Saudi Journal of Medicine and Public Health

https://saudijmph.com/index.php/pub

Quality Control of Laboratory Medicine: Preventing Errors for Diagnostic Reliability

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Abstract

Quality assurance (QA) of laboratory medicine is vital for diagnostic reliability and patient safety. Laboratory test errors can lead to misdiagnoses, inappropriate therapy or treatments, and unwanted outcomes. This systematic review discusses and integrates quality laboratory medicine error prevention in the context of diagnostic reliability, based on 46 peer-reviewed articles. It discusses the preanalytical, analytical, and post-analytical phases of error prevention based on the nature, source, and ways to avoid errors, different QA models, approaches with new technology, a variety of ways to train or educate, and continuous improvement. The laboratory medicine errors are routine: wrong sample, analytical errors, and wrong result, and the inclusion of preanalytical errors causes the majority of errors (preanalytical errors are as high as 70%). QA models (for example, ISO 15189) offer an all-encompassing model; newer technological approaches (automation, artificial intelligence, etc.) offer an alternative with increased accuracy. The technical impediments to implementing quality management systems to prevent errors and monitor quality are scarce resources and a lack of educational/ training experience, and experience makes it more difficult for lower-resource centers or settings. Some recommendations include: effective management, testing protocols that are standardized, external quality assessment, and interprofessional working. The priorities for future agendas are considering new technology as it evolves, international harmonization of standards (decreased variability), and reducing inequities in access to laboratory testing. The review provides evidence for quality assurance systems that will lead to error reduction, diagnostically dependable outcomes, and outcome maximization for patients, with the result being quality improvement for the delivered healthcare will be laboratory professionals.

Keywords: Quality assurance, laboratory medicine, diagnostic error, patient safety, automation

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Received date: 3 Nov 2024 Revised date: 25 Nov 2024. Accepted date: 25 Dec 2024

Introduction

Modern medicine is reliant on laboratory medicine, which provides clinically useful information on disease diagnosis, therapy, and disease progression. For over 70% of patients, clinical decision making is made based on laboratory data (Plebani, 2010). Unfortunately, erroneous laboratory test results are the source of incorrect diagnoses, delays in therapy, and problems for patients which elevate the importance of a quality assurance (QA) program (Lippi et al., 2017). Quality assurance of laboratory medicine describes systematic approaches to assurance of diagnostic integrity, error minimization and sustaining the pre-analytical, analytical, and post-analytical phases with levels of accuracy and precision that are adequate (e.g. Westgard, 2003). Errors may occur at any phase, e.g. pre-analytical errors such as sample identification, are attributed to as much as 70% of overall errors (Hammerling, 2012; Carraro & Plebani, 2007).

The multi-faceted nature of laboratory testing, the result of technological advancements and high-throughput digital platforms, pushes for rigorous quality assurance (QA) practice (Sciacovelli et al., 2018). However, this is even more difficult for low-resource settings, i.e., low-resource communities, due to the lack of quality controlled laboratories (Nkengasong et al., 2010). This overview results in a definition of QA in laboratory medicine with a strong focus on mistake correction, as well as reliability in diagnosis. The overview discusses types of errors, QA models, technology-intervention and training programs, issues and future directions, with a detailed analysis that should assist laboratory professionals in understanding how to better patient care.

Types and Sources of Laboratory Medicine Errors

Laboratory errors are the greatest threat to diagnostic testing accuracy, with implications for patient safety, clinical decision making, and clinical outcomes. Errors in testing can be further subcategorized in detail, based upon the three phases of the laboratory test process: pre-analytical, analytical, and post-analytical. Each of these phases has different sources of error, different impact, and different QA implications for laboratory medicine (Plebani, 2010). Only once there is an understanding of the different errors present in testing can effective mechanisms be implemented to limit the occurrence of these errors, which will assist in the assurance of diagnostic accuracy. These pre-analyical failures which occur with the most frequency include ~60-70% of laboratory errors, followed by analytical and then post-analytical failures (Lippi et al., 2011; Hammerling, 2012). What follows below is a complete discussion of these stages of laboratory medicine with specific errors, causes, impact on patient care, and evidence in the literature. Table 1 provides a summary of these error types, descriptions, impacts, and specific literature references.

