including networks of key and vulnerable populations and peer-led organizations, need to be meaningfully and effectively engaged** in developing, adapting, implementing, and monitoring HCV self-testing programmes.



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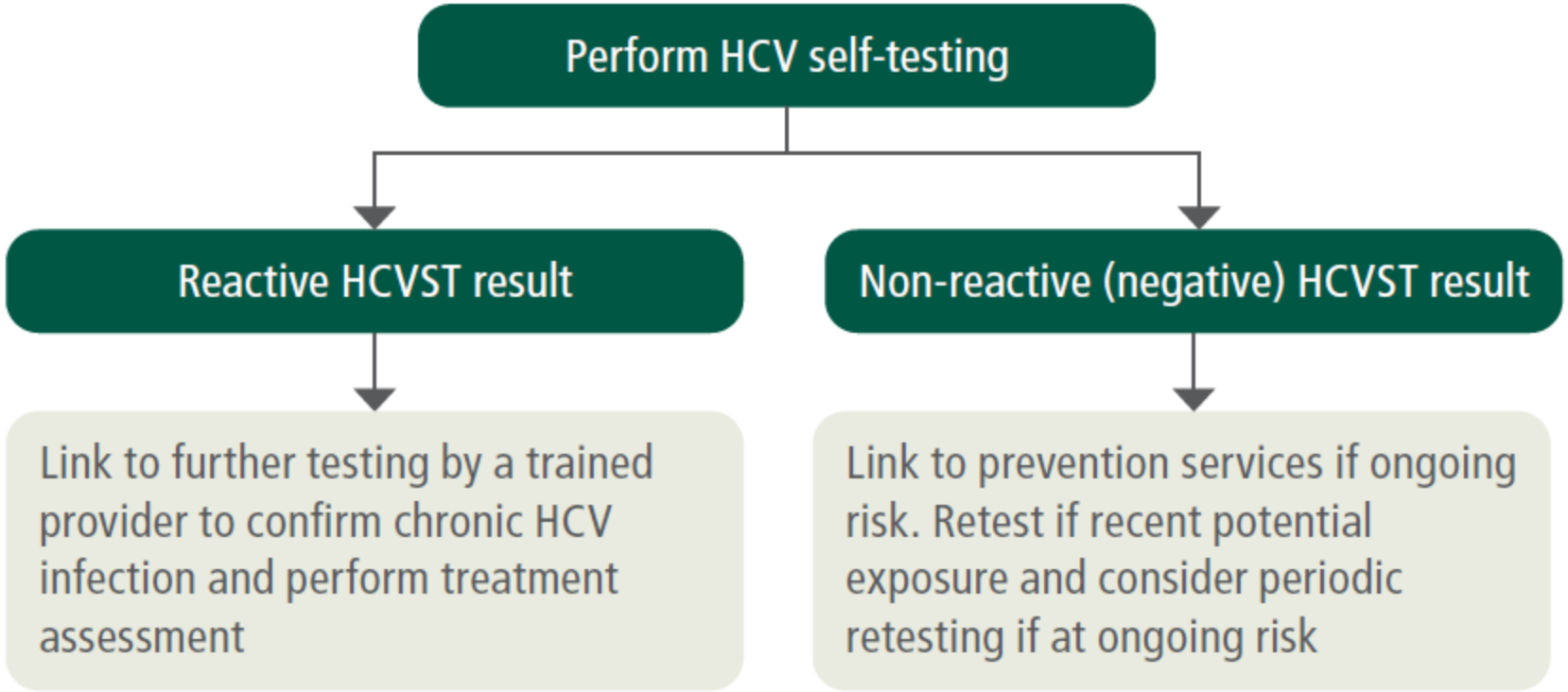
Source: WHO 2021

HCV self-testing does not provide a definitive diagnosis of chronic HCV infection –

All reactive HCVST results need to be followed by further testing to confirm viraemic infection and additional clinical assessment before starting treatment

