DIAGNOSTICS IN THE LABORATORY AND BLOOD COLLECTION QUALITY

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Abstract:

Background: Accurate laboratory results are critical for patient safety and enhancing medical diagnosis. The use of strict aseptic techniques by healthcare workers when obtaining blood specimens is an important factor in reducing errors.

Methods: Internal quality control procedures, objective analytical quality criteria, and the availability of Proficiency Testing (PT)/External Quality Assessment (EQA) programs have enabled clinical laboratories to assess, monitor, and improve analytic performance

Results: The interface between the laboratory and the clinical user to provide education and technology solutionsto correct any laboratory error.

Conclusions: To ensure that patients and other users have faith in the services delivered, the laboratory must take responsibility for "end-to-end" quality control, including remedial action to address the core source of error in thetotal tests process (TTP).

Keywords: Blood samples, blood collection, laboratory quality, laboratory diagnostics, pre-analytical errors, post analytical errors.

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1. INTRODUCTION

Diagnostic blood samples are the most common form of biological specimens obtained and submitted to laboratory medicine facilities for analysis, assisting caring physicians in patient diagnosis, follow-up, and/or treatment monitoring. Phlebotomy, a relatively intrusive medical technique, is undoubtedly necessary for the subsequent operations performed, whether in the laboratory for analysis or by physicians for interpretation. Poor phlebotomy quality can jeopardise patient diagnosis, management, treatment, and, ultimately, patient safety. [1]

Accurate laboratory results are critical for patient safety and enhancing medical diagnosis, and several studies have demonstrated that the accuracy of laboratory testing influences 70% of medical diagnostic judgements. Despite increasing automation in diagnostic labs, clinical diagnostic labs still have significant error rates.[2]

The whole testing procedure in clinical diagnostic laboratories covers all steps from the test request to the receiving of results. The lab testing procedure is often divided into three stages.[3] The first step is the pre-analytical phase, which, according to the International Organization for Standardization (ISO) 15189:2012 standard for laboratory accreditation, includes all steps from test request, sample collection, transport, and sample registration to the start of specimen analysis.

The second phase is the analytical phase, which includes analyte analysis and technical validation of the data. The third stage is the post-analytical process, which includes interpreting the data, obtaining approval from the lab manager, and reporting to the doctor. [4]

2. LITERATURE REVIEW

The implementation of several 'quality' methods ensures the quality of laboratory testing. Internal quality control (IQC) and external quality assessment (EQA) are critical to the quality of laboratory testing.[5]

Many human illnesses require laboratory medicine to be diagnosed and managed. Previous research revealed a greater rate of hemolytic samples. However, the frequency of hemolytic samples may be overestimated or underestimated because there are numerous other causes of high-rate in-vitro hemolysis, such as using serum rather than plasma, filling vaccutainers with a syringe rather than a vacuum system, and personal errors caused by staff collecting blood.[6]

Table 1. Types and description of most common pre-analytical errors

Pre-analytical errors	Description
Hemolyzed sample	Presence of pink to red tinge in serum plasma
Insufficient sample	Serum obtained not enough for requested tests
Incorrect sample tube	Most samples received should not be in anticoagulated tubes
Sample not on ice	Samples for arterial blood gases analysis not transported on ice
Incorrect sample identification	Mismatch between name on sample and request form
Tube broken in centrifuge	The use of different tube sizes for sample collection
Delay in sample transportation	Samples were not sent to the laboratory on time
Expired reagents	Some reagents expired before use
Sample mix-ups	Samples intended for other laboratories were sent to the biochemistry laboratory

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There is undeniable evidence that the preanalytical phase is the leading cause of errors in laboratory testing, whether utilized for diagnostic or research reasons. Virology is no exception, as many potential preanalytical errors are comparable to those seen in other diagnostic domains, while others are more particular. Among the former, the safety and quality of RT-PCR testing may be jeopardized due to patient and/or sample misidentification, collection of inappropriate or insufficient material (for quality or volume), inaccurate sample transportation and storage conditions (e.g., injury exposure, unreliable cold chain, prolonged transportation time), and the presence of interfering substances. [7] as well as a variety of operational difficulties

that arise during sample preparation, such as pipetting errors during manual sample preparation or aliquoting, cross-contamination, and sample mismatch, to name a few. The most common issues that can jeopardize the quality of RT-PCR assays are sample contamination (even small amounts of foreign DNA can jeopardize test findings) and testing in patients undergoing antiretroviral therapy, which can result in false-negative results [8].

Aside from microorganism-related difficulties, as with other fields of diagnostic testing, the accuracy of RT-PCR can be significantly hampered by a lack of harmonization (of primers and probes), as well as a number of technical and analytical errors, as detailed above. In general, issues include instrument malfunction (including improper PCR cycle settings), the use of insufficient or inadequate material, non-specific annealing of PCR to homologous sequences, misreading of expression profiles, and so on.[9]

False positive blood culture test results are prevalent, and they are caused by contamination induced by the entry of organisms from outside the bloodstream (e.g., skin or environmental pollutants) into the blood sample taken for culture, which cannot be totally eradicated. Overall blood culture contamination rates should not exceed 3%, according to the American Society for Microbiology (ASM) and the Clinical Laboratory Standards Institute (CLSI).[10]

False positive results can result in improper patient diagnosis, follow-up, and unneeded therapy, resulting in significant negative repercussions for patients and financial burdens on the healthcare system. This includes re-collection of blood cultures, re-evaluation of other laboratory tests, inaccurate or delayed diagnosis due to clinical interpretation errors, inappropriate antibiotic treatment, as well as unneeded and prolonged hospital admissions and the expenditures associated with these consequences. [11].

