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REVIEW

Navigating Quality Assessment Hurdles in Clinical Laboratory Services: A Comprehensive Review in Resource-Limited Settings

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Abstract: External quality assessment is the process of evaluating the performance of a laboratory and the competence of professionals. Participation in EQA and standardizing the quality of laboratory services are a mandatory requirements for accreditation. This review is aimed at identifying and discussing challenges that hinder the effective implementation of an EQA program in countries with resource limited setting. To obtain abundant information, articles were identified by searching the literature published in English using the National Library of Medicine, PubMed, Science Direct and AMC digital library databases. The articles identified in the references were manually searched and included. After the article was identified, it was imported to Endnote version 8.1 and exported to Microsoft Word for citation. Based on this review, the major identified challenges that hinder the implementation of an EQA program include the high cost of control materials, malfunction and lack of maintenance for equipment failure and breakdown, a knowledge gap among laboratory professionals, noncommutability of control samples, and difficulty in assigning target values. In addition, failing to participate in EQA and failing to take corrective action are the major challenges identified. As a result, applying to an EQA program in resource-limited counties was highly challenging. To attain high performance in the laboratory and to provide quality laboratory service for patient care, the EQA supplier and the user laboratory must pay attention to these issues and take appropriate corrective actions for ongoing quality improvement and accreditation.

Keywords: external quality assessment, proficiency testing, challenge, resource-limited countries

Introduction

Assessing and standardizing the quality of laboratory services and making corrections enables efficient delivery of healthcare services.[1–3] Internal quality control and External Quality Assessment (EQA) are complementary components of the quality assurance process and are crucial for quality management, process improvement, and the provision of high-quality health care.[4,5] Participation and improvement in analytical quality through EQA guarantee good laboratory performance.[6]

The EQA is a system of periodic evaluations of overall laboratory performance against the expected standard requirements of a specific discipline.[7,8] It evaluates trueness, intra- and interlaboratory variations, and linearity; distinguishes between methods; and tracks ongoing harmonization efforts.[5,9–11] It is a process in which commutable samples are sent regularly to members of a group of laboratories for analysis, and the results are compared with the anticipated target value or between laboratories in the group and/or with a given value and reported to the participating laboratories.[12] Most commonly, this can be implemented through proficiency testing (PT) because the majority of laboratory tests are conducted and most laboratory professionals are familiar with the procedure.[13] The EQA programme addresses the preanalytical, analytical, and postanalytical processes of the laboratory.[14]

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External quality assessment is a crucial part of a laboratory's overall quality management system (QMS) and is mandated by the Clinical and Laboratory Standards Institute and the International Organization for Standardization (ISO) 15189 accreditation.[15–17] The external quality assessment aims to address their inadequacies through interlaboratory comparisons and ensures the validity of test results.[18] The application of an EQA ensures the quality and standardization of laboratory test results and is vital for developing best practices for EQA providers.[11] All diagnostic laboratory services can participate in the EQA program to guarantee the accuracy and dependability of the diagnostic operations carried out by a laboratory.[19,20]

An effective EQA programme is the result of all the activities and procedures performed in medical laboratories to improve the consistency and relevance of test results.[1] To guarantee quality, EQA addresses the analytical procedures, the acquisition and maintenance of equipment and reagents, employee training, and result reporting and interpretation.[21,22] An international standard has been published that specifies management requirements and mandates that EQA providers set up and run such programs.[23]

Nevertheless, public health laboratories in resource-limited countries have recently begun to use national and worldwide QMSs to deliver quality laboratory services, including involvement in EQA programs. However, participation alone does not ensure analytical quality; rather, laboratory management and personnel must make concerted efforts to increase quality by addressing any gaps through EQA feedback.[24] However, in developing nations, there is a limited understanding of the significance of adopting laboratory testing quality for patient care. As a result, governments must understand the significance of laboratory tests and dedicate sufficient resources to ensuring quality.[6] To achieve this goal, a national quality testing programme needs to be established, local programme management competence needs to grow, and whenever possible, local proficiency test item preparation needs to be encouraged.[25] This review is aimed at illustrating EQA challenges and providing combined information for policymakers to establish local PT programmes and for researchers to conduct further root cause analysis studies.

Methods

This review aims to identify and discuss the challenges affecting the application of EQA by narrating different literature and providing comprehensive information for readers, researchers, and policymakers. To achieve this objective, we used basic searching methods to identify the literature published in English using key searching terms such as challenges, external quality assessment, proficiency testing, and resource-limited countries at the National Library of Medicine, PubMed, Science Direct, and AMC digital library databases. The articles identified in the references were manually searched and included. After the article was identified, it was imported to Endnote version 8.1 and exported to Microsoft Word for citation.

