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**HTH departement**

World Health Organization

Thanks a lot Francis for the introduction. I will now presented to you the WHO QMS tool kit adapted to non lab setting.

# Why quality of testing is important?

**Accepting a 1% error rate would mean in France, every day:**

- 22 newborns falling from midwives' hands
- 600,000 lunches contaminated by bacteria
- Three bad landings at Paris airport


**Testing errors (false positive, false negative) cost in:**

Time

Money

Personnel effort

poor outcomes

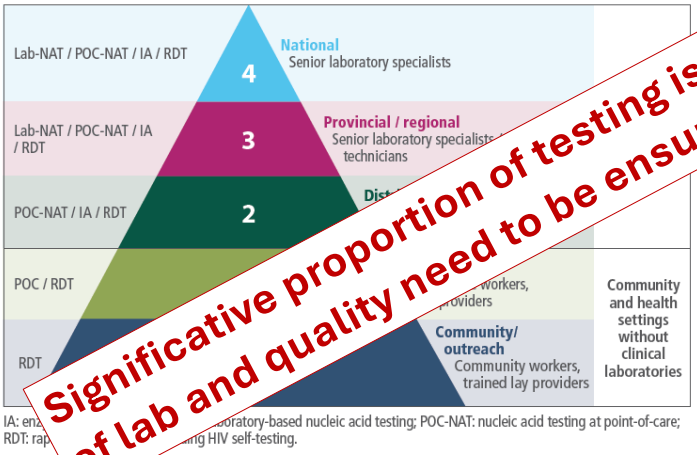


I'm going to he fast on this one as you allready all know that.
Ensuring and maintening quality of testing is important because testing errors cost in Time, money, personnel effort and in the end, more importantly in poor client outcomes
1% errors could be seen as acceptable, but accepting this level of error in France would mean:

- 22 newborns falling from midwives' hands
- 600,000 lunches contaminated by bacteria
- Three bad landings at Paris airport

Impact of just 1% error can have huge impact on people life

# Tiers of testing services




Significative proportion of testing is performed outside of lab and quality need to be ensured in those settings

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

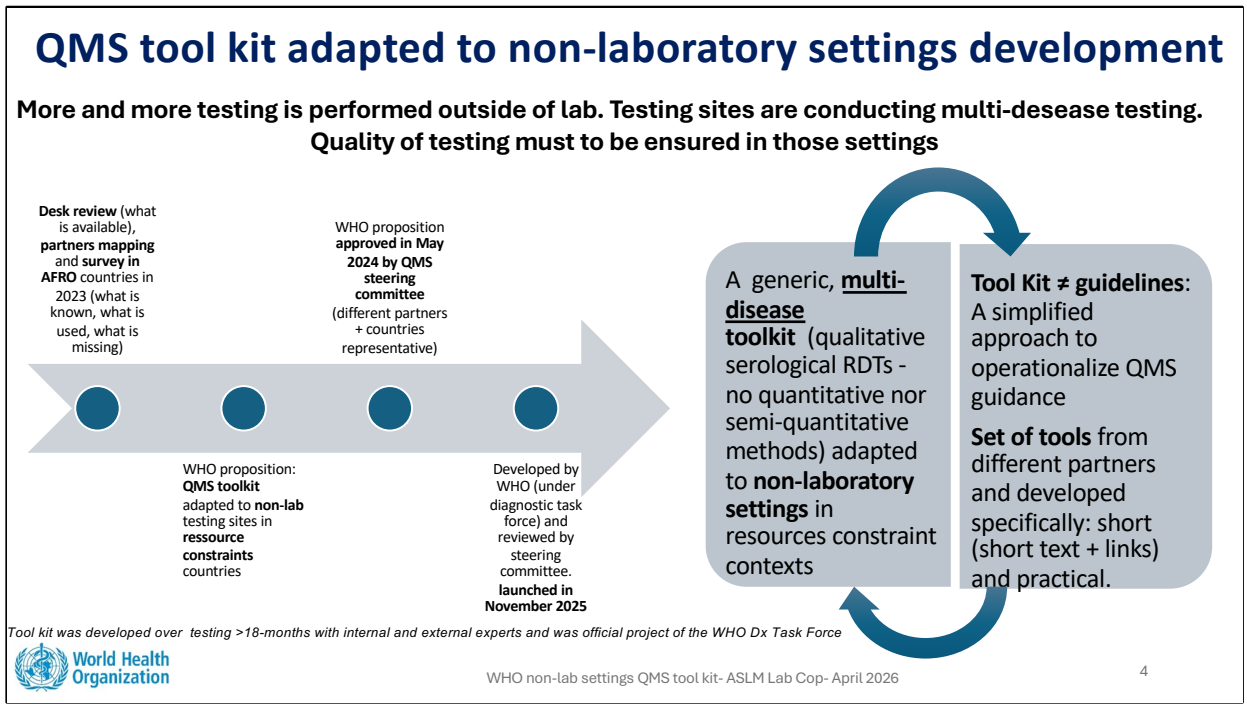
RDTs are most commonly used for HIV and RDTs/POCT increasingly key for STIs, hepatitis and TB

