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LABORATORY TESTING ERRORS: PRE-ANALYTICAL, ANALYTICAL, AND POST-ANALYTICAL PHASES

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Abstract

Laboratory testing is essential in patient care. Most medical decisions are based on laboratory test results. However, errors in laboratory testing can occur at different stages and these errors can impact patient care. Happ and coworkers published a study regarding the impact of laboratory testing errors on patient care in the Journal of General Internal Medicine. They indicated that nearly 85% of important clinical decisions on diagnosis or treatment were supported by laboratory tests. Of these decisions, 44% were influenced by laboratory results. In the setting of laboratory medicine being the single highest volume medical activity that influences medical decision making (70% of medical decisions are based on laboratory results), the prevalence of errors and the impact on patient care demonstrated the importance of understanding and managing errors in laboratory medicine. According to Happ's article, a systematic review by Bonini et al revealed that the quality and consistency of laboratory testing has not improved over the past 30 years. This caused the Institute of Medicine to make a quantitative patient safety objective to reduce laboratory testing errors by 50% over the next 5 years. Therefore, understanding laboratory errors and ways to prevent or manage them is extremely important and is the focus of this review. (Sutton et al.2020)

Keywords: Laboratory testing errors, pre-analytical errors, analytical errors, post-analytical errors, patient safety.

1. Introduction

Total quality management has been with us for a considerable number of years now, during which it has continuously illuminated the laboratory in an even more critical and discerning light.

Consequently, both the medical community and laboratory scientists alike have become acutely aware that an escalated level of attention and allocation of resources is now indispensable to proactively prevent and rectify errors that possess the potential to significantly impact patient care. As a direct consequence of this growing awareness, there has been a substantial surge of interest and fervent research within the field of laboratory errors over the past 5-10 years. A myriad of scholarly papers have been meticulously crafted, meticulously addressing a diverse array of error classifications and exemplifying various strategies to prevent their occurrence. However, it is important to note that this particular article possesses an unprecedented distinction as it is the first literary work to holistically examine errors throughout all three distinct phases in a comprehensive and all-encompassing manner, while simultaneously providing a cogent and systematic means to meticulously classify them based on their respective attributes and characteristics. (Zonnenshain & Kenett, 2020)

Laboratory errors are generally categorized into three distinct and crucial phases: pre-analytical, analytical, and post-analytical. These errors, which are commonly observed in medical laboratories, play a significant role in the overall accuracy and reliability of the results obtained. Notably, it has been extensively estimated that the range of medical decisions based on laboratory findings varies widely, spanning from 3% to a staggering 90%. This monumental figure emphasizes the critical nature of laboratory results in influencing patient care outcomes. Nevertheless, for laboratory findings to truly impact and improve patient care, multiple vital aspects must be meticulously addressed. Firstly, the appropriate test must be correctly requested, ensuring that it is specifically tailored to suit the patient's unique needs and circumstances. Additionally, it is imperative to collect the specimen from the correct patient, at the precise moment in their medical journey, guaranteeing the utmost accuracy and relevance of the sample. Furthermore, the analysis and examination process itself must be executed with utmost precision and accuracy to guarantee reliable and trustworthy results. Lastly, once the results are obtained, it is paramount that they are accurately interpreted and acted upon by healthcare professionals, enabling optimal and timely patient management and treatment decisions. (Huang et al.2020)

2. Pre-Analytical Phase Errors

Faults at this stage can lead to compromised sample integrity and are difficult to detect. As pointed out by Lippi and Guidi, in the case of mislabelled samples, it is unlikely that the problem will be noticed, and when it is, the patient will often not return for recollection. Misidentification of a patient often occurs when a sample is taken at the bedside. The request form and the sample must be labelled with at least two identifiers, and the sample should ideally be taken in the presence of the patient so that the patient can also confirm their identity. Samples that are taken in advance with no patient present run a high risk of being mislabelled or placed in the wrong patient's folder. An error in the clerical work relating to a laboratory test may occur when the order of the test does not correspond with the urgency of the result. This area represents a wide scope for error in communication between clinical and laboratory staff. Lippi et al. found that nearly 6.4% of requests are urgency-related errors, and concluded that increased communication and

