Quality Management Systems for non-laboratory settings – Toolkit

National Engagement Framework

World Health Organization

National Engagement Framework

The successful implementation and sustainability of a quality management system (QMS) for testing in a non-lab setting relies heavily on strong national engagement. When governments lead the development and oversight of quality assurance (QA) practices, it ensures that quality systems are consistently applied across all levels of the health system and are aligned with broader national health priorities. Central to this process is the development of national QA policies, implementation guidelines, testing provider training programs and standard operating procedures (SOPs), which serve as the backbone of quality standards.

These national documents not only define expectations for performance and compliance but also promote standardization and clarity throughout the testing continuum. To be effective, they must align with recognized global standards, such as ISO 15189:2022, ISO 22870 specific to point-of-care testing, Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results, and tools like the WHO Laboratory Quality Stepwise Implementation (LQSI), and Rapid Test Continuous Quality improvement (RT-CQI). They must also be accompanied by a clear governance structure and strong stakeholder collaboration to ensure their relevance, ownership, and accountability.

Standardized SOPs (Read more in Pillar 5: Documents and records) should cover every phase of testing. This includes pre-analytical steps like specimen collection, labeling, and transport; analytical procedures such as test execution, equipment handling, and use of quality controls; and post-analytical tasks like result interpretation, documentation, and timely reporting. Uniform implementation of these SOPs ensures consistency and accuracy regardless of testing location.

Equally important is the **institutionalization of proficiency testing (PT)** and external quality assessment (EQA) (Read more in Pillar 4: Process control, assessment and continuous quality improvement) and continuous quality improvement). National SOPs should define how these schemes are designed, managed, and evaluated, including logistics for sample distribution, reporting mechanisms, performance feedback, and corrective action procedures. Where feasible, countries should engage in regional or global PT/EQA initiatives, to benchmark and continually improve testing standards.

Governance and oversight structures play a pivotal role in managing and sustaining QA systems. Establishing a national QA technical working group (TWG) or assigning responsibilities to an existing regulatory authority helps anchor the QA agenda within the health system. These entities should include representation from the Ministry of Health, national reference laboratories, implementing partners, regulatory agencies, and civil society. Their roles typically encompass policy development, coordination of QA activities, stakeholder engagement, and monitoring the uptake and effectiveness of quality systems (Read more: Roles and responsibilities at different levels (PDF, 310 kB)).

Beyond policy and governance, **meaningful engagement with stakeholders** is critical for success. Countries can foster ownership and relevance of national QA systems through consultative workshops, review forums, and ongoing workforce development initiatives

(Read more about implementation in Pillar 2: Workforce development). This should include building training and competency-assessment programmes and implementing cascade training to ensure SOPs are understood and implemented at all levels, as well as mechanisms for regular review and revision of documents every two to three years to reflect technological changes or field experience.

Turning policy into action involves a structured and collaborative **implementation process**. This begins with mapping key actors and securing leadership buy-in from senior Ministry of Health officials, programme managers, and reference laboratories. A dedicated QA coordination team is typically established, with clearly defined roles and responsibilities based on a national situational analysis. This team leads the drafting of policies and SOPs, ensuring they are endorsed through inclusive national validation processes. Once finalized, the materials are disseminated widely, and training is delivered to support rollout.

Effective monitoring mechanisms must also be introduced from the outset, with key performance indicators and scheduled review cycles to track implementation progress and ensure ongoing relevance. Adequate planning of resources, both financial and human is essential (Read more: Financial planning for QMS implementation (PDF, 220 kB)). This includes forecasting QA needs (including reagents) and securing funding through government budgets or external partners.

To ensure early impact, countries may prioritize specific sites for **phased QA implementation**, focusing on high-volume, remote, or underserved areas. Additionally, selecting appropriate testing products that are validated, regulated, and suited to the national context ensures that quality assurance efforts are not undermined by inadequate technologies (Read more: Regulation of IVDs: selection and national registration of RDTs marketing authorization (PDF, 310 kB)).

In summary, national engagement in testing quality management is not a one-time effort but a continuous process requiring leadership, collaboration, and alignment with national and international standards. By institutionalizing policies, standardizing procedures, ensuring oversight, and fostering inclusive stakeholder engagement, countries can strengthen the delivery of reliable, timely, and patient-centred diagnostic services at the point of care.