HCV self-testing strategy



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Variety of support tools for HIVST

Virtual interventions have improved access to HIV testing, treatment and prevention services

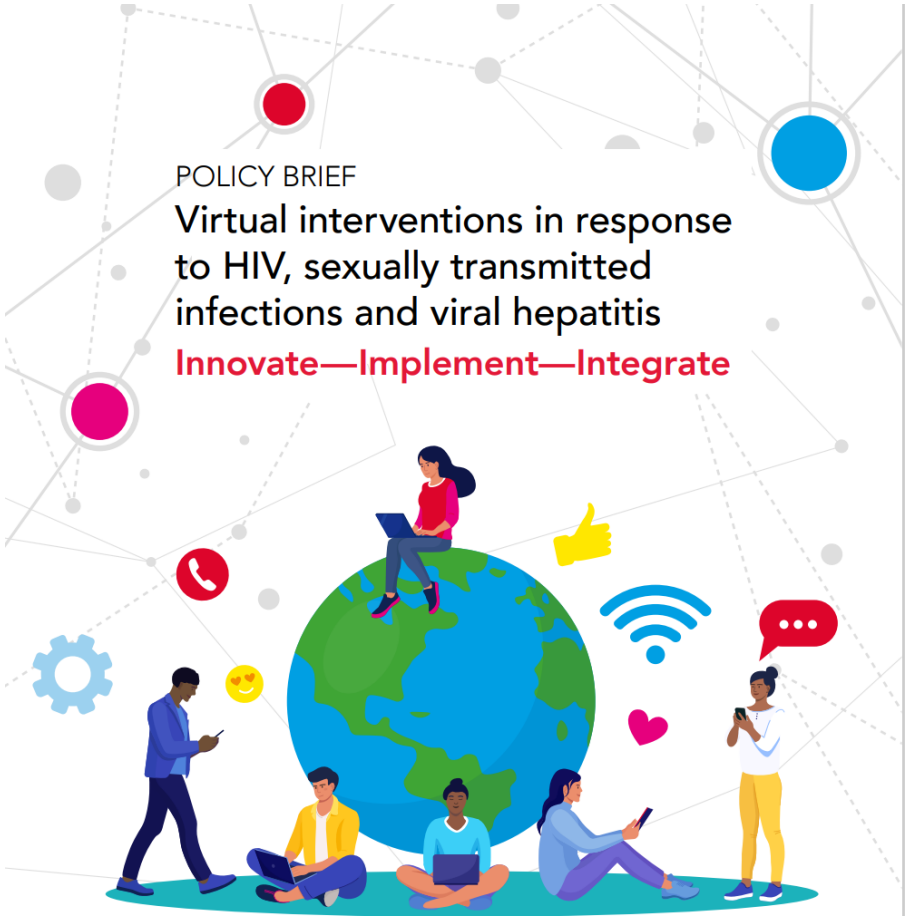
These can be adapted for local context and community preferences

- **In-person demonstration**, training or observation (one-on-one, with partners or in groups). Consider peer support/led options for key populations.
- **Video** instructions or demonstration (including online links to videos, QR codes, and virtual real-time support).
- **Telephone hotline** (can be integrated into existing national hotline services).
- **Messaging platforms** (short message service through telephone, Internet, social media).
- **Educational information** via radio, television, leaflets, brochures, the Internet, social media, and applications for smartphones/tablets.
- **Local information and resources** (for example, on counseling services, testing sites, treatment centers and where to access prevention services).
- online distribution of self-test

World Health Organization

VIRTUAL INTERVENTIONS

- Interventions that use any of the strategies or approaches virtually without coming face to face with the client is called virtual interventions.
- This can be internet-based awareness, social media posts, demand creation or mailing a HIV self test kit
- With the experience of COVID -19, globally HIV programs are looking for ways to mitigate the impact on the HIV programs
- Virtual interventions help programs to continue providing services to the populations without coming to the facility.