collaboration between physicians and the laboratory was the best way to improve the quality of the request process. Overall, errors in sample collection and handling represent a large area of vulnerability in the total testing process. Lippi and Guidi highlight that approximately 75% of all medical decisions are based upon a laboratory test result, so it is evident the sample you receive is a representation of the patient themselves, and should be treated as such. Therefore, it is important take notice the degree in which different samples react to pre-analytical variables, including haemolysis and lipaemia of blood samples. These samples may not be visually abnormal but can compromise the laboratory test, and it is important for the clinician to be informed the reason why a test has been changed or is inconclusive. A study conducted by Klee et al. showed that 86% of clinicians did not know which analytes were affected by a haemolysed sample, indicating there was an error in the reporting of results. It is important to build knowledge on the variables and their effects so that improved decisions can be made on whether to reject or accept a sample for testing. Finally, patient preparation sits within the pre-analytical phase and is often overlooked. Instructions for the collection of specific samples (e.g. 24-hour urine) and fasting or non-fasting status can greatly affect the result of a test. Changes in public healthcare and increased pressure for cost reduction have also seen an increase in the collection of samples in the general public to screen for specific conditions, and the handling of these samples by untrained staff or staff from other areas such as phlebotomists can often lead to errors. In order to minimize the occurrence of errors, it is crucial to establish thorough protocols and standard operating procedures for sample collection, labeling, and handling. Regular training and education programs should be implemented to ensure that all healthcare professionals involved in the pre-analytical phase understand the importance of their role in maintaining sample integrity and accurate test results. Additionally, improving communication and collaboration between clinical and laboratory staff is paramount. Clear and concise communication of patient information, test requests, and any changes or updates is essential to prevent misunderstandings and errors. Furthermore, the development and utilization of advanced technologies can greatly aid in improving the pre-analytical phase. Automation systems for sample labeling and tracking can reduce the risk of mislabeling or misplacement of samples. Barcode scanning and electronic interfaces between different healthcare systems can enhance the accuracy and efficiency of data transfer. Implementing quality control measures, such as regular audits and proficiency testing, can help identify and address any issues or deficiencies in the pre-analytical process. In conclusion, the pre-analytical phase of laboratory testing plays a crucial role in ensuring the accuracy and reliability of test results. By recognizing the potential sources of errors and implementing appropriate measures to mitigate them, healthcare institutions can enhance patient safety, optimize healthcare delivery, and ultimately improve the overall quality of healthcare services. (Sexton, 2023)

3. Analytical Phase Errors

Analytical error directly affects the probability of clinicians making incorrect medical decisions. This is closely related to the concept of diagnostic sensitivity and specificity. Systematic error may skew the sensitivity of a diagnostic test causing it to produce a greater number of false positive or

false negative results. If a laboratory analysis is incorrect but the condition is asymptomatic, the patient may be diagnosed unnecessarily and treatment may result in an iatrogenic illness. Steps to eradicate systematic error may involve repeating an assay to confirm questionable results or setting clinical decision limits closer to the healthy or diseased reference range. Random error increases the probability of overlap between patient sample results and reference ranges, reducing the precision of separation between healthy and diseased states. In this event, clinicians may incorporate greater overlap into their consideration of clinical tests or choose to revise the reference ranges. (Whelehan et al.2020)

The clinical detective work of the pathologist extends to the monitoring of analytical error in a laboratory. Many countries have schemes such as the United Kingdom's National External Quality Assessment Schemes (NEQAS), which enable laboratories to compare their results to those of their peer groups and to acceptable limits of error. This is particularly important in identifying systematic error and choosing whether to implement changes in equipment, methods of analysis, or simply retraining staff to adopt remedial action. (Buchta et al.2024)

The various types of analytical error can be classified in two different ways: those which are random and those which are systematic. Random errors in analysis occur non-reproducibly, are caused by unknown factors, and do not tend to occur in one direction. Examples of random errors are clerical errors or misidentification of specimens. These are rarely due to primary causes in the laboratory and are often due to inaccuracies in the pre and post-analytical phases. Systematic errors occur reproducibly, are consistent in one direction, and are often due to faults in an instrument. Standardization and calibration of instrumentation is essential in preventing systematic error, as is monitoring the quality of reagents that are used. Changing batches of reagents can introduce systematic error, some of which may go unrecognized. (Rickard et al., 2023)

4. Post-Analytical Phase Errors

Coronado and Mancini describe the post-analytical phase as "the most crucial—and the least monitored and controlled-step of the total testing process." Indeed, by this time, the physician is committed to some course of action that will be influenced by the results. If the results are not what the physician expected (or are different from the current diagnosis), the physician is likely to review the case and reorder tests or seek further information. Changes in diagnosis following the return of lab results have been found to occur in ranges from 20% to over 60% of cases. This means that the timing of when a physician makes a diagnosis in relation to when lab results are received is critical, as results can influence decisions made about patient treatment. It is clear that post-analytical errors have the potential to have a significant impact on patient care. (Dugad & Deshmukh…, 2022)

The post-analytical phase, the stage at which results are returned to the source of referral, is emerging as an important area in which errors may impact patient care. These errors are attributed to a failure in the healthcare process, rather than a fault of the laboratory or its personnel. They may occur in any setting where laboratory services are utilized, and attributed to a number of different stages; most commonly, however, they occur as a result of failure in communication (or

lack of) between the laboratory and medical staff. The duration of the post-analytical phase may also have an impact on the occurrence of errors, as short hospital stays or high volume practices may result in medical staff reviewing results without a clear patient diagnosis in mind. (Dugad & Deshmukh…, 2022)

5. Conclusion

It is necessary for clinical laboratories to establish reporting systems that allow all laboratory personnel to document errors and events that can lead to errors. It is only in this way that effective interventions can be put in place after the cause of an error is identified. With the widespread adoption of information technology in health care, we envision a future in which the capture of laboratory error data will be an intrinsic part of the computer-based order entry and result reporting process. In this future environment, patient identity errors and detectable preanalytic and postanalytic errors such as unacceptable specimens, incorrect orders, and clinically discrepant results may become very rare events. Finally, an understanding of the content and principles in this article by all personnel involved in the test processes can in itself help to induce a substantive reduction in laboratory error rates. If effective use is made of the tools and practices described here, despite the many challenges that the continuing evolution and diversification of laboratory testing present, we can anticipate a future in which the error rate for laboratory testing falls significantly below its current range. This can redound to substantial benefit for patient safety and the quality and cost of medical care. (Srivastava et al., 2021)

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