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Updates on the World Health Organization's HIV Testing Services Guidelines

A CQUIN/WHO Webinar Collaboration

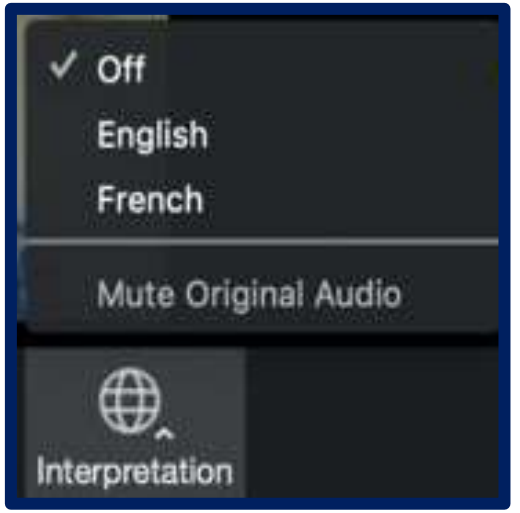
Tuesday, February 6, 2024

HIV Coverage, Quality, and Impact Network

Welcome/ Bienvenue

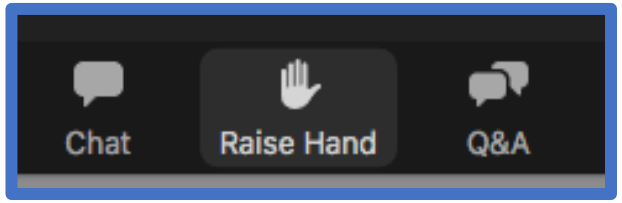
Violet Oramisi
CQUIN Regional SI Advisor
ICAP in Kenya

- Be sure you have selected the language of your choice using the “Interpretation” menu on the bottom of your screen.
- Assurez-vous d’avoir sélectionné la langue de votre choix à l’aide du menu <<Interprétation>> en bas de votre écran Zoom.



Housekeeping

- 60-minute webinar with two presentations followed by a panel discussion and Q&A session
- Slides and recording will be available on the CQUIN website (www.cquin.icap.columbia.edu)
- Please type questions in the Q&A box located on the toolbar at the bottom of your screen
- If you would prefer to speak, please use the “raise hand” function on the toolbar and we will unmute you so that you have control of your microphone
- There is simultaneous French/English interpretation on this Webinar



Agenda

Timing	Topic/Activity	Facilitator
5 Minutes	Welcome/Introductions	**Oramisi Violet** *Regional SI Advisor, ICAP CQUIN*
5 minutes	Framing Remarks	**John Bosco Matovu** *Regional Clinical Advisor* *ICAP-CQUIN*
20 minutes	Key updates on the WHO HTS guidelines	**Céline Lastrucci** *Consultant, HIV Testing Services,* *WHO*
25 minutes	Panel discussion & moderated Q&A session • **WHO-**Céline Lastrucci, Consultant, HTS • **Malawi-**Lawrence Khonyongwa-Executive Director MANET**+** • **MOH Uganda-**Taasi Geoffrey-Program Officer HTS	**Violet Oramisi & John Bosco Matovu** *ICAP-CQUIN*
5 minutes	Next steps	**John Bosco Matovu** *Regional Clinical Advisor* *ICAP-CQUIN*

Speakers

John Bosco Matovu

CQUIN Regional Clinical Advisor, dHTS Lead

ICAP in Sierra Leone

Céline Lastrucci

Consultant, HIV Testing, WHO Geneva

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Framing Remarks

John Bosco Matovu

Regional Clinical Advisor, ICAP-CQUIN

HIV Coverage, Quality, and Impact Network

The CQUIN network

The HIV Coverage, Quality, and Impact Network (CQUIN) is an African learning network designed to advance HIV differentiated service delivery to enhance recipient of care outcomes and strengthen health systems

- The CQUIN network is funded by the Bill & Melinda Gates Foundation and convened by ICAP at Columbia University
- Supported by an Advisory Group inclusive of Ministries of Health, civil society, PEPFAR, CDC, USAID, WHO, Global Fund, UNAIDS, ITPC (International Treatment Preparedness Coalition)
- Supported by a Community Advocacy Network chaired by ITPC

21-country African learning network

The CQUIN approach

- CQUIN is a **multi-stakeholder learning community** designed to support countries to move beyond pilot programs to DSD implementation at scale.
- The network supports experience-sharing, peer-to-peer learning, and collaborative problem-solving that is focused on the gap between policy and implementation at scale.
- Ministries of health that opt into the network gain access to a wide range of resources, including technical assistance, workshops, **webinars,** country-to-country learning exchange visits, and **communities of practice,** as well as support for DSD program evaluation, quality improvement initiatives, and strategic planning.

How does CQUIN work?

- Convenes health system leaders from network countries to participate in joint learning and information exchange, with the goal of fostering the scale-up and spread of high-quality, high-impact HIV services
- Countries join at MOH level. MOH engage a core team, including recipients of care, implementing partners, civil society, donors, academic institutions, etc.
- This country team then:
  - ✓ conducts baseline and periodic self-assessment using three CQUIN capability maturity models (testing, treatment and advanced HIV disease)
  - ✓ develops DSD action plans, commitments and targets
  - ✓ participates in network activities (including communities of practice) via an opt-in demand-driven approach
  - ✓ exchanges knowledge and tools/resources and shares data on progress of scale up, best practices and lessons learned

What is a capability maturity model?

A systems strengthening approach that:

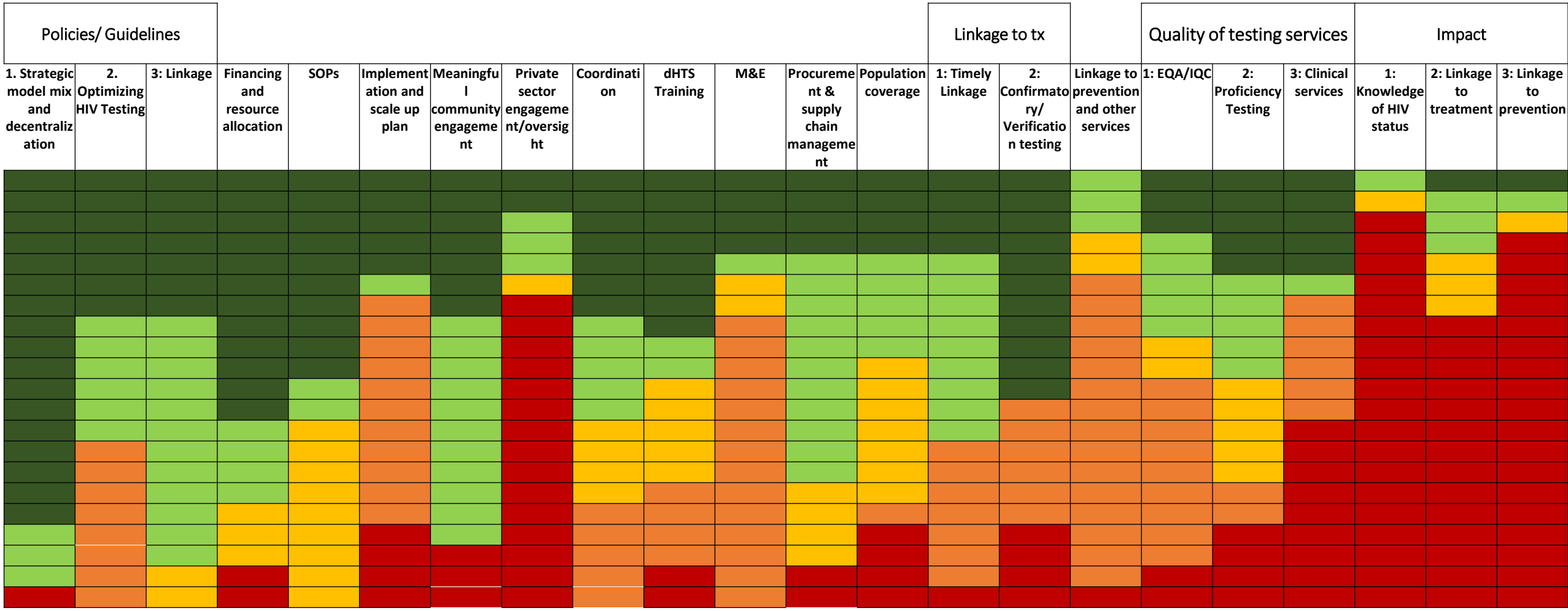
- Identifies core functions/domains in which capability is required to achieve organizational goals
- Describes sequential stages of maturity within each domain
- Sets a clear path towards achieving maturational goals
- Is used repeatedly over time to track change