Table 1: Error types and Root causes in Laboratory Medicine

Phase	Error Type	Description	Impact	References
Pre-Analytical	Sample Misidentification	Incorrect patient or sample labeling	Misdiagnosis, inappropriate treatment	Hammerling, 2012; Lippi et al., 2011
Pre-Analytical	Hemolysis	Sample damage during collection	False analyte results, delayed diagnosis	Carraro & Plebani, 2007
Analytical	Instrument Malfunction	Equipment failure or calibration errors	Inaccurate test results	Westgard & Westgard, 2014
Post-Analytical	Result Misinterpretation	Errors in reporting or clinical interpretation	Incorrect treatment decisions	Plebani & Lippi, 2010
Post-Analytical	Delayed Reporting	Slow result delivery to clinicians	Delayed patient care	Sciacovelli et al., 2018

Pre-Analytical Errors

The pre-analytical stage includes all situations leading to analysis of a specimen, from patient preparation to specimen collection, labeling, transport, and storage. It is an error-rich stage simply because it requires a lot of human dependence, plus the potentially complex coordination of multiple steps (Lippi et al., 2011). Some of the most common pre-analytical errors include specimens being misidentified, specimens being collected incorrectly, and hemolysis. An example of specimen misidentification, such as a patient being mislabeled or bar code not matching patient, can result in an incorrect sample being tested, which can result in a misdiagnosis or incorrect therapy being provided (Hammerling, 2012). drug therapy initiated with the false positives from an unidentified sample, could potentially create nasty side effects such as erroneous doses of their chemotherapy for oncology patients. (Carraro & Plebani, 2007) The second common form of pre-analytical fallibility is a process called hemolysis wherein the red blood cells fracture during phlebotomy or transport to the particular laboratory site. Hemolysis results in the contents of the red blood cell leaking into the plasma or serum, confounding test results. Hemolysis can spuriously elevated potassium and lead to a false positive diagnosis of hyperkalemia and further undesirable medicative effects, including treating patients with insulin therapy (Lippi et al., 2011). There are numerous other opportunities for inept phlebotomy practice aside from hemolysis that influence the quality of the sample, such as incorrect use of anticoagulation agents and blood tubes' ineffective mixing. Therefore, there are possible influences on the integrity of the sample, including the analytes, such as the coagulation factors (Simundic & Lippi, 2012). Additionally, if the transport of the sample has delay and/or the temperature was incorrect, then the sample could be damaged, more prevalent for time-sensitive analyses such as blood gas analyses (Carraro & Plebani, 2007). These pre-analytical fallibilities are far more common in vulnerable populations, such as patients from resource-poor settings who have had little or no exposure to standardized training on phlebotomy (Nkengasong et al., 2010).

Analytical Mistakes

The analytical phase is the period where laboratory and laboratory-like samples are analysed by laboratory machines and instruments, reagents, and analytical methods. Automation and robust equipment mean that there is typically fewer problems with analytical errors versus pre-analytical errors. However, there can still be analytical errors associated with instrument failure or a breakdown in the instrument's more careful analytical process in calibration. Also, unguided, incompetent personnel in the procurement and use of reagents could delusive the validity of the sample analysis (Westgard & Westgard, 2014).

Reagents, such as via contamination or due to expiration, can impact the accuracy of tests such as immunoassays, whereby poor-quality reagents might produce false negatives (Sciacovelli et al., 2018). While less frequent than pre-analytical impairment, analytical impairment has life-changing consequences, primarily for major tests, for example, troponin assays for the diagnosis of myocardial infarction (Plebani & Lippi, 2010). A false negative troponin analytical impairment example can delay life-saving treatment. Automation devices, such as closed-tube sampling, and in-real-time quality control will reduce these impediments through less human manipulation of samples and accurate results (Zaninotto & Plebani, 2010). While analytical impediments can also be a challenge for laboratories that have aging technology or refuse to conform to maintenance procedures like those often present in resource-constrained centers (Sayeed et al., 2020).