*Source: WH... 2024*



When we look at where testing is performed. Today, more than 95% of HIV testing is done at level 0 or 1 using RDTs and it is becoming also key in STIs, Hepatitis and TB space.

Which means that Significative proportion of testing is performed outside of lab and quality need to be ensured in those settings as well

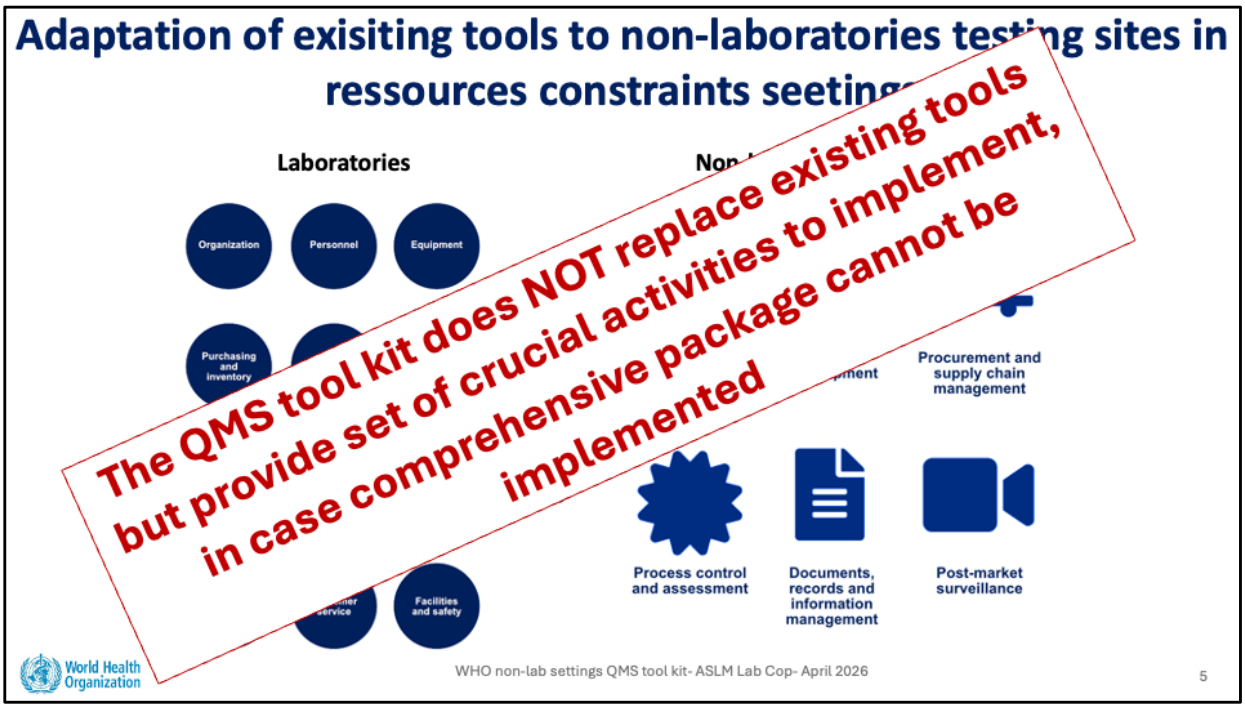



The story of this QMS tool kit started in 2023 when we were wondering what QMS activities countries were implemented outside of laboratories. So we did by a desk review to understand what guidance and tools were available to countries specifically for those settings, we also mapped partners that could support countries (technically and financially) and we did a survey in AFRO countries to understand what was known, what was used and what might be missing.
What we learn from the 21 countries that answered to the survey was in a short summary: while most of countries knew about PMS guidance and tools existence (RT-CQI, SPI-RT among others) and were implementing some QMS activities in lab, non-lab settings were not systematically include in QMS national plans. And we observed significative difference in term of implementation between countries receiving external funding and countries that did not received funding.