RED	ORANGE	YELLOW	LIGHT GREEN	DARK GREEN
Early or preliminary stages of planning and development; Useful in identifying next steps to take in the scale-up process	Work has begun and the initial efforts are ongoing; Highlights areas that can prioritized for improvement	Efforts have resulted in measurable progress, such as a draft for review or achievement of more than 25% progress to a target	Considerable progress has been made, resulting in over 50% progress to a target or working systems only in need of finalization	Achievement of a highly-evolved implementation of the domain; Further improvements and refinements can be made as needed

How does CQUIN support network countries on dHTS?

- TA to conduct self-staging meetings
- Focused country TA to address gaps identified
- Collaboration with other stakeholders e.g., WHO, PEPFAR, CHAI, IAS, ITPC, etc.
- Quarterly CoP calls
- dHTS-focused webinars
- CQUIN meetings
- C2C learning exchange visits
- Co-creation and sharing of tools/resources

The dHTS CMM 2023: Stacked by stage (not by country)



Lessons from network countries

Areas that need clarification

3-test professional algorithm using Rapid Diagnostic Kits:

- Need to use a 3-test algorithm after HIVST use?
- Need for verification testing after a 3-test algorithm?

Re-testing

- Who should/should not receive retesting?
- When should retesting be done?
- Where should retesting be done?

Areas that require ongoing discussions

Integration

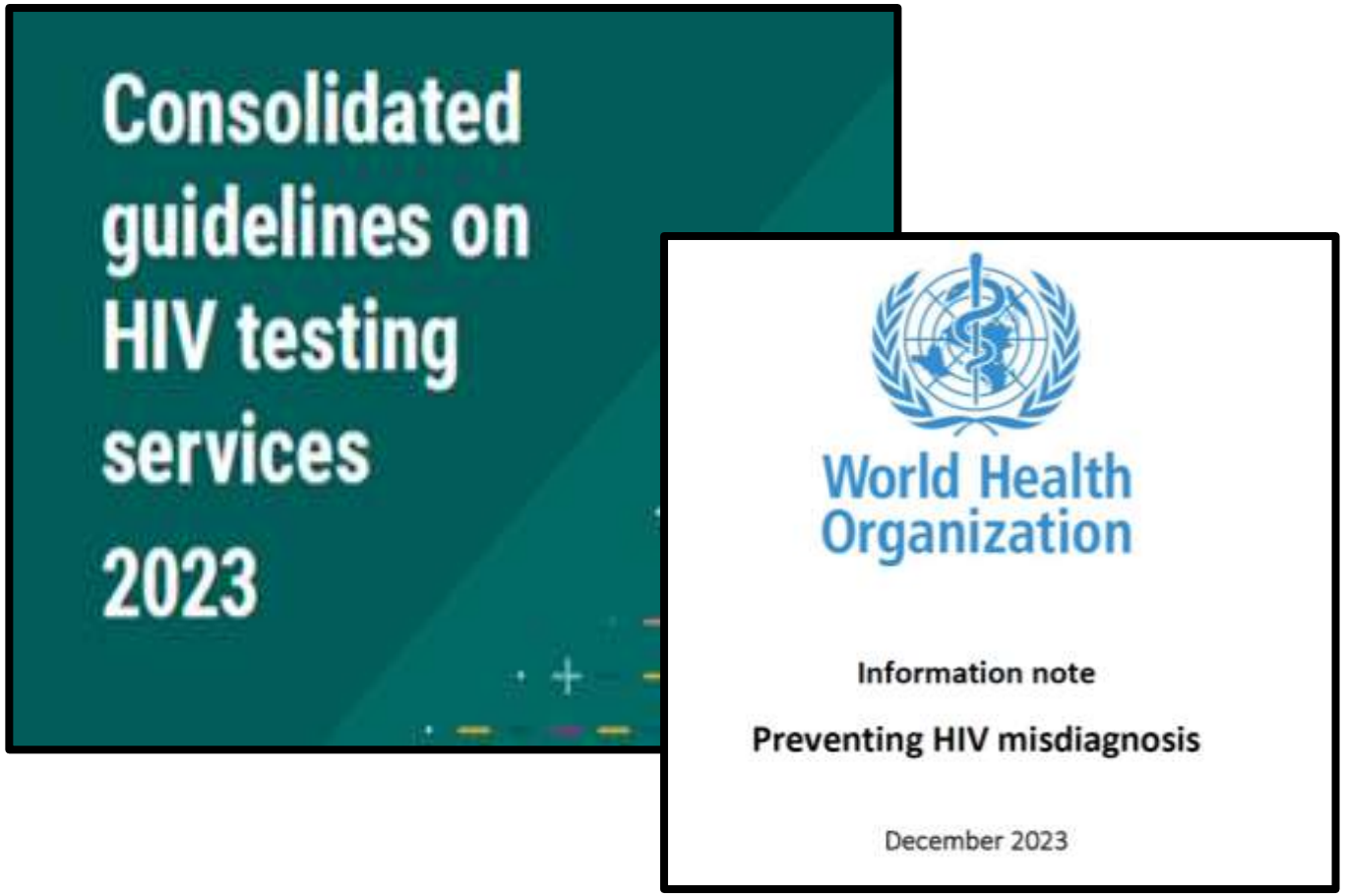
- How to maintain quality HTS in multiple contexts? *E.g., Multi-disease screening, Point of Service Testing*

Quality

- For HIV rapid testing, what quality standards can countries use to assess themselves?
  - Safe and ethical index standards?
  - Certification framework?