Post-Analytical Errors

The post-analytical phase comprises reporting, transmission of results, and testing interpretation for the clinician. This phase can cause errors, such as result misinterpretation, result transcription, or delayed reporting on patient care indirectly (Plebani & Lippi, 2010). Result misinterpretation describes the situation where laboratory results are not accurately placed into context, when the laboratory results are inaccurately correlated clinically or due to improper reference ranges. Taking adequate age- or sex-specific reference ranges may lead to a misdiagnosis, e.g., missing a failure to diagnose anemia from older

subjects (Sciacovelli et al., 2018). Transcription failures, while reduced through computerized laboratory information systems (LIS), are manifest as notable results are entered manually or which may have been mistakenly taken action from wrong (Baron et al., 2010).

Delayed reporting - common as a result of inefficiencies in workflow, sometimes complicated by communication issues, is something which may hinder timely clinical action - particularly in critical care where timely results are very significant as for sepsis markers, for example (Plebani, 2012). Post-analytical errors are also a type of miscommunication of results, in the sense results are not communicated effectively to clinicians or even to patients, leading to lost follow-up or delayed therapy for example (Epner et al., 2013). These are most difficult to control in resource-limited settings with manual reporting procedures, and where there is little or no digital capacity, creating second delays (Fonjungo et al., 2017).

Consequences and Further Reflections

The cumulative effect laboratory errors are substantial, resulting in diagnostic error, poor treatment and extra health costs. Pre-analytical errors are of the greatest risk, and due to their high frequency, are estimated to account for as much as 70% of total errors (Hammerling, 2015). Analytic and post-analytical errors, although lower frequencies occur at higher impact, with greater focus on the serious diagnoses with higher complexity (Plebani, 2006). Human error, e.g. fatigue, lack of skill, or lack of standardization, is involved at all levels, highlighting the importance of an adequate QA system (Reason, 2000). Vulnerable and marginalized sectors of society, e.g., poorer populations or those from rural communities, are at greater risk of errors with system related problems, e.g., spatially separate laboratories, and inadequate infrastructure, which increase the error burden (Nkengasong et al. 2010).

Quality Assurance Systems

Quality assurance (QA) systems are essential for laboratory organizations to establish consistent practices, reduce errors and misuse, and produce reliable laboratory medicine diagnoses. These systematic methods provide a foundation for procedures for the way quality management systems will be applied, monitoring the performance of laboratory service and improvements that continue to enhance patient safety and clinical outcomes (Plebani, 2010). QA systems create a platform for improvement and reduction of errors, and to create consistency, accuracy and compliance when addressing errors in the pre-analytical, analytical, and post-analytical phases (Sciacovelli et al., 2010). Some of these reputable frameworks, ISO 15189, Six Sigma, Total Quality Management (TQM), and Clinical and Laboratory Standards Institute (CLSI) guidance, provide detailed processes for the minimization of errors. External Quality Assessment (EQA) programs facilitate laboratories in attaining further credibility by comparing processes and outputs to peer institutions. Although there is a proven success record of these frameworks, actual usage is heterogenous, and facilities with limited resources are impeded by profound challenges around cost, infrastructure, and availability of expert workforce (Nkengasong et al., 2010). Below, we discuss these frameworks, including types of uses, advantages, limitations, only being concerned with diagnostic reliability enhancement.