The main barriers to implement QMS highlighted by countries were: availability of funding (85,7%), lack of training (76,2%), lack of dedicated HR (71,4%) and availability of tools (for 52,4%), limited infrastructure and logistics 47,6%).
We also realised that more than half of the countries did not have a national entity responsible of IVDs PMS.
From those findings we proposed to the QMS steering commitee to develop a

QMS tool kit adapted to **non-lab** testing sites in **ressource constraints** countries. We initially thought about countries not receiving external funding but within the new funding environement, we think this tool kit might benefit more countries.
We developed:

- A generic, **multi-disease toolkit** (qualitative serological RDTs - no quantitative nor semi-quantitative methods) adapted to **non-laboratory settings** in resources constraint contexts
- **Tool Kit ≠ guidelines** (we already have QMS guidance available): A simplified approach to operationalize exisiting QMS guidance**. We Put together a Set of tools** from different partners and developed specifically: short (short text + links) and practical.

The tool kit has been validated by the steering committee and launched in Nov 2025



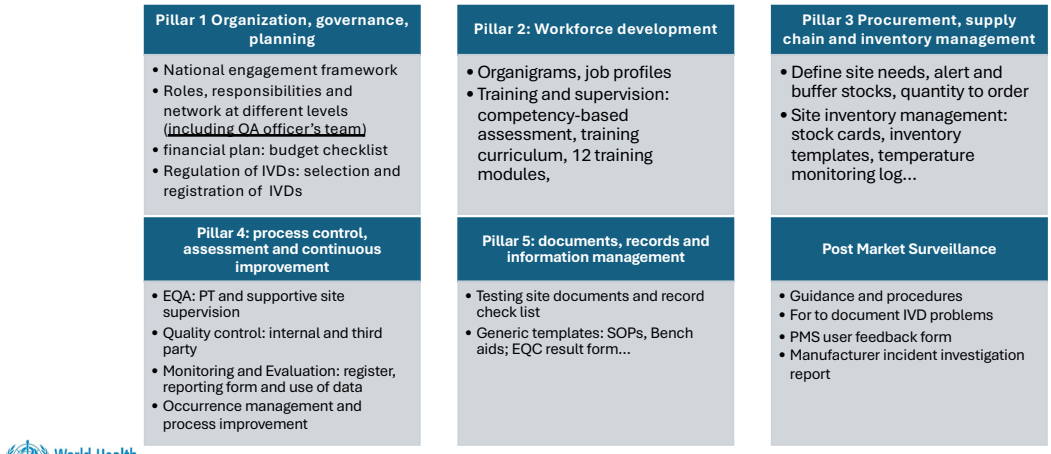

We selected a minimum set of QMS activities from the 12 QSE into 6 Pillars adapated to non-lab settings in ressources limited contexts.
We also included a PMS pillar as we think PMS is a powerfull tool to identify any quality concerns.