In today's webinar

- WHO HTS guidelines updates
- Clarifications on various aspects of including HTS quality to prevent misdiagnosis



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World Health Organization

2023 WHO HIV Testing Services guidelines update

- **Céline Lastrucci**
- *Consultant HIV Testing, WHO*

HIV Coverage, Quality, and Impact Network

Outline

1. 2023 WHO HIV Testing Services guidelines update: Key recommendations

2. Preventing HIV misdiagnosis
   A. 2019 guidance on testing strategy and algorithm
      A. 3 tests algorithm (incl no WB/IB and dual HIV/syphilis tests)
      B. Verification studies to decide tests combination
      C. Retesting for verification
   B. Quality Management Systems (QMS) for HIV Testing Services (HTS)

2023 WHO guidance on HIV Testing Services - summary

New, updated and other key recommendations in the 2023 Consolidated guidelines on HIV testing services

key recommendations (continued from 2019 consolidated HTS guideline):

HIV self-testing is recommended as an approach to HIV testing services *(strong recommendation, moderate-quality evidence).*

Western blotting and line immunoassays should not be used in HIV testing strategies/algorithms *(strong recommendation, low-quality evidence).*

In response to changes in the HIV epidemic, WHO encourages countries to move toward **using three consecutive reactive tests to provide an HIV-positive diagnosis**.

WHO recommends that **pregnant women receive testing for HIV, syphilis and hepatitis B (HBsAg) at least once** during pregnancy, preferably in the first trimester *(syphilis testing: strong recommendation, moderate-quality evidence; HBsAg: strong recommendation, low-quality evidence).* **Dual HIV/syphilis rapid diagnostic tests can be the first test in HIV testing strategies and algorithms in ANC and Key Population settings.**

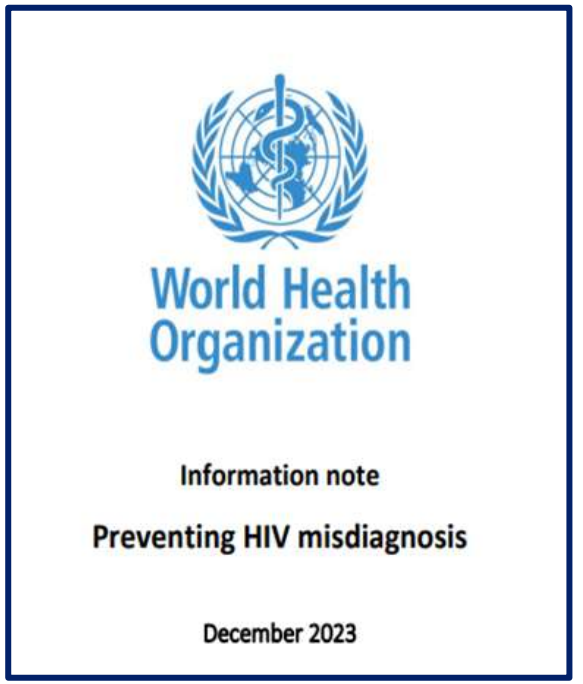
New and Updated (to be published soon):

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

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

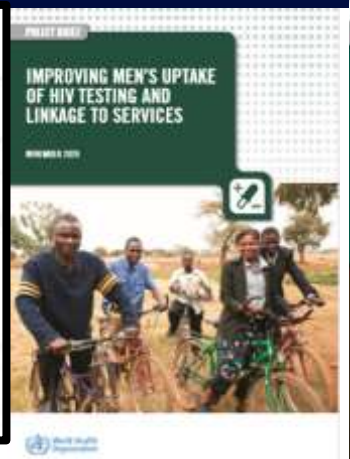


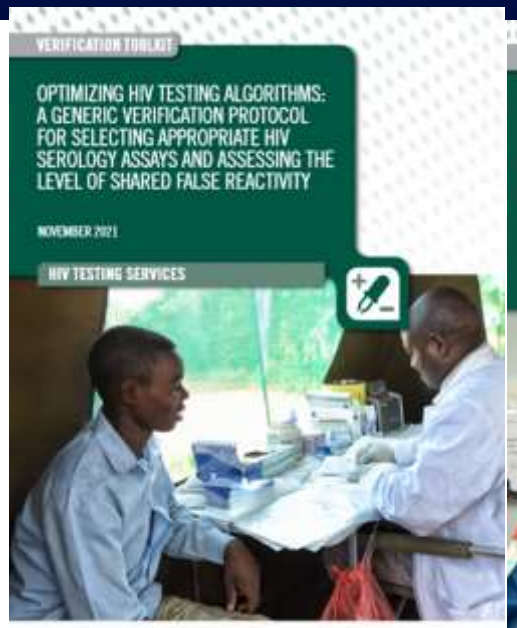
https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/hiv-testing-information-note.1.12.2023.pdf

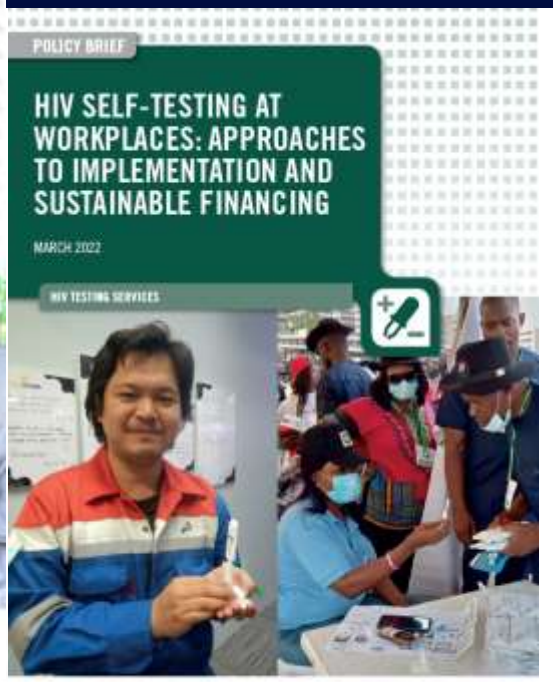
WHO guidelines on Testing Services

Other testing updates

- HIV algorithm **verification toolkit** (2021)
- **Virtual intervention** (policy brief 2022)
- **Key populations** (KP guideline 2022)
  - Optimal retesting frequency
  - Dual HIV/syphilis RDT
- Use of **self-testing extended to Hepatitis C and Syphilis**
- **Trep/Non trep RDTs** to improve **active syphilis** diagnosis
- **Partners services extended to STIs and Hep-C**
- **Improving men uptake**: Reaching men by testing in the **workplace (including HIVST)**
- **Risk screening tools** to optimize testing should be considered for **<u>screening "IN"</u> those with symptoms & risks** that might otherwise be missed (not screening "out").