Challenges to External Quality Assessment

The laboratory services in resource-limited countries suffer from insufficiencies in consumables, basic equipment, skilled employees, training programs, logistical assistance, and national standard quality evaluation.[26] Most public health laboratories in resource-limited countries provide services but are less likely to support an effective healthcare system. This is because of outdated infrastructure, poor development and application of quality management systems, and insufficient involvement in EQA programs.[27] Participation in the EQA program in resource-limited countries faced different challenges, including sample commutability and assigned target values; transportation and shipment; expenses from the EQA program; equipment and reagent supplies; awareness and motivation of laboratory professionals; and utilization of feedback, which has a direct impact on the implementation of the EQA.

Infrastructure and Technology

Major challenges facing laboratory services in underdeveloped settings include weak infrastructure, human capacity shortages, a lack of laboratory policies, strategic plans and integrated national quality management systems. The infrastructure of national laboratories in resource-constrained countries declines precipitously at each subsequent laboratory tier level, and national governments' oversight of laboratories is dispersed. With time, there will be fewer updates to the physical infrastructure of laboratories, including upkeep of already existing facilities and the creation of desperately required facilities.

Laboratory Equipment and Consumables

Technological advancements in performance measurements are required to reduce errors in data processing, analysis, and presentation.[28] Nevertheless, even if technology has the ability to assist EQA programs, their execution is frequently difficult and can provide fewer than ideal outcomes.[29] The adoption of these technologies is influenced by political and economic factors, organizational characteristics and leadership.[30]

The utilization of laboratory reagents and equipment is the basis for providing clinical laboratory services. However, the main issues that resulted in a laboratory service interruption and further impacted the implementation of an EQA program were malfunction, lack of maintenance, and a shortage of consumables.[31,32] Depending on the organization, between 50 and 96% of the medical equipment in low-income nations is broken and not in use.[32] The challenges that affect the implementation of EQA include laboratory equipment failure and downtime due to stockouts of reagents, improper handling and use of medical equipment, frequent power failures, aging equipment, inadequate operator training, lack of preventive maintenance, shortage of spare parts, insufficient maintenance capacity, and little knowledge of sophisticated equipment as contributing factors to equipment breakdowns.[33–35]

EQA Sample Management

Patients may be misdiagnosed incorrectly due to bias in the results reported from various laboratories using the same measurement tool. When commutable samples are used to identify these discrepancies, this risk can be decreased by adopting EQA programs. Variations may result from assay imprecision, variations in analytical specificity, individual laboratory procedures, or the traceability of the calibrators.[36–38] However, the preparation of ideal EQA material is limited due to the large number of samples required for a large number of participating laboratories. Moreover, the quality of stained smear images deteriorates, which results in difficulty in assessing staining capability.[39,40]

Another challenge for the provision of EQA for laboratory testing is the choice of assay material for automated cell counting. Because of the inherent contradiction between material commutability and stability, as well as the lack of verified reference materials and techniques available for tracing results, there is no optimal assay material for automated cell counting.[41,42] Furthermore, as EQA products are not approved control materials, the participating laboratories are not permitted to use them as controls for diagnostic tests. The European Union's Vitro Diagnostic Device Directive expressly exempts the EQA sample distribution, which is not included in the diagnostic laboratory as a clinical test control.[43]

Using verified commutable samples and assigning a target value determined from a reference measurement method or by comparison with an approved reference material are the two main components of an efficient EQA program.[39] When the results from many methods are comparable to those from patient samples containing the same number of analytes, the EQA sample is considered commutable.[37,44,45] Nevertheless, cost-effectively attaining commutability poses a challenge for EQA providers when developing fit-for-purpose EQA materials.[12] The need for large sample volumes, a wide range of concentrations of the measurand, and sample stability has led providers to use materials treated with stabilizers and supplemented with materials of human or nonhuman origins, leading to EQA samples that are not commutable with authentic clinical samples.[37,46] It is impossible to assess method accuracy in the absence of commutable samples. Using the same procedure and assuming matrix-related bias, peer groups or participant groups are used to evaluate and classify laboratories because it is not feasible to compare them to the same given value.[44,47,48]

Assigning a target value for noncommutable EQA samples is a challenge. A reference measurement method is less helpful when sample commutability is unknown because it is impossible to distinguish between a calibration bias and a matrix-related bias of uncertain size when deviation from the target value occurs.[49] Under these circumstances, the target value is the peer group mean or median after the outlier is excluded; however, the size of the peer group affects this value; larger peer groups will have a greater influence on the target value; the value may vary based on the proportion of participants using different measurement procedures; and the target value is probably inappropriate.[39,50]

Logistics and Supply Chain of EQA Samples

To maintain the integrity of the EQA samples throughout transportation, ISO/IEC 17043 mandates that EQA suppliers set up and oversee these circumstances.[51] It must be packaged in compliance with international and national hazardous

material rules. These packing techniques should be used, and indicator strips in packages containing EQA samples should be used to regularly check transportation temperatures.[51,52] However, there has not been a regular definition or monitoring of transportation temperatures for EQA samples. The unseasonably warm temperatures were the cause of the temperature failure. Moreover, determining the appropriate packaging temperature to accommodate predefined transportation temperatures for all the EQA samples was time-consuming.[51–53] In addition, the delivery of EQA samples may sometimes be delayed. Furthermore, frequent changes in address by the participants and/or contact persons not informed regularly to the PT provider hinder smooth delivery of EQA samples as well as important communication regarding the EQA scheme.[40]