But, **The QMS tool kit does NOT replace existing tools, it provides set of crucial activities to implement, in case comprehensive package cannot be implemented**

If countries are able to implement and sustain comprehensive packages (RT-CQI, SPI RT) they should continue to do so but if that's not possible, then countries should focuss on this minimun set of activities.

# QMS tool kit for non-lab settings using RDTs

**Essential activities where resources are limited: simple, multi-diseases, decentralized and integrated approaches**

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WHO non-lab settings QMS tool kit- ASLM Lab Cop- April 2026 6

So, as I said the QMS tool kit provides a package of **Essential activities where resources are limited: we have included simple, multi-diseases, decentralized and integrated approaches**

**We put together exisiting tools developped by different partners and we also developped tools specifically for the tool kit.**

Pillar 1 compliles tools related to gouvernance, planning and organisation such as task repartitions, coordination mechanisms, QMS budget check list, regulation of IVDs

Pillar 2: workforce developement: organigrams, job profile, training cirriculum, modules and competency-based assesmeent program

Pillar 3 is about how to ensure availability of test in testing site. It compiles tools to define needs and site stock management tools

Pillar 4 compile quality assurance and process control tools: QC, EQA (PT and site supervision visit), M&E tools, occurrence management and process improvement

Pillar 5: information management and record: check list of documents and records needed, generic templates (Sop, Bench aids, record forms…),

Pillar 6: PMS It contains guidance and tools to implement PMS for IVDs

## Exemples of simplification (1/2): Autorization of practice, integration, frequencies

- **Sub-national testing provider competency-based assessment program instead of national certification program: initial and regular assesments**
- **Reduced frequencies for:**
  - **Site supportive supervision visits:** once a year/testing site; integration of different activities
  - **Regular testing provider competency-based assessments (during supervision visits)**

    Once every 2 years (during supervision visits, by the QA officer)
  - **Frequency for PT scheme event**

    Once/year for each ***TESTER***
  - **EQC samples (known pos and neg samples)**

    Every ***new user*** (during competency-based assessment), every ***new batch*** of test, every ***storage condition*** concerning ***events***

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As exemple of simplification and integration of activities to optimize cost keeping in mind feasibility, I can mention quickly

-Centralized certification program which were highlighted by countries to be extremely dificult to implement and run has been replace by subnational competency-based assesment program. The idea of assessing the comptences of testing providers remain the same but decentralsing its management will allow countries to assess more testing providers quicker (high turn over of testers)

-In addition to initial assessment, regular assesment are recommanded one/2 years (instead of once a year) and could be done during supervision visit

-The minimum frequency of PT is once/year per tester

-The minimum frequency of EQC samples is : every new user, every new batch of test and every storage condition concerning event.

-Site supervision visit is recommended once/year (instread of once/6 months) and will integrate different activities (and multi-diseases)

## Eg of simplification (2/2): What kind of specimens to use for QC and PT/EQA scheme?

- **Simplified options for specimen**
  - **EQA/PT programs**
    - Ideally, EQA/PT scheme provider ISO certified (commercial or non - profit)
    - Locally produced and characterized samples (DTS)
      - Characterization protocol using tests (strategy) in use in the testing sites
  - **QC solutions *(every new user, every new batch of test, every storage condition concerning events)***
    - Ideally, commercial samples (<u>often not existing</u>),

  So:
    - DTS is characterized using tests (strategy) in use in the testing sites
    - Sites stored samples characterized using tests (strategy) in use in the testing sites



Other exemple of simplification is about type of sample to use for EQA scheme and QC