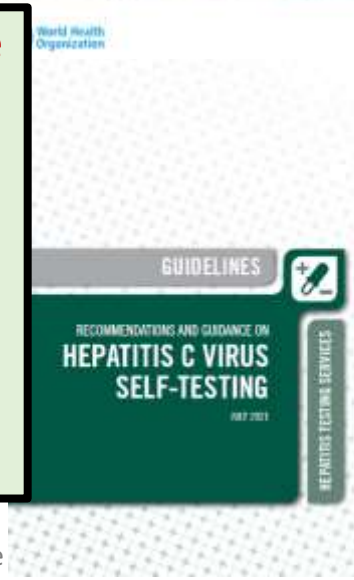






Self-testing and self-care becoming standard of care across many different areas

- HIVST
- HCVST
- C19ST
- Syphilis ST
- ST for pregnancy,



WHO new 2023 recommendations on HIV self-testing

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

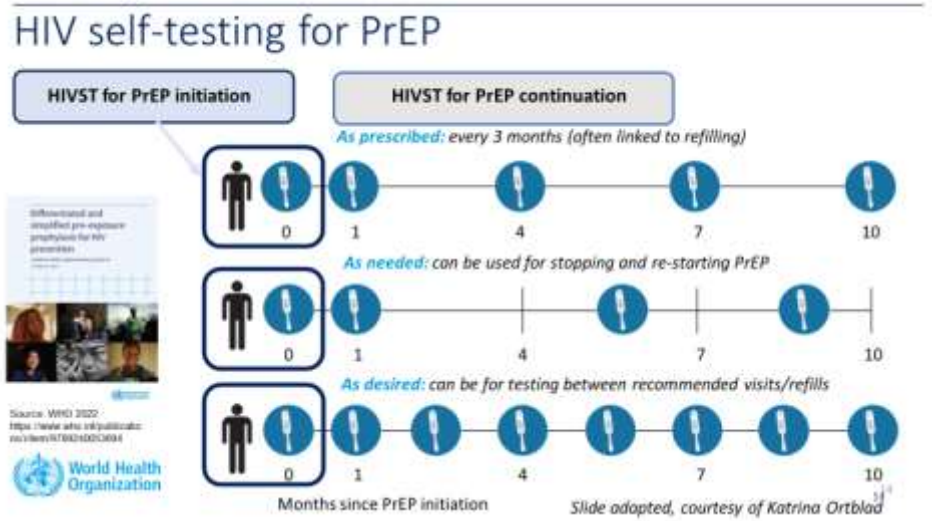
Remarks

- HIVST-supported PrEP delivery may be an important tool to reach underserved populations.
- HIVST is an option to support PrEP delivery; its use should be driven by client needs and preferences.
- There is a range of PrEP options available for which HIVST use could be considered, including oral PrEP (daily or on-demand) and the dapivirine vaginal ring (DVR). HIVST can also be considered as part of post-exposure prophylaxis (PEP) implementation. Further research on the role of HIVST in implementing long-acting injectable prevention options, such as cabotegravir (CAB-LA), is needed.

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

Remarks

- HIVST does not replace provider administered testing. Individuals with a reactive self-test result should receive further testing from a trained provider using the full national testing algorithm.
- HIVST can replace risk screening tools* to optimize testing among those presenting at health facilities.



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

Therefore, prior to further implementation, challenges, concerns, and research gaps need to be addressed

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** for testing clinical settings

Social network testing - Beyond KP

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

Remarks

- SNA is offered as part of a broader package of voluntary HIV partner services that include a range of options, such as provider-assisted referral, enhanced patient referral and patient referral.
- Offering HIVST as a testing option, already recommended by WHO, within social network testing approaches may increase acceptability, feasibility and uptake. However, it is important to tailor the use of HIVST in SNA to the programme based on the context, epidemiology and resources available.
- To increase efficiency and optimize resource use, programmes should aim to provide a short, focused orientation when initially preparing individuals to be "test promoters" who recruit and encourage others to test for HIV.

What are social network-based HTS approaches?

- Sexual networks
- Drug injecting
- Social contacts
- HIV+ or HIV –
- Key populations

Social network testing:

- **May increase HIV diagnoses and identify additional people with HIV**
- May increase the **acceptability** of HIV partner services
- **Feasible** to implement
- Can be an efficient use of resources when they focus on people with high ongoing HIV risk
- **Seldom results in social harm** or adverse events.

WHO does not recommend using recency assays in routine HIV testing services

Recency testing for surveillance

WHO recommends use of recency assays in surveillance

- Utility of recency testing has been demonstrated in population-based surveys to measure HIV incidence
- Use of recency testing in programmatic settings should only be considered when existing HIV testing coverage of the population being studied is high, when a combination of assays including viral load can be delivered to reduce false recent results and analysis plans make appropriate statistical adjustments and infer population-specific trends in recent infection

- **There are no WHO prequalified recency assays**
  - No WHO prequalified recency tests in the pipeline or planned to be in the pipeline for WHO prequalification at this time.
  - No current pathway for recency testing to receive WHO prequalification as process reserved for recommended HTS interventions & diagnostic tests.

NO benefits of recency testing in routine HTS,

2023 HTS consolidated guideline

New WHO recommendation

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

Remarks

- This recommendation calls for excluding recency testing from routine HIV testing services. HIV testing services are defined as a package of services including brief pre-test information and post-test counselling; linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.
- Recency assays can, however, be used for surveillance of HIV incidence. WHO has published guidance on this in Using recency assays for HIV surveillance: 2022 technical guidance (https://apps.who.int/iris/rest/bitstreams/1486096/retrieve

Quality of Testing = ensuring timely, affordable and correct HIV diagnosis

- **Accurate diagnosis is essential especially in the context of "treat all"**

Misdiagnosis of HIV status – both false-positive and false-negative- happens

WHO systematic review from Africa, the Americas, Asia and Europe: 3.1% of individuals were diagnosed false HIV-positive (interquartile range: 0.4–5.2) and 0.4% were diagnosed false HIV-negative (interquartile range: 0–3.9)

Different reasons:

- ✓ Sub-optimal testing strategy (single RDT, tie breaker…)
- ✓ User errors: sample collection, testing procedure (time, vol…), algorithm interpretation, transcription errors…
- ✓ Quality of test used (batch default, expired, damaged tests)
- ✓ Sub-optimal training and regular supervision of testers
- ✓ Poor participation in EQA schemes

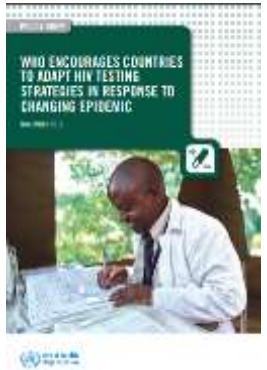
- **Quality Management System (QMS) is essential to ensure correct diagnosis**

Programs are responsible of ensuring Quality of testing in all testing sites

Source: Johnson CC, Fonner V, Sands A, Ford N, Obermeyer CM, Tsui S et al. To err is human, to correct is public health: a systematic review examining poor quality testing and misdiagnosis of HIV status. J Int AIDS Soc. 2017 Aug 29;20:21755. doi: 10.7448/ias.20.7.21755

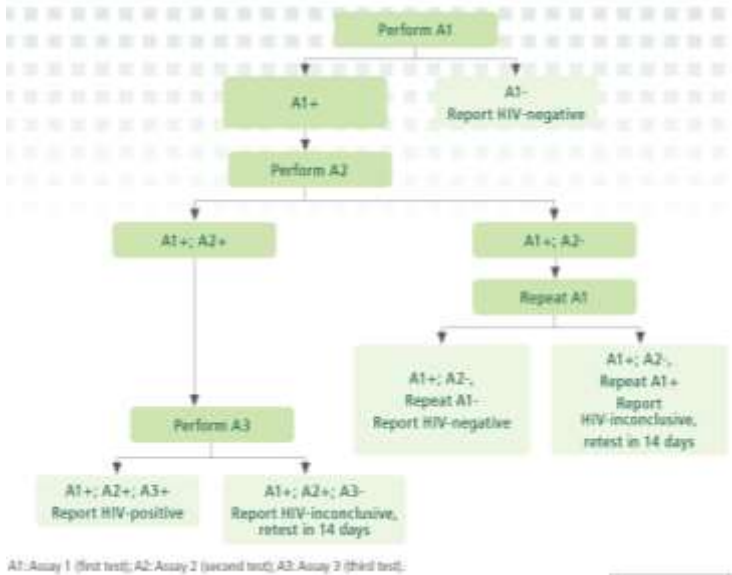
2019 WHO recommendations on HIV testing strategy for people >18th months old – The cornerstone