ISO 15189, for medical laboratories, is a QA basis, which necessitates quality and competence requirements of laboratory practice (ISO, 2012). ISO 15189 emphasizes establishing a quality management system (QMS) via document control, confirmation of staff competence, instrument calibrations, and internal audit. ISO 15189 necessitates laboratory application of risk management measures for probable errors, for example, due to improper sample handling or incorrect calibration (Plebani & Lippi, 2010). For example, ISO 15189-accredited laboratories are expected to perform proficiency testing regularly and provide traceability of measurement to international standards, providing consistency of results such as blood glucose or lipid profile results (Sciacovelli et al., 2018). Literature suggests that ISO 15189 accreditation reduces the rate of errors by up to 40% in accredited laboratories via establishing a culture of continuous improvement (Jansen et al., 2013). Accreditation is, however, an expensive process, which necessitates a great deal of investment in training, infrastructure, and forming a limitations for laboratories in least developed countries (Fonjungo et al., 2017).

Six Sigma, data-driven, targets near-zero error rates through minimisation of variability with statistical process control (Gras & Philippe, 2007). It is from manufacturing but was transformed for laboratory medicine intention to optimise processes, defects, or errors involved, which are common with patient care. It uses DMAIC (Define, Measure, Analyse, Improve, Control) for identification of sources of errors, performance monitoring, and implementation of corrective procedures. Six Sigma was implemented for turnaround time minimisation of urgent tests, e.g., troponin, for enhanced outcomes for emergency patients (Westgard, 2003). Gras and Philippe (2007) supported that through Six Sigma, analytical errors were minimised by 50% for high-throughput assay-based laboratories. Nevertheless, effective application demands highly developed statistical know-how and, robust data infrastructure, which can be costly for resource-limited settings (Sayeed et al., 2020).

Total Quality Management (TQM) integrates all processes to manage quality comprehensively, with respect to leadership, staff involvement, and patient care (Westgard, 2003). Because TQM promotes an all-encompassing approach, it forces laboratories to integrate pre-analytical, analytical, and post-analytical processes with quality improvement measures. For example, TQM philosophy was applied to standardize phlebotomy procedures and eliminate pre-analytical errors, such as hemolyzed samples, through the use of standard operating procedures and staff training (Lippi et al., 2011). Additionally, TQM establishes a culture of accountability, which is staff engaged with the motivation to report a mistake and propose corrective action that improves the laboratory's performance (Plebani, 2012). TQM is successful, but the lack of commitment is not without continuous organizational will. Applying TQM in laboratories is difficult as a result of high staff turnover and limited resources (Agyeman et al., 2023).

Clinical and Laboratory Standards Institute (CLSI) provides comprehensive standards, including quality control, proficiency testing, and method verification, for laboratory disciplines, such as clinical chemistry and microbiology (CLSI, 2016). CLSI guidelines, such as QMS01-A4, provide methods when developing the procedure for internal quality control (IQC), which includes reaffirming the performance of reagents and equipment. CLSI procedures for glucose testing prescribe frequent reaffirming of reagents to detect analytical faults that could misdiagnose diabetes (Boyd, 2015). Proficiency testing is a hallmark of CLSI and generally means the periodic testing of laboratory performance assessing the ability to produce consistent results for standardized samples that can warn of early systemic errors (Sciacovelli et al., 2010). The CLSI guidelines are often seen as progressive standards in the developed world, but face many barriers to implementation. These barriers include how to get staff trained to carry out the mandated expert skills required to diagnose use of new funds and the infrastructure to support widespread use (Nkengasong et al., 2010).

External Quality Assessment (EQA) Programs like that outlined by the College of American Pathologists (CAP) or the World Health Organization (WHO) can give laboratories the opportunity to align numbers to peer sites and identify differences which help to increase reliability (Sciacovelli et al., 2010). EQA is the assessment of testing systems where standardized samples are analyzed and accuracy is reported, which you need as part of a testing program, such as hemoglobin A1c or infectious disease coverage (WHO, 2011). In a study, the authors Epner et al. (2013) associated participation in EQA with a 25% decrease in diagnostic error of participating laboratories. However, EQA is limited by defined funding and by defined infrastructure, therefore limiting implementation and usage in low-resource settings where the laboratory may not be able to participate (Fonjungo et al., 2017). In summary, the guidelines as a whole improve reliability in diagnostic capability but are not often used due to laboratory leaders supporting the guidelines, expertise and training of staff and the availability of resources.