# Crucial role of laboratories to ensure QMS implementation

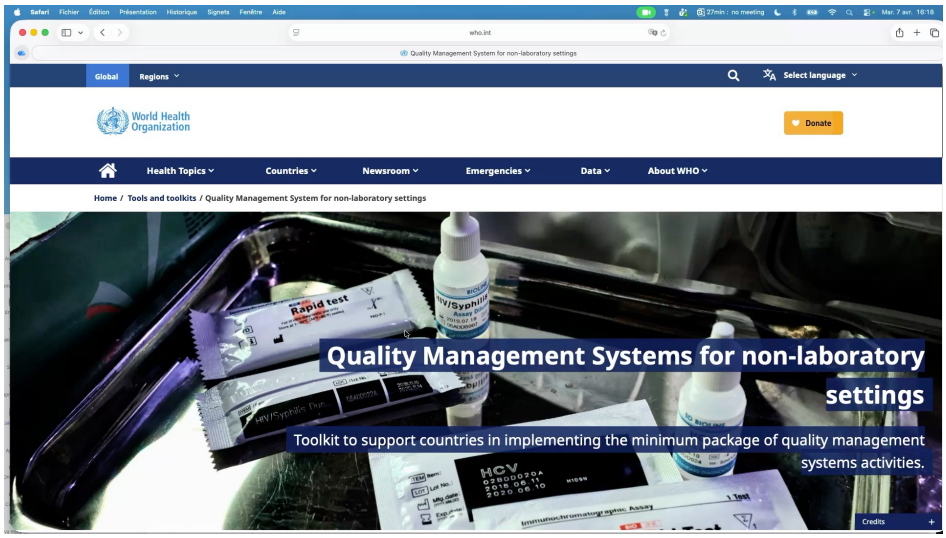
**Role of the laboratories continue to be crutial** (list non-exhaustive):

- Developing and validating national **QMS tools**: training curriculum, comptency-based assesment programs, M&E tools, SOPs, site supervision template…
- **Training and supervision** of non-lab settings personals
- **Developing national site supportive supervision visits** plan
- **Conducting site supportive supervision** visits
- **PT/EQA programs:** production of specimens, management of the program (send PT panel to testing sites, analyse results, provide feedback)
- **Follow up:** support process improvement activities (Incl: preventive and corrective actions)



I want to finish my presentation by highlighting that to implement those activities, the involvement and strong support of laboratory network and lab personnal in countries. And these activities should be included in the laboraroties workload.
Role of laboratories are going to be particularly crucial for:

# How to nagivate into the QMS tool kit webpage ?



# Thanks a lot of your attention

- Any questions please contact:
  - lastruccic@who.int
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# Panel discussion

## South Africa's Rapid Test Continuous Quality Improvement (RTCQI) Program


**Ms Alarice Marsh**

Deputy Director: HIV Testing Services Manager

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NATIONAL HEALTH LABORATORY SERVICE

## Mozambique perspectives on QMS implementation in non-laboratory settings

**Deonilde Sarmento**

Focal Point for Laboratory Diagnostics, National STI, HIV and Viral Hepatitis Control Program,

REPÚBLICA DE MOÇAMBIQUE
MINISTÉRIO DA SAÚDE
DIRECÇÃO NACIONAL DE ASSISTÊNCIA MÉDICA

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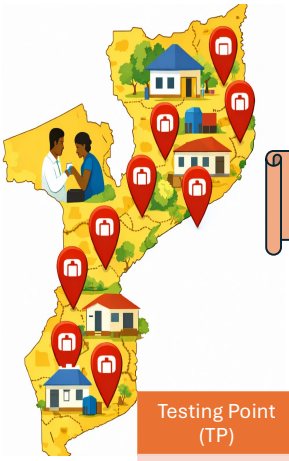
# HIV Rapid Testing Quality in Mozambique - Overview



**1897 health facilities provide testing services.**

| Testing Point (TP) | TP enrolled in QC | TP enrolled in EQA (Central) |
|---|---|---|
| • 8076<br>• 100% | • 3936<br>• 49% | • 369<br>• 86% |

## Current Context

- >95% of tests with RDTs outside laboratories
- Nationwide RT-CQI implemented
- Training & Certification of Testers
- EQA / Proficiency Testing
- Supervision & Data Monitoring
- Decentralized Laboratory Support

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# Key Challenges

**Workforce: High Tester Turnover**
- Low retention of personnel, especially lay providers
- Increased demand for initial training and testers certification
- Limited commitment to quality among testers

