Quality Management Systems for non-laboratory settings – Toolkit

Roles and responsibilities at different levels

World Health Organization

Roles and responsibilities at different levels

A strong commitment from the health ministry and partners is essential for successfully reinvigorating and strengthening the overall national quality assurance program. A significant ramp-up and resource contribution is likely to be required in many cases, and strong leadership and advocacy are therefore crucial. The health ministry and national laboratory leaders with the appropriate government authority should engage leadership to ensure buy-in at the highest level for the quality assurance program. Defining roles and responsibilities and the network system between different people with different responsibilities is an important component of making the implementation process efficient and successful. Ensuring the safety and quality of testing of non-laboratory settings requires planning, resources, oversight, coordination, and implementation of quality assurance measures at all health system levels, including national, subnational, and local. Countries need to create comprehensive national normative documents that outline QMS standards, set targets for various diseases, and provide an operation plan detailing the implementation of the QMS national policy.
National laboratory leaders are the cornerstone of the QMS implementation. They should provide robust leadership, and technical advice, and advocate for necessary resources. They should also be involved in the design, implementation, and monitoring of quality assurance measures.

The testing site manager/supervisor or anyone leading the testing activities is responsible for establishing policies and processes, ensuring that all personnel understand their duties, and providing the necessary resources. Lines of communication must be established for all personnel who manage, perform, or verify work affecting testing results.

A. The roles and responsibilities should be defined at different levels:

I. National Level:

The **Ministry of Health (MoH),** through the Department of Public Health, defines the overarching policies and quality assurance frameworks at the national level, while the **Regulatory bodies** (such as NRA) develop and review regulations and enforce compliance. The **National Laboratory Directorate*** is responsible for the strategic and operational management of the entire national laboratory system, and the **National Reference Laboratory/ies (NRL)** provides technical leadership, conducts proficiency assessments, and validates diagnostic practices, supporting both the MoH and the Regulatory Body. Together, these entities collaborate to ensure the highest levels of quality, accuracy, and reliability in national laboratory services.
If not in place already, the country should implement a multi-sectorial body identified by leadership (National Laboratory Directorate*) as a "**National QA Coordination Team**" or "National QA Technical Working Group" (TWG). This team should include individuals with relevant expertise in laboratory and testing services, supply chain, quality assurance, quality improvement, monitoring and evaluation, and program management. This multi-sectorial team should define quality assurance standards and targets, develop a national QA work plan, and supervise its implementation across the country (and across diseases).

A national QA Manager(s)/officer(s) should be appointed. He/she should set up a team of subnational QA Manager(s)/officer(s) organized as a network to ensure good country coverage.

As an example, a similar model that was established in Uganda for QI activities: read more: Continuous quality improvement as a tool to implement evidence-informed problem solving: experiences from the district and health facility level in Uganda; BMC Health Serv Res. 2021 Jan 22;21(1):83.

*Can be named differently according to the country's organization. E.g., National Public Health Institute, Pharmacy and Laboratory Department, National Institute of Public Health, Laboratory Unit, National Laboratory Directorate.

II. Subnational (Regional, Provincial, or district) Level:

Subnational (regional, provincial, district...), health authorities serve as intermediaries between the national level and testing sites, ensuring that national policies and work plans are implemented as expected. The national level can delegate some of its tasks to the subnational levels (e.g., training and supervision activities).

The team of subnational QA Manager(s)/officer(s), under the supervision of the national QA manager/officer, should have expertise in RDTs procedures and QA; they are responsible for coordinating quality assurance activities across the health pyramid, supervising and supporting testing sites, collecting data, and providing feedback to the management line.

III. Testing Site Level (Health Centers, Clinics, Hospitals, laboratories, community testing):

At the testing site level, testing providers (trained lay providers, healthcare workers, nurses, laboratory technicians...) are responsible for conducting and managing testing activities, including QA. In each testing site, dedicated personnel should be assigned to the supervision of testing and QA activities. In the table below, you can find a summary of roles and responsibilities at different levels, adapted from the WHO Quality document for malaria RDT and WHO 2015 guidance (Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results: 1 December 2015). These roles and responsibilities are essential to ensure that Rapid Testing is effectively integrated into health systems, providing timely and accurate diagnoses at all levels of care.