Technological Advancement of QA

Technological advances have revolutionized QA in laboratory medicine and made significant improvements in error reduction and diagnostic accuracy at all stages of testing. The important technologies that have been transforming laboratory practice include automation,

barcoding, artificial intelligence, and laboratory information systems (Zaninotto and Plebani, 2010). As these technologies do not contain human errors, are efficient, and can provide continuous real-time monitoring of quality, they are not being used to their fullest potential, especially considering the costs involved and issues with infrastructures (Sayeed et al., 2020).

As a result of automation, analytical error has been remarkably reduced by reducing or even eliminating manual handling during sample analysis and processing. Automated laboratory analyzers, devoted to clinical diagnostic testing like clinical chemistry and hematology, provide high-throughput testing with accuracy, reducing errors an average of 50% or more by minimizing pipetting errors in a fully automated laboratory (Zaninotto and Plebani, 2010). Examples of this phenomenon are automated blood gas analysis machines, which provide reproducible handling of samples so that samples will not be contaminated with air (Hawker, 2017). Besides reducing errors by providing automation, automation can also provide workflow and timeliness. In preserving workflow, turnaround time for urgent or "stat" tests like cardiac biomarkers will be minimized, which is the highest priority for a laboratory in an emergency situation (Plebani and Lippi, 2010). The downside of automated systems is that they require considerable capital investment and, they require daily maintenance, which can be an obstacle for a low-resource laboratory (Sayeed et al., 2020).

Barcode systems have improved pre-analytical QA by limiting errors due to sample misidentification, which is one of the main causes of diagnostic errors. Barcodes ensure proper tracking from practice and sample collection through to analysis so that errors, such as improper patient identifications, can be avoided (Hawker, 2017). Hawker (2017) reports that 70% of pre-analytical errors were reduced in laboratories using barcodes in sample identification. Barcodes are also integrated into LIS software and thus computerized reporting of data negates transcription errors that result from reports dictated by human transcription. Barcoding does require information technology resources, which are not commonplace in resource-limited settings (Fonjungo et al., 2017).

Artificial Intelligence (AI) and Machine Learning are emerging QA tools for improving results interpretation and predictive maintenance. AI algorithms are used to identify outlying test results, as in glucose or thyroid function tests, before being reported (Topol, 2019). Through performance data analysis, machine learning algorithms may be able to identify instrument failure preventing analytical errors (Rajkomar et al., 2019). Artificial-intelligence-based quality-control systems, for example, can detect microbial contamination from cultures by recognizing patterns that indicate contamination (Ceriotti, 2017). Ironically, the promise of deploying AI is limited by costs, privacy, and the need for knowledge (mainly in low-resourced settings) (Sayeed et al., 2020).

Point-of-Care Test (POCT) devices such as portable glucometers and rapid tests expand diagnostic access mainly in remove or emergency contexts; however, they need systems for Quality Assurance (QA) to work reliably. Variability overall in operator technique such as temperatures, can produce errors for POCT's results, such as a false hemoglobin reading (Price & Christenson, 2019). Rigor QA procedures, such as established systemic calibration and operator training, are required for the expected accuracy of POCTs. A clinical intervention with a learning intervention, institutionalizing a QA of POCT service, resulted in a decreased combined service error rate of 20% for emergency service (Price & Christenson, 2019). Performing procedures such as QA is difficult in resource-limited settings as training is limited and devices are few (Nkengasong et al., 2010).

Laboratory Information Systems (LIS) is integrated information system of pre-analytical, analytical, and post-analytical processes, and is a strategy to bypass missteps such as delays in reporting or transcription errors. At the post-analytical level, LIS can help eliminate errors by computerized flags for abnormal results, reporting of test results as they occur in real time, and messaging to the clinician to report interesting results (Baron et al., 2010). For instance, in hospitals that implement superior LIS, the integrated processing of critical results, that is, delays in reporting blood culture results, has decreased by approximately 30% (Allen, 2013). LIS implementation, however, does carry a sizable investment in IT infrastructure

and training personnel, hence deterring the roll-out of LIS settings that are not resource-rich (Sayeed et al., 2020).