**Sites organization and performance**
- Low performance in proficiency testing
- Weak follow-up of action plans
- Deficiencies in infrastructure and biosafety

**EQC:**
- reduced availability and low stability of whole blood samples
- High test consumption to run current EQC frequency target

**Testing site level Data Use**
- Weak critical analysis of reports

**Functioning of "Núcleos"**
- Logistical and financial constraints affecting operations

# QMS tool kit

**Pillar 2: workforce development**
- Implement subnational training and competency based assesment program
- Implement re assesment of competencies during site supervision training

**Pillar 4: Sites organization, data use and EQC**
- Implement (/reduce to) yearly integrated supervision visits : to assess site / operators and follow up on action plans
- Decentralize conduction of supervision visit
- Implement integrated testing register and train on indicator calculation and use at site level
- EQC :
  - Diversify sample types: DTS and onsite/closest possible stored samples
  - Reduce frequency to: new batch, new operator and if storage condition concerns
- PT/EQA scheme

**Pillar 1:** review activity frequency related to budget and task repartition (decentralization)

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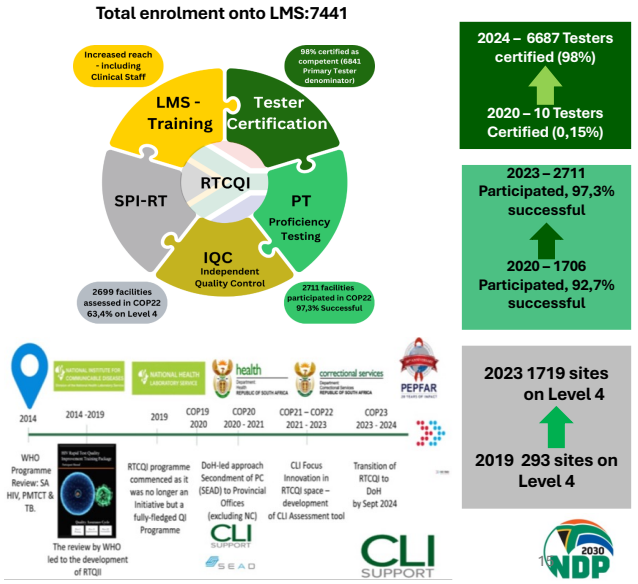
# RTCQI PROGRAMME & TESTING CONTEXT OVERVIEW

- HIV testing services are delivered across multiple platforms in South Africa, including primary healthcare facilities, hospitals, community-based outreach services, mobile units, and targeted key population programmes through Domestic funding
- Testing is conducted both within clinical settings and through decentralized community models to improve access and coverage.
- A significant proportion of testing is conducted outside traditional laboratory settings, with approximately 85–90% of HIV screening tests performed as point-of-care (non-laboratory) rapid tests by trained lay providers and healthcare workers.
- However, in high-burden settings, services may still be delivered in a disease-focused manner to meet specific programme targets.
- Laboratory-based testing is primarily reserved for confirmatory testing, quality assurance, and special populations (e.g., infants)
- Increasingly integrated (HIV, TB, STIs, NCDs), though some disease-focused delivery remains
- Continuous mentorship, proficiency testing, and quality assurance systems support competency across all cadres.




2024 – 6687 Testers certified (98%)

2020 – 10 Testers Certified (0,15%)

2023 – 2711 Participated, 97,3% successful

2020 – 1706 Participated, 92,7% successful

2023 1719 sites on Level 4

2019 293 sites on Level 4

Focus was on the RTCQI space, process started for the transitioning to NDOH in 2023. There was various trainings and successes. SA did not have a tester framework through the support of SEAD the country has certified 98% of the testers. Prior to the framework in 2020 only 10 testers were certified. The digitalization of the program was able to reach approximately 6687. SPI RT has also improved and this was due to the digitalization of the program. Prior to the review an IQC pilot was conducted in Limpopo. RTCQI started with an initiative where it was known as RTQII, adopted in 2014. Adapted to RTCQI program focusing on continuous support. In 2020 adopted the NDOH approach where CLI co-ordinators.