The use of strict aseptic techniques by healthcare workers when obtaining blood culture specimens is an important factor in reducing contamination, and there is enough evidence to evaluate the effectiveness of three blood culture specimen collection methods: venipuncture, phlebotomy teams, and prepackaged prep kits. Clotted specimens are the most common reason for automated counting and coagulation rejection. In a comprehensive study of about 10 million haematology samples collected in China, 57% of the 11,000 rejections were due to specimen clotting.[12]

These mistakes could have a huge impact. If the error is discovered before the result is issued, for example, through delta checking or a change in a genetically determined factor (such as an ABO blood group), it may delay diagnosis or treatment, cause inconvenience and anxiety for the patient, and, in some cases, result in a missed opportunity for diagnosis or screening if the specimen cannot be retaken.[13]

3. METHODS

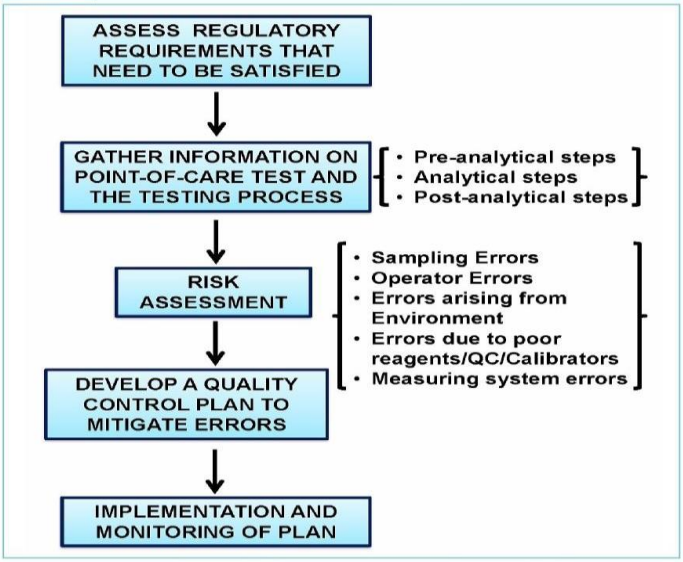
Internal quality control procedures, objective analytical quality criteria, and the availability of Proficiency Testing (PT)/External Quality Assessment (EQA) programmes have enabled clinical laboratories to assess, monitor, and improve analytic performance over time. [14]

3.1 Quality indicators

Quality indicators (QIs) are key instruments for quantifying the quality of laboratory services: they are objective metrics that may evaluate all critical areas of the testing cycle, including pre-analytical procedures and processes. Data should be collected continually over time in order to identify and repair flaws in performance and patient safety by finding and implementing appropriate treatments.[15]

Lippi and Plebani reported six stages in the TTP complete testing process and fourteen potential quality indicators connected to Institute of Medicine (IoM) health care domains. The six stages are as follows: (a) test ordering, (b) patient identification and specimen collection, (c) specimen identification, preparation, and transportation, (d) analysis and reporting, and (f) interpretation and action. Although the descriptions of the TTP phases and the quality indicators are comparable, the absence of consistency in both the number of indicators and the nomenclature used in the TTP has the potential to complicate data collection and error tracking.[16]

Figure (1): Schematic showing the thought process in developing a quality control process



RESULTS

Sample collection using intravenous (IV) catheters is a primary source of possible haemolysis during specimen collection. Haemolysis has been estimated to be 29% in serum samples collected via IV catheters, compared to 1% in straight needle venepuncture.

Patients with severe burns or other illnesses that cause a considerable increase in red cell fragmentation may experience similar consequences.

The information produced by Microspherocytes can be used at the interface between the laboratory and the clinical user to provide education and/or technology solutions to correct the underlying cause.[17]

The use of vein-mapping or visualisation technologies with infrared light eliminates the necessity for a tourniquet while locating a vein.[18]

4. DISCUSSION

Automation and information technology advancements have played a significant role in reducing some pre-analytical mistakes. The automation of repetitive, error-prone, and bio-hazardous pre-analytical operations done in the laboratory, in particular, has effectively reduced mistakes in specimen preparation, centrifugation, and aliquot.[19]

It has been demonstrated that training phlebotomy staff and standardizing phlebotomy practise increase specimen quality.

This study can help to direct and support in developing quality improvement goals, including corrective measures, and developing a systematic quality assessment instrument to monitor errors and evaluate laboratory performance.

5. CONCLUSIONS

To ensure that patients and other users have faith in the services delivered, the laboratory must take responsibility for "end-to-end" quality control, including remedial action to address the core source of error in the TTP.[20]

Laboratory errors have a substantial impact on laboratory findings quality and patient safety. Errors in three phases might have major repercussions and the effective diagnosis and treatment of patients. Managers may be persuaded to implement internal or external quality monitoring systems. Furthermore, this may result in a greater emphasis on audit trails that give documentary evidence prior to making judgments and policies, as well as implementing or enhancing methods or practises. [21]

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