Training and Education in QA

Proper training and education are the foundation of QA because errors emanating from a lab including one arising from a person, are typically due to lack of knowledge or deviations from procedure (Reason, 2000). There is a necessity for extended coursework in phlebotomy, quality control, and error reporting to minimize errors and the competency of staff (Lippi et al., 2017). CPD and interprofessional education are two distinctive aspects of QA that will keep laboratory staff together with the standards and to enable working as a team with clinicians (Plebani, 2010).

Quality Control training and Phlebotomy training involves the standardization of collection and handing of samples for the purpose of minimizing pre-analytical errors. Education of venipuncture techniques, tube usage, and shipping has reduced errors such as hemolysis by 30% (Lippi et al., 2017). Standardization of Phlebotomy has reduced erroneous elevation of potassium during clinical chemistry testing increasing diagnostic accuracy (Simundic & Lippi, 2012). Education of reporting errors improves reporting of errors throughout the laboratory staff, analysis and identification of causes and initiation of root cause analysis (RCA) to prevent reoccurrence (Carraro & Plebani, 2007).

Simulation-Based Training enhances competence for complex instrument and test interpretation. Simulation can also be pilot tested for laboratory staff to simulate troubleshooting of analytical problems; for example, instrument calibration, or recognizing reagent breakdown, all completely without risk (Sampson et al., 2014). This is best described when Sampson et al. (2014) discussed a study where the use of simulation training meant the team had improved staff confidence, specifically with fewer errors in a hematology laboratory by 25%. This situation is also true for equipment that comes on high throughput analyzers, and also equipment used in POCT, where equipment error can severely affect patient outcome (Price & Christenson, 2019).

Continuing Professional Development (CPD) enhances laboratory staff knowledge of QA standards, technology, and regulations. CPD has been approved by CLSI and CAP continuingly for recognizing competence in Quality Control topics, e.g., method validation (CLSI, 2016). CPD programs, i.e., workshops and webinars, are efficient at increasing knowledge retention and compliance with QA protocols, where compliance reduced error by 15% across CPD-compliant laboratories (Sciacovelli et al., 2010). Unfortunately, CPD is mostly unfeasible in resource-limited settings due to funding, environment, and capacity for competent instructors (Agyeman et al., 2023).

Interprofessional Education increases clinico-laboratory collaboration with a decrease in post-analytical errors such as misinterpretation of results. Case-based rounds, group activities, part of training programs, improved clinician communication and clinical correlation of results (Plebani, 2010). Interprofessional training of interpreting liver function tests improved diagnostic errors for primary care practice (Epner et al., 2013). These programs can never be a replacement to assure that laboratory results have optimal impact for patient care, particularly with challenging cases in diagnosis like cancers or communicable disease (Braga & Panteghini, 2014).

They provide a cost-effective and scalable approach to QA training, ideally suited with resource limitations across all systems. QA standards related to error prevention, instrument maintenance segments presented by the internet and distance delivered training increased knowledge transfer by 20% for laboratory personnel (Slobodin et al., 2021). E-learning is the preferred platform to share CLSI recommendations, ISO 15189 standards, yet some challenging limitations, including restricted in-use internet capacity, and low digital literacy levels, preclude potentially widespread access for laboratories (Sayeed et al., 2020).

