

Strengthening Laboratory Testing: A Call for Quality, Innovation, and Systemic Change

Laboratory testing plays a pivotal role in modern healthcare, forming the backbone of clinical decision-making across the globe. With approximately 70% of clinical decisions relying on laboratory data, the importance of accuracy, timeliness, and reliability in diagnostic testing cannot be overstated. The COVID-19 pandemic exposed weaknesses in laboratory systems worldwide, underscoring the urgent need to strengthen diagnostic capacity, not only to respond to emergencies but also to support routine care.

During the July 2025 Pacific Islands Pathologist and Laboratory Scientist CME webinar, Dr Innocent Mupunga (Senior Scientist – Consulting and Training) delivered an engaging presentation highlighting both the foundational and future-facing elements of quality in laboratory services. His address, titled ***“Quality Laboratory Testing: Addressing Challenges, Implementing Best Practices and Innovating for the Future,”*** dissected the multifaceted challenges laboratories face, outlined best practices for quality management, and showcased emerging innovations poised to transform diagnostic services.

Uncovering the Iceberg of Laboratory Errors

The address started by emphasised that laboratory testing is a complex, multistep process encompassing pre-examination, examination, and post-examination phases. While most attention often focuses on errors during the examination phase, these represent only a small portion of the total error burden. Laboratory errors can be likened to an iceberg: highly visible examination-phase mistakes are just the tip, while the bulk of issues lie hidden beneath the surface in the pre- and post-examination phases.

- **Pre-examination errors**, accounting for up to 70% of mistakes, may arise from poor patient preparation, incorrect test orders, or improper sample handling.
- **Post-examination errors** (10–30%) include delayed reporting or miscommunication of results.
- **Examination errors**, although critical, make up just 15–20% of all laboratory errors.

This distribution of errors highlights the need for systemic, not just technical, interventions.

Quality Management Systems: The Missing Foundation

At the root of persistent quality issues in many laboratory settings is the absence of a strong Quality Management System (QMS). A QMS provides the framework to prevent, identify, and correct errors across all phases of testing. The presentation pointed out several recurrent weaknesses:

- Inadequate documentation and standard operating procedures (SOPs) and record keeping processes
- Weak risk management and internal auditing processes
- Lack of structured training and competency assessment
- Poor monitoring and evaluation mechanisms

Importantly, participants were warned against treating QMS as a mere “tick-box exercise,” and were urged to embed quality into their culture and operations. “Leadership commitment is essential,” said Dr Mupunga, “not just for resources, but for setting the tone and vision for quality.”

Best Practices: Building a Culture of Quality

To guide laboratories through quality system implementation, a practical five-step approach was outlined:

1. Secure Management Commitment – Ensure leadership champions quality improvement efforts, sets priorities, and allocates necessary resources.
2. Conduct a Gap Analysis – Review current practices to identify areas where policies, procedures, or training are lacking. Apply a risk-based approach to prioritise actions based on the findings of the gap analysis.
3. Strengthen Documentation and Process Control – Develop and standardize SOPs, implement risk management strategies, and establish training systems.
4. Implement Key QMS Processes – Introduce tools such as internal audits, customer feedback loops, incident reporting, inventory management and equipment management systems.
5. Monitor and Continuously Improve – Use quality indicators, error trend analysis, and management reviews to drive sustained improvements.

Innovation as a Catalyst for Change

While foundational quality systems are essential, innovation is also transforming the laboratory landscape. Several promising developments were highlighted:

- Point-of-Care Testing (POCT) is an under-rated innovation which is improving access and reducing turnaround times, especially in hard-to-reach areas. However, POCT also presents challenges for maintaining quality control when performed outside traditional laboratory environments.

- Automation and Robotics are streamlining workflows, reducing human error, and enhancing efficiency in areas such as phlebotomy, sample processing, and result verification.
- Digital Tools such as cloud-based calibration, barcode tracking, and integrated Laboratory Information Systems (LIS) are improving traceability and reducing errors.
- Artificial Intelligence (AI) and Predictive Analytics are being integrated into diagnostic platforms to support clinical decision-making and forecast quality risks before they materialize.

These innovations, while promising, must be carefully integrated with robust QMS frameworks to ensure they enhance rather than compromise quality.

Conclusion: Quality as a Cultural Imperative

The address concluded with a powerful reminder: quality improvement is not just technical—it's cultural. Laboratories must foster environments that encourage learning, collaboration, and accountability. "Cultural change is gradual," noted Dr Mupunga, "but essential for sustainable quality."

As health systems around the world prepare for future challenges, strengthening laboratory services must remain a top priority. Reliable diagnostics are not optional; they are a critical foundation for universal health coverage, pandemic preparedness, and improved patient outcomes. The path forward is clear: **embed quality into every step of the testing process, embrace innovation responsibly, and foster a culture that values continual learning and improvement.**