Financial Constraints

Another hurdle for the participation and implementation of an EQA program is the allocation of sufficient budgets and resources. Clinical laboratories in resource-limited settings are expected to cost $512,751, or 32% of the overall cost of quality. Approximately 94% of the overall quality cost was incurred in developing and adhering to procedures that guarantee good laboratory practices and support high-quality results.[54] The costs and registration fees for an EQA scheme should not be underestimated.[15,55] Exorbitant registration costs have the potential to induce withdrawal from EQA participation, which could undermine accreditation by exposing errors that go undetected or delay the detection of testing issues. To guarantee that adequate effort can be placed into the selection and validation of samples as well as the evaluation of EQA outcomes, EQA providers must have a sizeable budget. Establishing an organization to promote patient safety-oriented educational EQA programs is advised.[56,57]

The main expenses for managing an EQA program were pay and benefits (52%), costs associated with the EQA survey materials (15%), shipping costs (10%), and travel costs (4%). The capacity to predict shipping costs and the practicalities of shipping, including customs and broker fees, were major obstacles to EQA participation in resource-limited nations, such as Ethiopia. Depending on the location in question and the material hazard classification, shipping prices can vary by a factor of more than ten.[58] Based on the quantity of survey materials, the cost of a typical laboratory that offers regular shipping along with basic chemical, hematological, and serological tests may vary from $3000 to $5000 each year.[49]

Staff Awareness and Motivation

An effective EQA necessitates appropriate staff involvement and reported evaluation. It is expected that EQA providers will communicate with and be aware of the departmental head to notify the laboratory in the event of performance problems. General laboratory personnel should be aware of the performance of the laboratory and any emerging difficulties. It is imperative to establish channels of communication for EQA performance and difficulties within laboratories.[11] However, the major challenge for the implementation of an EQA program is that most employees lack knowledge and expertise, and they do not fully understand the objective of PT, which leads to a failure to identify gaps based on EQA feedback.[15,27]

The challenges affecting the implementation of EQA include institutional factors, such as a lack of adequate facilities, a scarcity of qualified workers, and a lack of laboratory policies, strategic plans, and integrated national quality management systems.[59,60] Although the aforementioned issues are obstacles to the efficient use of PT, no regulatory bodies or national central laboratories are responsive to these problems, possibly because regulatory bodies are not under scrutiny of the low performance of the laboratory.

Future Opportunities

Additional updates will be made to the EQAP tool. A more robust assurance of superior program management must be provided via scheme accreditation. The significant steps include validating EQA program sample sets, applying statistical evaluation techniques, and drawing inferences about participant or method performance. Laboratory performance is considered valid only when impermeable sample data and statistical methods are present.[61,62]

The EQA schemes can develop into more creative setups and lack an asset framework. Traditional EQA systems evaluates performance at the laboratory level; however, current problems, such as variations in staining performance and interpretation, call

for a change to the evaluation of individual participation.[63] Individual-based EQA programmes strive to improve practices through training and offer the opportunity to identify issues that are specific to individuals.[64] The training of laboratory staff to operate at their best daily may benefit from this kinds of EQA strategy.

The issue of not wishing to employ false samples, which may differ from routine cases, and the lack of material from real samples are also avoided by using digital technology. All pathologists are capable evaluating real samples and interpreting real cases complete with all the complexities and potential hazards, even in the situation of minimal tissue. Furthermore, the most recent developments in machine learning and artificial intelligence in pathology have led to more accurate diagnosis, prognosis, treatment prediction, and detection, minimizing interindividual variability.[65–67]

Web applications will further improve the service of the EQA program; electronic replies and images imitating a microscopic view offer new possibilities for cytology, histopathology, and the bone marrow EQA program. It is also better to use photographs of urine sediments and videos of sperm motility. International collaboration with European EQA organizers offers opportunities to exchange experiences, share common sample materials, and establish international schemes. This approach offers unique opportunities to improve the quality of programs.

Conclusion

We conclude from this analysis that there are several obstacles to overcome when applying or implementing an EQA program in clinical laboratory services. The majority of the difficulties found fall under the category of external difficulties and involve managing and preparing samples, allocating funds and supplies, shipping, and transporting goods. Other issues that were shown to be related to internal issues included employee engagement, equipment validation and maintenance, and integrated national management systems. Overcoming these obstacles through Establishing national EQA program and providing training about quality management system for laboratory professionals is vital for better quality of laboratory results and continuous improvement.

Abbreviations

EQA, External Quality Assessment; ISO, International Organization for Standardization; PT, Proficiency Testing; QMS, Quality Management System.

Data Sharing Statement

The data used to support the findings of this review are available from different articles obtained by searching the literature published in English using the National Library of Medicine, PubMed, Google Scholar, and Google Scholar databases.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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