Universal 3 tests strategy (RDTS and/or IA)



Moving away from WB/IB

Verification study to select the right 3-tests in the right order

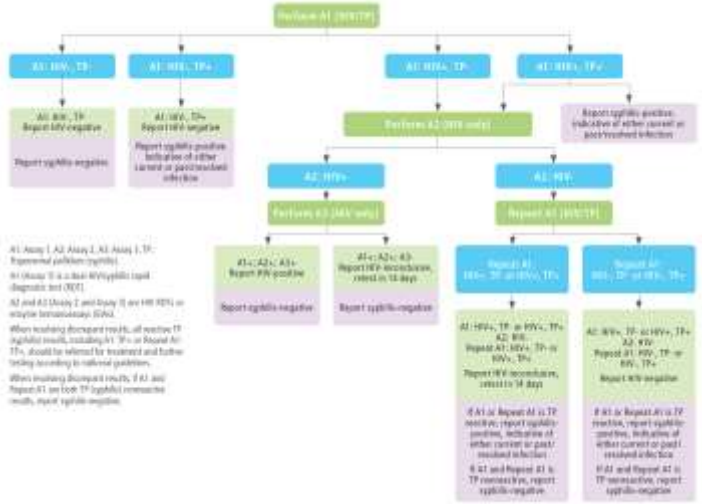


Other settings: HIV standalone tests

Dual HIV RDT in ANC and KP settings

Lay providers testing

ANC settings and KP: dual HIV-Syphilis test for A1



Retesting for verification: Each newly diagnosed HIV person Prior to ART initiation using the same 3 tests algorithm

Why? Because diagnostic errors occur for different reasons :

- Human errors: procedures, identification ...
- Quality problem of a test or a test batch
- Change of test in the algorithm (stock rupture)

Each of these causes of error can/should be addressed through the implementation of a solid Quality Management System aimed at improving a system but there will always be errors.

Retesting before initiation = Identifies an individual problem

- Same national algorithm (verified PPV)
- Ideally, at a different site (initiation) and at least by a different operator and a different test batch
- Should be seen as one step in a Quality Management System

It does not replace the need of a 3 tests strategy to ensure PPV>99%

Retesting for verification: HIV testing client pathway - TB clinic example

If same testing and ART sites: another sample, another tester but same 3 tests algorithm

1
TB pos client at TB clinic.

2
PICT HIV testing using serial 3 tests algorithm

3
Client diagnosed HIV positive

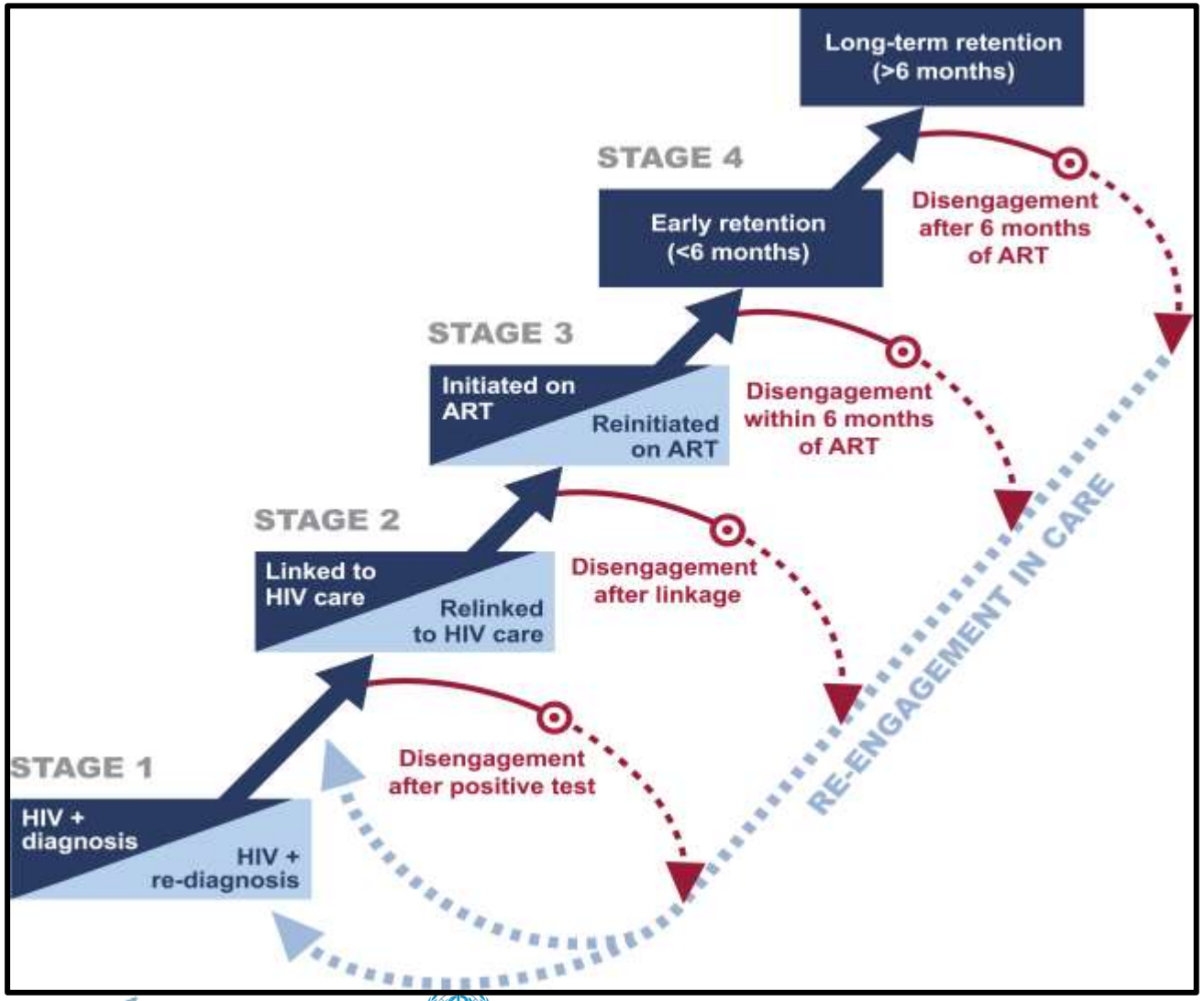
4
Client referred to the ART site

5
Retesting for verification using same 3 tests algorithm

6
Client retested HIV pos

7
ART initiation

ART initiation is not the end of story



- In 2020, **58%** of individuals attending testing sites and diagnosed HIV-positive in sub-Saharan Africa had already been diagnosed and already knew their HIV-positive status

- People previously on ART and re engaging in care should be welcomed back; individual decision:
  - Re-establishing their status
  - Medical history/ file transfer…

Source: The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals | PLOS Medicine

Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000–20: a modelling study using survey and HIV testing programme data. Lancet HIV. 2021;8:e284-e93

WHO recommended different types of retesting for HIV

1. **Verification (prior to ART initiation): same algorithm twice:** WHO recommends that programs retest people newly diagnosed with HIV prior to ART initiation. To avoid clerical errors, sample mix ups etc. (full algorithm at testing site, test again using full algorithm at ART site.)
2. **After pos screening in the community (HIVST)** - testing at least once with full algorithm completed by the trained tester.
3. **Retesting individuals to resolve an HIV-inconclusive status:** people coming back after 14 days
4. **Retesting as an entry point for re-engagement in treatment and care** (NOT for everyone)