# SUCCESSES, CHALLENGES AND PLANS FOR ADOPTION OF WHO QMS TOOK-KIT

## SUCCESSES

- **Strong national leadership** by NHLS supporting QA systems
- **Proficiency testing (PT/EQA)** programmes with broad facility participation
- **National HTS guidelines, SOPs and job aids** standardising practice
- **Routine supportive supervision and audits** (including RTQII and site assessments)
- **Effective task-shifting model** with trained lay counsellors expanding access

## CHALLENGES

- **Variable compliance** with HTS algorithms and SOPs
- **Gaps in PT participation,** result submission and corrective action follow-up
- **Inconsistent supportive supervision** and post-audit quality improvement
- **Data quality issues** (register completion, linkage to DHIS)
- **Stock-outs and supply chain constraints** impacting quality
- **Limited continuous competency** assessment for lay providers

- Identify QMS gaps (quality, stock, workforce)
- Adapt World Health Organization toolkit to SA context
- Train staff and roll out SOPs
- Phased rollout in priority provinces
- Track performance (DHIS, National Health Laboratory Service EQA) and review PT for bi-annually to annually in provinces that achieve over 100%
- Continuous corrective actions and optimization

## WHO QMS KIT ADOPTION

### PLANS FOR ADOPTION/ADAPTING THE WHO QMS KIT

| | | | |
|---|---|---|---|
| Discussion with the 9 provinces to identify how the tool can be adopted | Review the current tool-kit that we are using to identify how the two toolkits can be integrated | Roll-out on a small scale to identify if any challenges from the end users | Coordination and roll out on the large scale to the country and all the facilities that are offering HIV testing services |

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***Merci***

***Thank you***

***Obrigada***

***Kanimambo***

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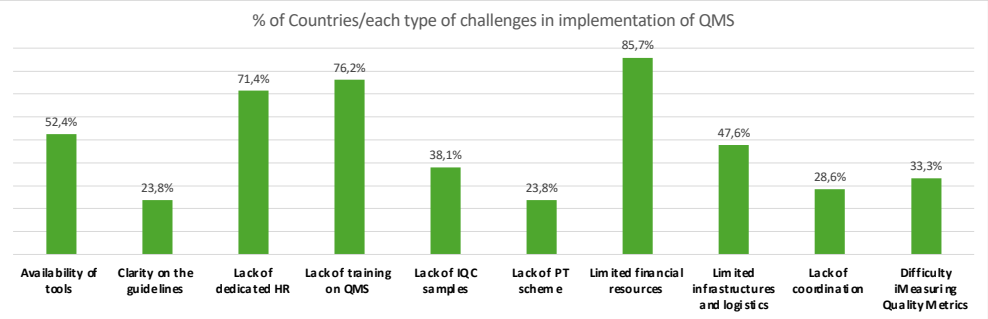
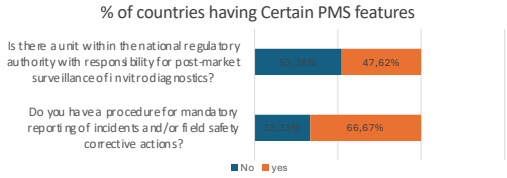
- Annexes

# 2023 Survey: challenges of establishment of QMS and availability of PMS* in the countries




*PMS= post-market surveillance

## Summary of findings 2023 WHO country survey

- Multiple testing sites at different levels/ in health pyramids, different pathologies, with different types of tester profiles
- Several existing QMS/QA tools and resources
- Some for laboratories and some for POCT sites
- Based on countries' feedback those tools can be challenging to implement in some contexts (specifically in low-resource countries/with limited external technical and financial support)
- Despite existing national QMS guidance (62%, 13/21), only 5 countries implemented EQA for community testing sites
- A need to reinforce countries' capacity to establish PMS, strengthen incident reporting procedures and mechanisms



Thousands testing sites