Source: UNAIDS and WHO Policy brief, 2022

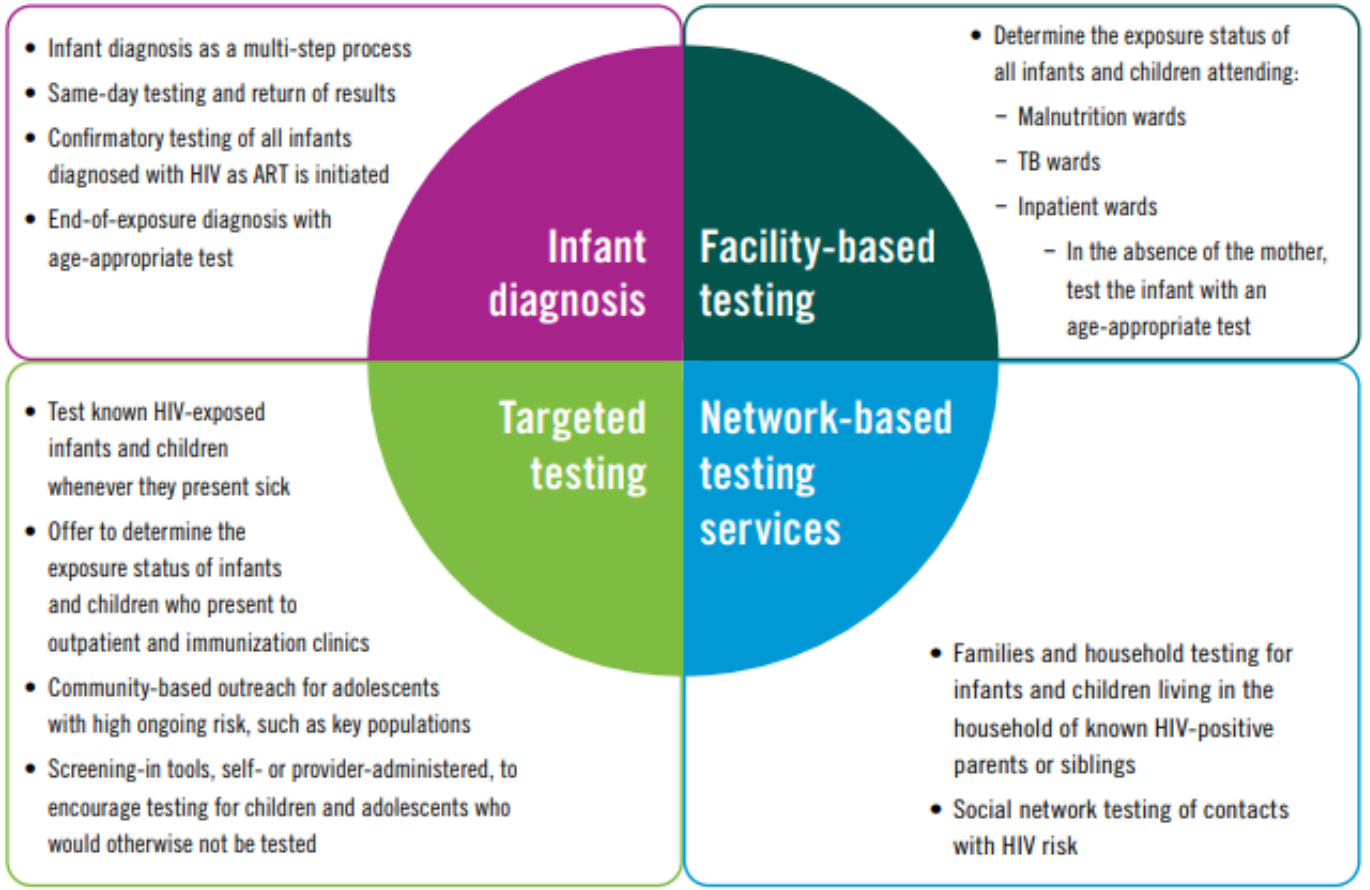
World Health Organization

No recommendation on the use of HIVST test kits for parents/guardians to test children