   For Example:

   - Those who re-engage through HIV testing services on their own should be welcomed back
   - Those who say they are HIV positive without any evidence should be re-tested using the full algorithm *as long as they are not taking ART*
   - Those who say they were on ART in the past and want to be given medication without any documentation can be tested using full algorithm for re-engagement

   WHO does NOT recommend re-testing individuals on ART – the risk of false negative. However, if they have a concern about their test results this should be discussed with appropriate follow-up actions

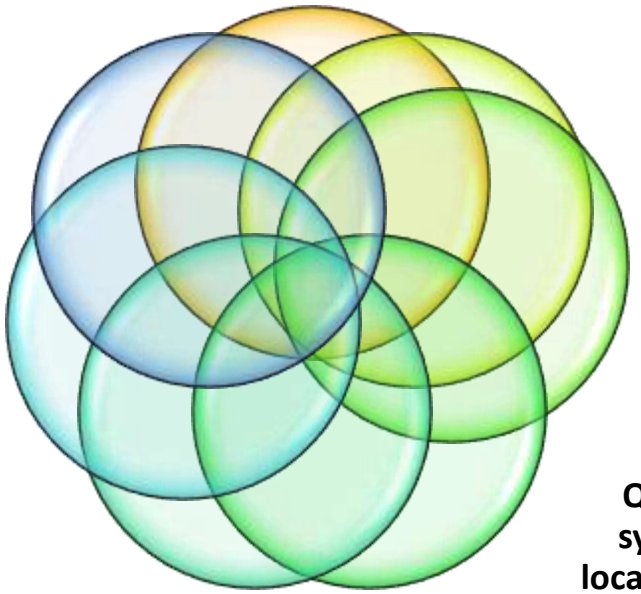
5. **Re-testing HIV-negative individuals at ongoing risk of acquiring HIV (according to pre-defined frequency of testing)**
   - **PrEP, PEP, PMTCT, etc.**

Key elements for successful HIV Testing Services

National HIV testing policy linked to laboratory policy and strategic plan

Access to **quality-assured in vitro diagnostics** with regulatory controls

Accurate forecasting and **procurement systems**



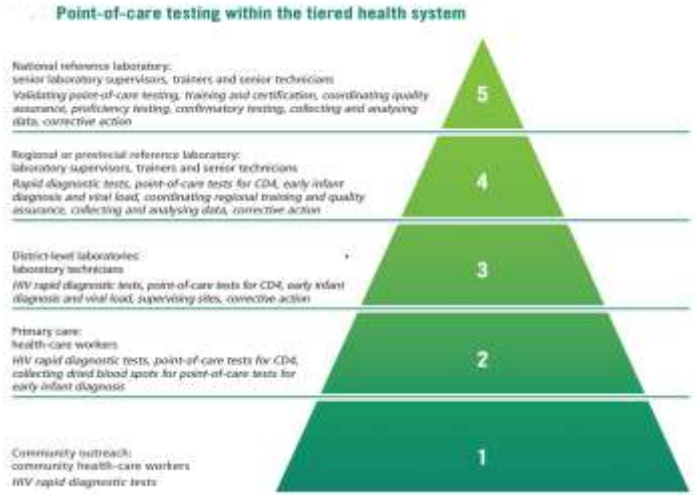
Validated national testing algorithm(s) with backup options

Training and supervision of HIV testing providers

Quality management systems for all testing locations, regardless of the type of testing site and testers

Lab and non –lab settings

QMS affects every stage of testing and should be implemented everywhere



Testing stages

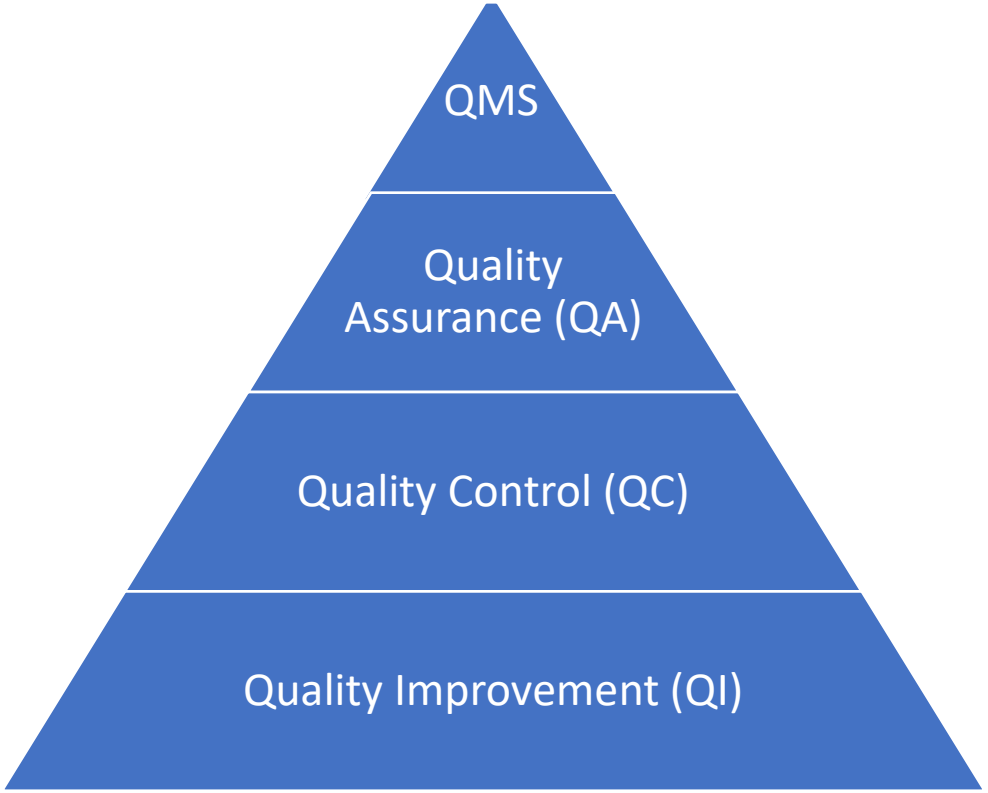
Pre-analytical stage: sample collection, registration, and processing

Analytical stage: performing the test and recording the result

Post-analytical stage: result authorization, reporting, and archiving

What is Quality Management system ?