This table is an example of how tasks can be distributed among different stakeholders, which should be tailored to the local context by the health authorities. Depending on the country's governance organization, roles/responsibilities might be assigned to other entities than outlined in this table.

Roles and responsibilities of key stakeholders	
Who (Entity)	**What/Tasks/How**
Department of Public Health (MOH)	● **Health Policies and Regulations**: Define policies, regulations, and decrees to guide QA in testing activities. ● **Roles and Responsibilities**: Clearly define the roles and responsibilities of different national bodies/institutions. ● **National Diagnostic Network**: Define the national diagnostic network that includes all testing tiers including public-private partnerships to improve testing coverage. ● **Task Sharing Policy**: Develop testing activities task sharing national policy, including training, supervision, and authorization requirements for testing providers. ● **Resource Allocation**: Use situational analysis to determine necessary resources (e.g.: QA officers' team) and the QA activities (e.g.: training, site supervision, PT/EQA schemes...). ● **National QA Coordination Team**: Establish a team to develop guidance and oversee QA and QI implementation and host the national QA coordination team ● **QA Implementation**: Oversee nationwide testing activities and plan for QA implementation.
Regulatory body (National Regulatory Agency)	● **National Policies and Standards**: Define and develop national policies, guidelines, and standards for selecting quality-assured products including national registration procedures and ensure adherence to international guidelines. ● **Product Selection**: Ensure that appropriately regulated products are selected for Rapid Testing: e.g. Review manufacturers' product dossier, quality of manufacturing practices, and independent product performance evaluations. ● **National PMS Implementation**: Develop and support the implementation of national policies and procedures for post-market surveillance (PMS).
Procurement/Supply division	● **forecasting and quantification:** Ensure adequate national forecasting quantification of needed reagents and materials through the establishment of a multisectoral national committee which will analyze country consumption data and needs. ● **National Procurement Plan**: Incorporate non-lab test commodities into the national procurement plan ● **National supply chain plan:** Develop a national supply chain policies and plan, including last mile distribution and site stock management guidance, taking into consideration country logistical resources and constraints identified through situation analysis
National Laboratory	● **Engagement and Expertise**: Engage in high-level leadership and provide technical expertise to the Ministry of Health (MOH).

Directorate *	● **Seek resource commitment** from MOH. ● **Diagnostic network coordination**: Organize and coordinate the national dia gnostic network in collaboration with National Reference Laboratories (NRLs). ● **QMS policies, standards, targets, and work plan:** under the leadership of the MOH, develop the national normative and operational documents for QMS definition and implementation nationwide and across diseases ● **HR planning:** Define HR needs, including knowledge, competencies validation process (certification, licensing, practice authorization...), training, and supervision requirements ● **National QA coordination team**: Host the national QA coordination team in charge of developing national QA policy, and plans and overseeing the implementation of QA activities nationwide and across diseases. ● **PMS strategy**: Support the development of a national post-market surveillance (PMS) strategy. ● **Certification, accreditation, and authorization of performing testing**: Set assessment and proficiency criteria for tester authorization/certification and site accreditation. ● **Supervisory plan**: Develop a site supervision plan supervisory plan with appropriate human resources.
Disease programs (through NRLs)	● **Testing:** Perform reference testing and confirmatory diagnosis. ● **Assay validation**: Validate assays, platforms, testing strategies, and algorithms, ensuring alignment with international standards. ● **National quantification and forecasting**: support the procurement and supply division during annual exercise. ● **Technical document development:** Develop and update technical Guidelines, Standard Operating Procedures (SOPs), bench aids, etc. for laboratories and non-laboratories settings through desk review of national and international guidelines. ● **M&E tools**: Validate data collection and reporting forms ● **EQA program:** support the coordination of national External Quality Assessment (EQA) programs and monitor laboratory performance through proficiency testing (commercial or locally produced). ● **Training and Support:** Provide ongoing training and technical support to testing providers to ensure they follow best practices in diagnostics and quality control.
National QA coordinatio n team	● **QA work plan**: Develop a national QA work plan (across various diseases and technologies) and support, coordinate, and supervise its implementation. ● **Goals and standards**: Set goals and standards for testing providers. ● **Technical documents and tools:** Develop, validate, and review guidelines, SOPs, bench aids, and M&E tools through technical working groups.