NEW: Caregiver-assisted testing using HIVST: There is insufficient evidence to support caregiver-assisted testing using HIVST kits currently

- this does not mean WHO recommends against it
- **WHO does urge already recommended approaches to reach children**
- EID, index/family testing, Indicator testing (eg testing in malnutrition clinics) Screening tools to **screen in** clinical settings

Use comprehensive HIV testing approach for infants and children



Source: WHO consolidated HTS guidelines, 2024

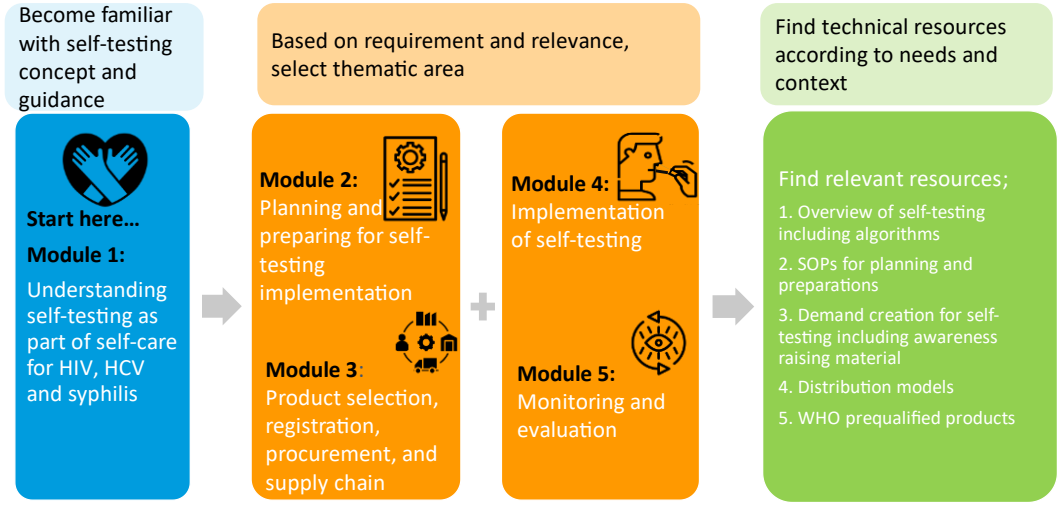
World Health Organization

Self-testing toolkit

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

- The toolkit provides **practical guidance, tools, and resources to support countries in implementing self-testing for HIV, viral hepatitis and STIs.**
- Focuses on HIV self-testing (HIVST), HCV self-testing (HCVST) and syphilis (SST)
- Follows **a modular framework** providing guidance and resources for the process of implementing self-testing services including:
  - **understanding self-testing: principles, guidance**
  - **policy and planning**
  - **product selection and procurement**
  - **Implementation: demand generation, distribution models**
  - **monitoring and evaluation**
- **Has a main document plus web page with modules and resources**

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



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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.