- **QA**= Provide confidence-quality requirement are in place. Proactive
- **QC**= verifies products meets quality requirement. Reactive
- **QI**= proposes solutions to improve

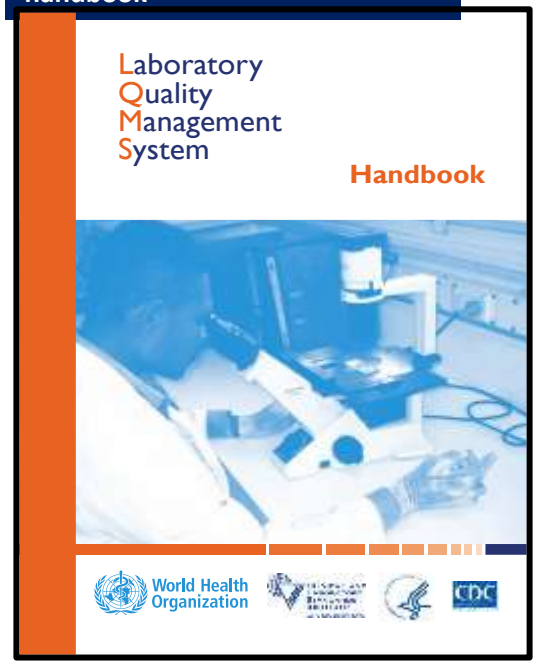


QMS: Frameworks of 12 building blocks (Quality System Essentials)

QMS Guidance and tools available

2011 | **2015** | **2015 & 2019** | **2022**

CDC, WHO Lyon; Laboratory quality management system: handbook



https://www.who.int/publications/i/item/9789241548274

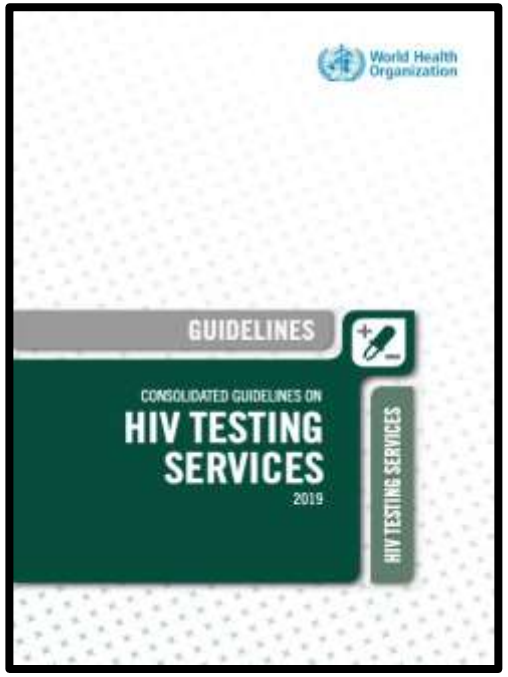
LQMS Training Toolkit and LQSI tool

WHO improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results

https://iris.who.int/bitstream/handle/10665/199799/9789241508179_eng.pdf

RTCQI and SPI-RT and SPI-POCT

WHO Consolidated guidelines on HIV testing services quality chapter



https://iris.who.int/handle/10665/336323

ISO 15189: 2022

https://www.iso.org/standard/76677.html

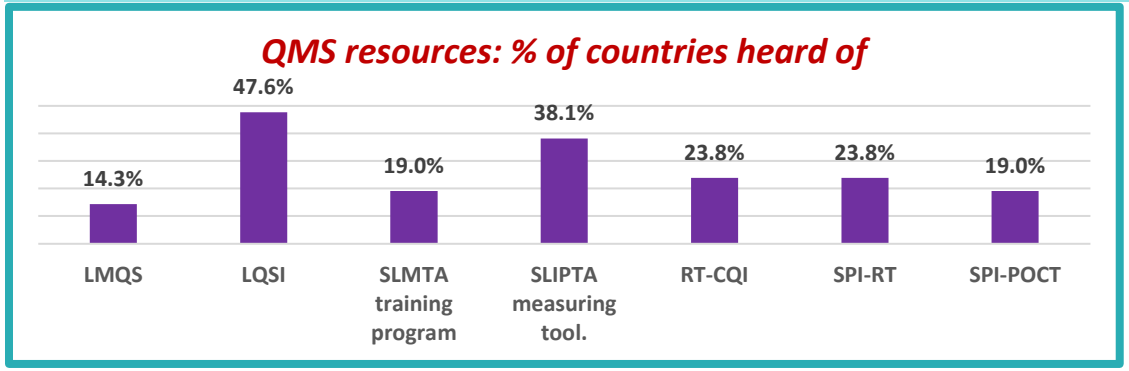
SLMTA and SLIPTA check list

2023 Survey on QMS implementation in AFRO region

Survey focused on: what is done in country and what are the challenges ?
21 countries (PEPFAR supported and non supported countries) from the AFRO region did answer to the survey

I. What are the QMS resources available, known and used by countries?

WHO/CDC laboratory quality management system handbook and training toolkit (LQMS)	Laboratory quality stepwise implementation tool (LQSI)	Strengthening Laboratory Management Towards Accreditation (SLMTA) training program	Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) measuring tool.	Rapid test continues quality improvement initiative (RT-CQI)	WHO/CDC Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT)	WHO/CDC Stepwise Process for Improving the Quality of HIV-Related Point-of-Care-Testing (SPI-POCT) Checklists.