Barriers to Good Practice Implementation in QA

Laboratory medicine quality assurance experiences challenges, which are indicated in Table 2

Table 2: Challenges to Good Practice Implementation in QA

Barrier	Description	Impact	References
Resource Constraints	Limited funding, equipment, and staff	Hinders adoption of QA technologies	Nkengasong et al., 2010; Agyeman et al., 2023
Training Gaps	Insufficient QA education in curricula	Increases error rates, reduces competency	Plebani, 2010; Sayeed et al., 2020
Lack of Standardization	Variability in protocols across laboratories	Inconsistent quality, comparability issues	Sciacovelli et al., 2010
Resistance to Change	Staff reluctance to adopt new QA practices	Slows the implementation of effective systems	Gras & Philippe, 2007
Systemic Inequities	Limited laboratory access in underserved areas	Exacerbates health disparities	Fonjungo et al., 2017

Insufficiency of resources, mainly for the developing nations, constrains the EQA program or automated instrument utilization (Nkengasong et al., 2010). Insufficiency of training leads to inconsistency of utilization of QA protocols, resulting in enhanced risks of errors (Plebani, 2010). Lack of, especially in resource-poor and developing countries, availability of resources limits EQA program or automated instrument use (Nkengasong et al., 2010). Lack of adequate training diminishes the reliability of QA protocol use, which in turn increases the risk of error (Plebani, 2010). Lack of laboratory standardization impairs reliability and comparability (Sciacovelli et al., 2010). Staff resistance towards organizational changes, from demands of workloads, is behind QA implementation (Gras & Philippe, 2007). Systemic inequities, such as a commensurate lack of laboratories serving poor or rural communities and related to QMS use, compound the disparity of diagnostic equity (Fonjungo et al., 2017).

Methods to Enhance QA

Labs can take several actions to enhance the QA of the lab. In terms of processes, reporting, sample handling, and sample collection should be standardized to minimize variability and error (Lippi et al., 2011). Performance monitoring by EQA programs, along with ongoing proficiency testing, is the most powerful approach (Sciacovelli et al., 2010). Root cause analysis (RCA) can systematically identify the direct cause of error that can be addressed by targeted action (Carraro & Plebani, 2007). Interprofessional practice and collaborative work between clinicians and laboratories should enhance interpretation of results in clinical decision-making (Epner et al., 2013).

Automation and barcoding are a top priority to reduce human error (Hawker, 2017). Feedback loops through regular audits can help cultivate a culture of continuous improvement (Westgard & Westgard, 2014). Quality assurance resources are available through partnerships with external organizations (e.g., World Health Organization [WHO]), which provide QA materials, representing value for laboratories with limited resources (WHO, 2011). Patient-centered practices (e.g., patient engagement on reporting errors) enhance accountability (Bates & Singh, 2018).

Future Directions

There is a need for planned future programs of harmonization of QA standards internationally for inter-laboratory comparability (ISO, 2012). Increasing regular use of additional AI and machine learning for diagnosis can further minimize errors, while more efficient predictive maintenance can be realized (Topol, 2019). E-learning can be increased, e.g., simulations for training, to offset learning deficit, even for resource-constrained situations (Slobodin et al., 2021). Long-term outcome effects of QA interventions need to be taken up through studies on cost-effectiveness, alongside scaling up (Plebani & Lippi, 2010).

Inequities in health need to be tackled through specially designed QA programs for the underserved, in such a way that all are equally benefited from access to effective diagnostic testing (FonjLookAndFeel et al., 2017). International health agencies can be assisted in designing low-cost, scalable QA solutions (WHO, 2011). Laboratories also need to implement sustainable practices, like energy-efficient equipment, to meet overall healthcare goals (Sayeed et al., 2020).

Conclusion

Laboratory quality assurance (QA) is paramount to diagnostic certainty and patient safety, given the high-risk nature of detecting errors at the pre-analytical, analytical, and post-analytical levels. QA processes, using models like ISO 15189 and Six Sigma, using technology, are effective ways to minimize errors through education, automation, and standard processes. Obstacles exist that the use of inadequate resources, or a knowledge gap, can obstruct the effective use of these frameworks. The evidence and experience-based approaches, use of technology, and elimination of inequity will ensure laboratories maximally reliability for patient diagnosis and improved patient outcomes. This review highlights the importance of systematic QA systems being qualified for the demands of contemporary healthcare, with lab medicine forming the backbone of best practice.

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