	● N**etwork facilitation**: create and facilitate multi-entities QMS network involved in testing activities and report regularly to the laboratory directorate. ● **Training and supervision**: Develop, plan, and coordinate training, competency assessment, and supervision programs for testing providers and testing sites. ● **QA program**: Ensure the PT/EQA program, QC, corrective actions, process improvement measures, and PMS are in place. ● **Data Aggregation and Analysis**: Aggregate and analyze sub-national QA data to provide national QA performance results, identify bottl enecks, and propose improvement measures. ● **Support sub-national QA**: Provide support to sub-national QA officers. ● **Delegation to local team**: Delegate activities such as training, site supervision, and document development to sub-national and local QA teams as needed.
Sub-national QA officer	● **QA activities**: Plan, support, and supervise QA activities, and ensure accurate testing activities at the sub-national level. ● **QA compliance**: Ensure compliance with QA and QC standards. ● **Training programs**: Plan and conduct initial and refresher competency-based assessment training for testing providers. ● **Supervision programs**: Conduct regular supportive site supervision visits. ● **Data analysis:** Aggregate and analyze local data to evaluate QA activities implementation and performance, identifying bottlenecks and proposing co rrective actions. Report to the national coordination team. ● **Feedback and corrective actions**: Ensure testing sites receive feedback and follow-up for corrective actions. ● **Link between sites and national team:** Act as liaison between local testing sites and the national QA team, providing technical support and guidance. ● **RDT âvailability**: Ensure the availability and proper use of RDTs by supportin g needs identification procurement, and distribution of reagents and consumables.
Site supervisors /QA officers	● **RDT availability:** Monitor consumption of reagents and consumables, ensuring proper storage conditions. ● **HR:** Coordinate facility-wide training and capacity-building efforts. ● **Testing and supervision of testing sites:** Conduct testing when needed, and implement QMS in facilities. Supervise the whole testing activities including adherence to SOPs, Guidelines, safe handling, and disposal of hazardous material. ● **Site performance monitoring:** Monitor the performance and quality of testing services in the facility through regular data review and analysis, ensuring implementation of external quality assurance measures (PT scheme, supervision visits), and ensuring occurrence management and corrective actions are implemented based on national policies.

	● **Post market surveillance (PMS) implementation:** Ensure PMS activities are implemented in case any quality complaints or non-conformities are detected, and reported to the manufacturer and national PMS team. ● **Reporting**: Report on testing site activities and performances according to defined timelines to the management line (subnational QA team). ● **Link between sites and sub-national team:** Act as a liaison between local testing sites and the subnational and national QA team, providing technical support and guidance to the testing site.
Testing provider (Community Health Workers (CHWs), lay providers, nurses, laboratory technicians)	● **Authorization to work**: testing providers should be trained and authorized to conduct testing, through competencies-based assessment, by the QA officer and/or site supervisors or any relevant person. ● **Sample collection and testing**: Ensure accurate sample collection, handling, ● testing, and result interpretation. ● **Testing:** Operate assays according to the manufacturer's instructions for use (IFU). ● **Infection control**: Adhere to infection control protocols. ● **Documentation**: Document and report test results appropriately. ● **Client information, counseling and referral**: Provide Client information, counseling when relevant based on test outcomes, and/or refer patients to appropriate health facilities for care or prevention services. ● **Stock management**: Implement stock management procedures including regular inventories, and orders, and maintain adequate storage conditions.

*: Depending on the countries' MOH organization:

- Can be named: Laboratory Directorate, Pharmacy and Laboratory Department, Laboratory Unit,
- It can be under the direct supervision of the National Institute of Public Health or the supervision of the Pharmacy and Laboratory Department.

1) Organigram

It is important to define a clear organizational chart (organigram) that illustrates roles, responsibilities, and management lines between the different entities/personnel involved in the quality of testing activities from the national to the local level. (QMS organigram (PDF, 260 kB)) Examples of governance and quality officers team organigrams are included in the toolkit. The country should adopt those organigrams to their national organization.

2) Non-governmental partners (NGOs):

In some countries, based on the needs and context, an external party like NGOs or donors might support MOH or other national entities in implementing testing activities, including QMS. While they are not included in the backbone of the national organigram, they can play a pivotal role in implementing testing, especially at the community level. According to the Memorandum of Understanding (MOU) between MOH and NGOs, NGOs can be involved in different activities at all stages of the health pyramid.