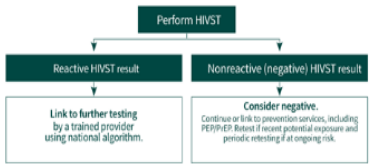
More information and resources

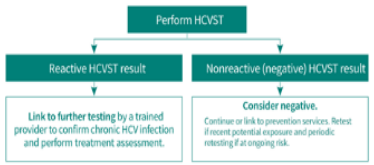
World Health Organization

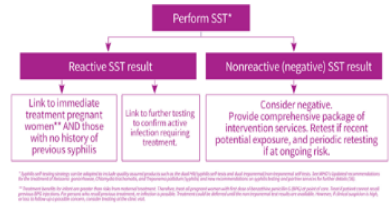
Key messages

- **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

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8. QMS

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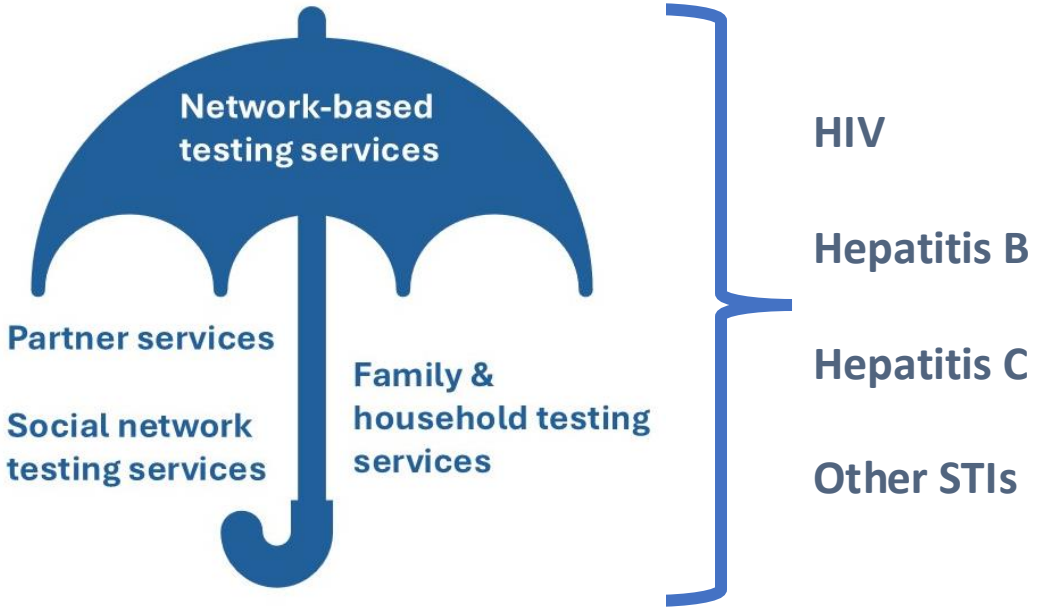
What is “network-based testing?”



Partner Services	NBT approaches in which sexual and/or injection partners of clients who have been diagnosed with an infection are contacted, notified of potential exposure, and offered testing and other services
Social network testing services	NBT approaches in which individuals living with or at risk of infections encourage and support social contacts to seek testing and other services, or distribute self-testing kits to social contacts
Family & household testing services	NBT approaches in which family members (such as biological children for HIV or HBV) and other household members (for HBV) are contacted, notified of potential exposure, and offered testing and other services

Network-based testing services

Partner services

- Recommended for HIV & STIs (some evidence for HCV)
- Provider-assisted partner services should be encouraged as still most effective strategy
- Provide options based on client needs (partner referral, provider-assisted, expedited partner therapy*)
- Services must always be voluntary

RECOMMENDED

Social network testing now for all with risk (not only key populations)

- Recommended for HIV (some evidence for HCV)
- Self-test distribution, community-led, multiple rounds
- Virtual or in-person
- No need for incentives or in-depth training

RECOMMENDED

Family and household testing

- Recommended for HIV (children) and HBV (family and household members)
- Offer prevention services-- HBV vaccination for household members who test negative, PrEP for HIV negative partners

RECOMMENDED

Optimizing implementation of network-based testing	
Self-tests	Recommended for HIV, syphilis, and HCV. Can increase uptake and linkage, but can be costly
Integration	Integrate service delivery within other services (e.g. ANC) and for multiple infections (e.g. dual HIV/syphilis RDTs)
Rounds of recruitment	Evidence suggests multiple rounds increases effectiveness in case-finding
Incentives	Without incentives, uptake, positivity and 1st time testing are still high. No need for incentives
Training	Prioritize simple one-time training, as is just as effective and more practical.
Prevention	Offer prevention services to contacts who test negative—including PrEP, condoms, hepatitis B vaccine
Virtual networks	Can use apps or other virtual tools for partners and social network outreach