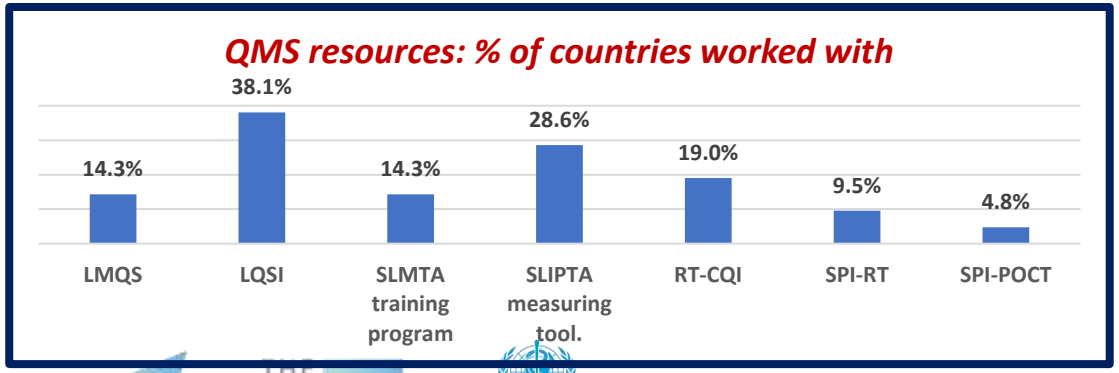


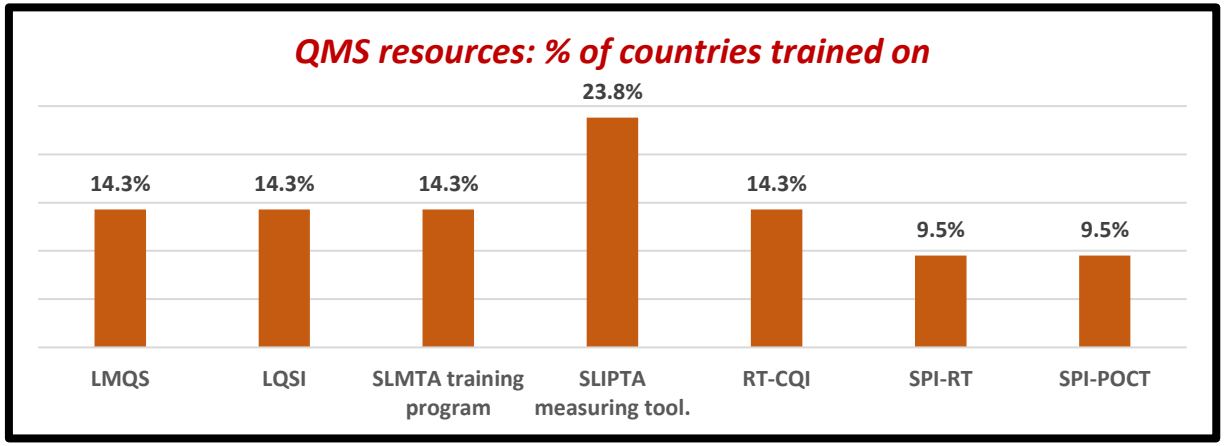
LMQS
LQSI
SLMTA
SLIPTA

Lab tools

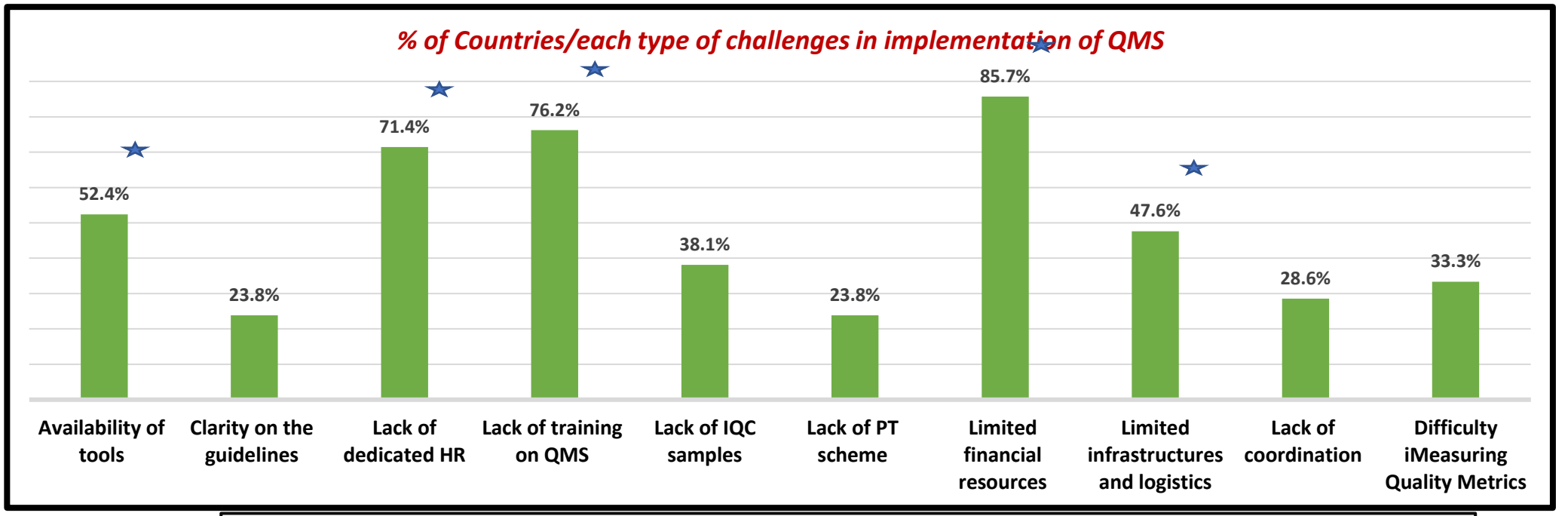
RT-CQI
SPI-RT
SPI-POCT

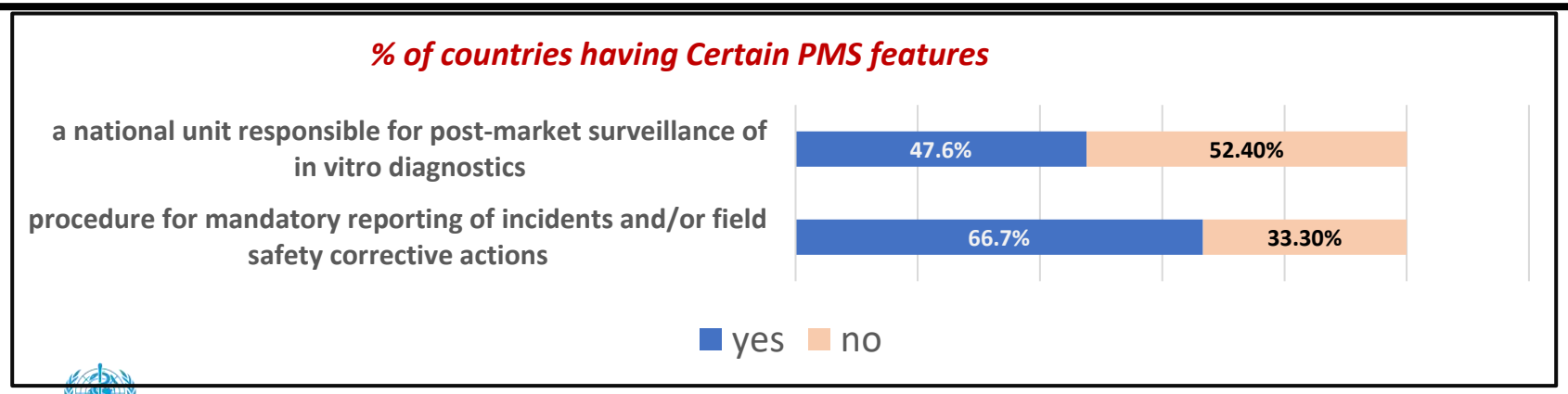
Lab + non-lab tools





II. Challenges of establishment of QMS and availability of Post Market Surveillance (PMS) in the countries





Quality Management System: WHO way forward

In 2024:

- Set up a pool of experts to discuss the review, propose way forward, and develop a QMS tool kit (see below)

- **Develop a tool kit from already existing guidance and tools but <u>adapted to non-lab settings</u>**
  - Tester training curriculum (including competencies check)
  - EQC/PT implementation tools: what, where, when (frequencies)
  - Corrective actions for quality improvement
  - Testing Register templates
  - Define a set of « quality » indicators to monitor (pos rate, invalid rate, discordant rate….)
  - Supervision check list for onsite visit
  - PMS tools
  - Stock management and ordering tool

Key testing messages from new WHO testing guidelines

1. Select a strategic mix of **differentiated testing approaches** to fill the testing gaps
2. **Community based testing**, by **trained providers** will increase access and coverage, including for key populations
3. **HIV self-testing** should be expanded widely to allow greater access for people not testing in facilities and to increase ease of using oral PrEP, DVR and PEP
4. **Testing quality is critical**. **Avoiding misdiagnoses is critical**

    •Misdiagnoses have serious implications for people, programmes and public health

    Misdiagnoses can be avoided by:

    Using the **serial 3 test strategy**

    Re-testing prior to ART initiation

    Conducting **verification studies: the right tests in the right order**

    Instituting strong **Quality Management Systems** in all testing site
5. **Voluntary partner services**, including **Social Network Testing** may be used to increase HIV diagnoses and identify additional people with HIV
6. Use Dual HIV/syphilis tests in ANC and for KP
7. Think about **STI** and **viral hepatitis testing** alongside HIV testing
8. Recency testing adds complexity and costs in HTS and is not recommended by WHO

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All other partners for permission to use slides

For more information on HIV testing services

WHO HIV Testing Services Dashboard	WHO HIV Testing Services Info App	WHO HTS GL

Questions?

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Thank you!

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Next steps

- **Next Webinar**: *Integration of TPT into DSD models*-**Tuesday March 5, 2024**
- **Next dHTS Community of Practice call:** *Social Network Testing Services: Reaching Key and Priority Populations*- **Thursday, March 21, 2024**

  We welcome case studies

- Country **dHTS staging** is ongoing; results to be discussed during the dHTS Focused meeting in July

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Thank you!