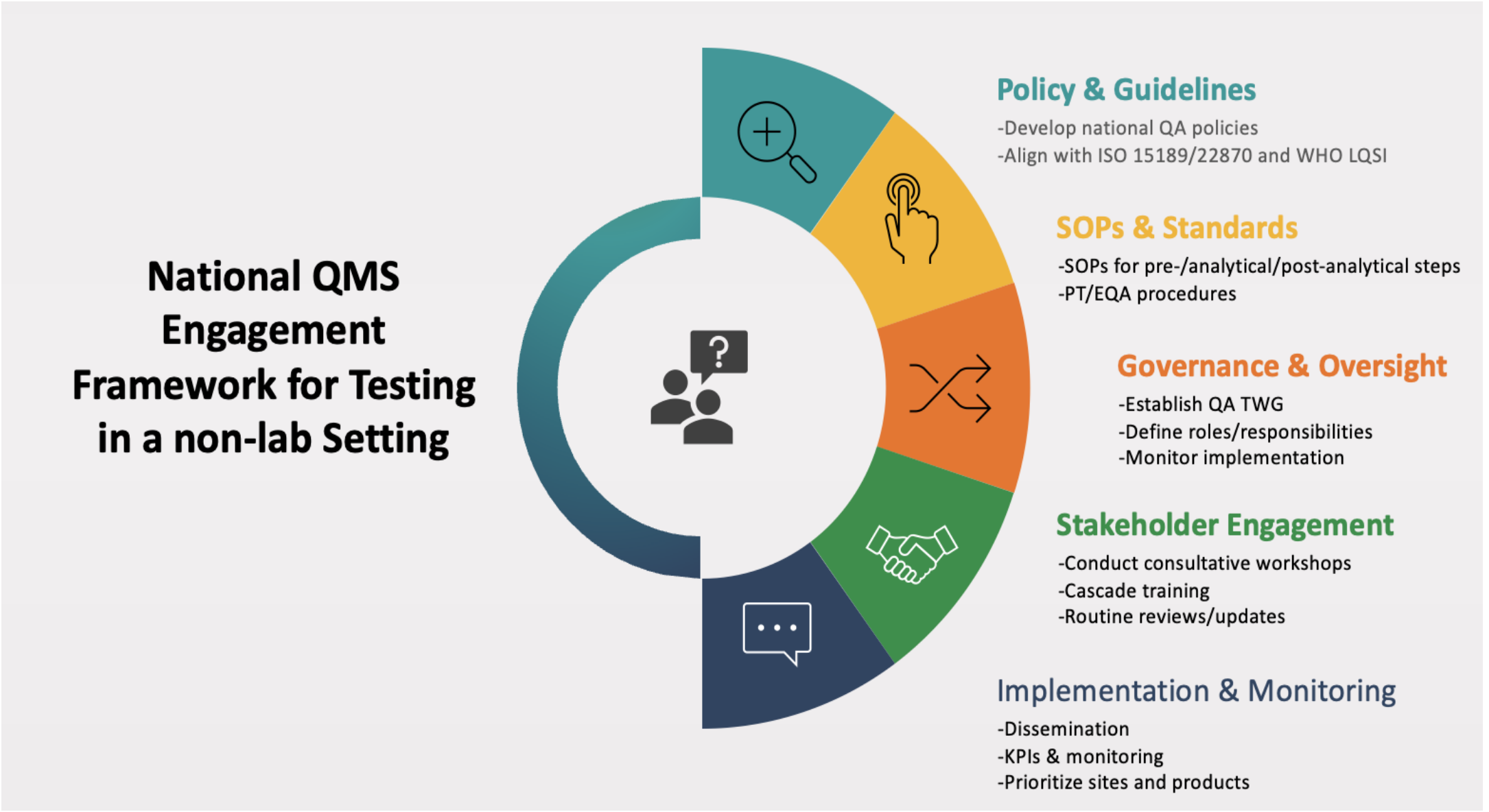

Figure 1: National QMS Engagement Framework for testing in a non-lab setting.