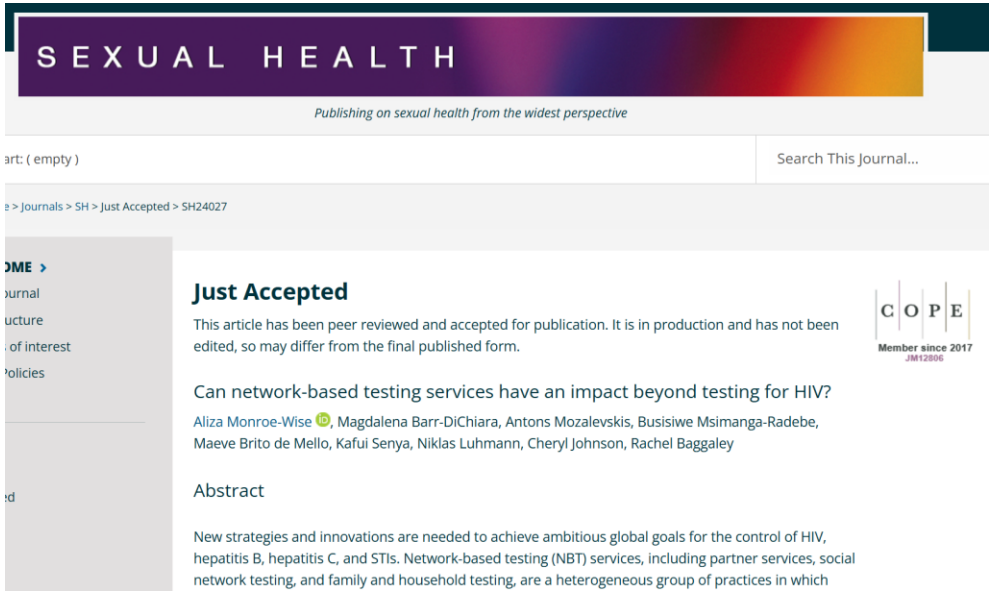
Source: Choong 2023, WHO 2024

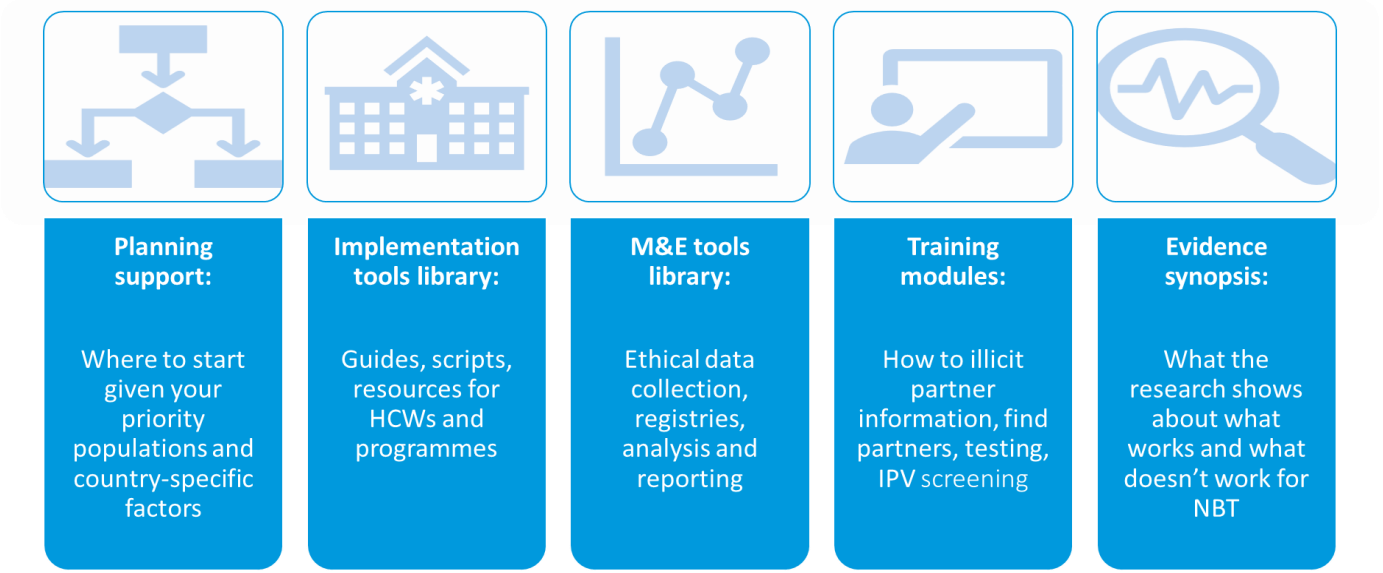
World Health Organization

Coming in 2025: Network-based testing toolkit

WHO is developing a network-based testing toolkit for HIV, other STIs, hepatitis B, and hepatitis C

- The toolkit provides **practical guidance, tools, and resources to support countries and programmes in implementing integrated network-based testing across HIV, hepatitis B & C, and other STIs**
- Follows **a modular framework** providing guidance and resources for the process of implementing network-based testing services including:
  - **Planning support: country- and epidemic- specific considerations**
  - **Implementation tools library**
  - **M&E tools library**
  - **Training modules**
  - **Evidence synopsis & library**
- Commentary on network-based testing recently accepted in ***Sexual Health***





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World Health Organization

What is QMS in testing services?

Recent reports suggest that the quality of HIV testing may be suboptimal in many settings leading to Misdiagnosis of HIV status – both false-positive and false-negative

QMS encompasses organizational processes aimed at ensuring the quality, accuracy, and reliability of testing services.

Each pillar represents a vital element of the testing process, and their correct management is essential for accurate and reliable results.

The focus is on process quality, not j
the product used for testing (IVD).

The Quality System Essentials (QSEs) framework consists of 12 building blocks that are crucial for ensuring quality.

It includes Quality Assurance (QA), Quality Control (QC), and Quality Improvement (QI).

Ministries of health should establish robust QMS for their HIV testing services.

What to do at the national level

1. NATIONAL POLICIES, STRATEGIC PLANS, M&E FRAMEWORK: NATIONAL AUTHORITIES TO SUPPORT QMS AT TESTING SITES.

2. WORKFORCE DEVELOPMENT: TESTING PROVIDERS ARE TRAINED AND SUPPORTIVELY SUPERVISED.

3. TESTING STRATEGIES AND ALGORITHMS: ADOPTING WHO-RECOMMENDED TESTING STRATEGY (VERIFIED TESTING ALGORITHMS).

4. PRE-MARKET ASSESSMENT: USING WHO'S PREQUALIFICATIO N LISTING, STRENGTHENING REGULATORY CAPACITIES.

5. POST-MARKET SURVEILLANCE: REPORTING COMPLAINTS AND PARTICIPATING IN EQA SCHEMES.

6. PROCUREMENT AND SUPPLY CHAIN MANAGEMENT: ENSURING UNINTERRUPTED SUPPLY AND APPROPRIATE STORAGE OF TEST KITS.

7. ACCREDITATION OF TESTING SITES: ENSURING TESTING SITES ARE SUPPORTED AND ARE HELD TO A STANDARD OF QUALITY

World Health Organization

ACKNOWLEDGEMENTS

WHO HTS team /TPP unit

Global HIV, Hepatitis, STI Programmes

Geneva