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Contribution to Lab Errors as a Healthcare Professional

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

With the emergence of new diagnostic markers every day, laboratory investigations have become an essential and integral part of healthcare. It is prudent to ensure that this dependence on diagnosis and treatment in laboratories is serious and responsible. This responsibility does not lie solely within the confines of a laboratory but extends to any healthcare personnel involved in the process of report generation. Reviews revolving around this topic focus on the laboratory's roles and conclude with the emphasis on paying attention to the extra-analytical phases. In this review, we attempt to expand our audience to include all healthcare professionals and highlight their role in increasing or minimizing laboratory errors. The process of creating a reliable report will be viewed as a shared responsibility. This includes the patient who has the responsibility to follow the direction given before specimen collection and extends to the doctor who interprets the results, keeping in mind all the inherent limitations that a test encompasses.

Keywords: Lab; monitor; error; analysis; report; investigation.

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1. INTRODUCTION

The diagnostic tests for admitted patients are also routine to monitor the progress of the patient. In such a framework [1], a clinical laboratory acts like a scaffold on which all departments rely for timely delivery of patient care [2]. Approximately 70% of clinical decisions stem from the path cleared with diagnostic tests [3].

The importance of the credibility of reports cannot be overemphasized to ensure quality care.

A sample is then translated to a verified text, pre-analytical, analytical and post-analytical, through three phases [4].

i, *Pre-analytical* stage consists of all the measures before a laboratory study are performed, ranging from order of a test, patient preparation, sample collection, transportation, accession, and centrifugation [5].
ii, *Analytical phase* refers to sample preparation or analysis with a specific auto analyzer or system [6].
iii, *Post-analytical phase* starts after a result/signal is received from an instrument in the form of a value that can be reported (either automatically via LIS or by manually transcribing the report) and extends up to the interpretation of the said report by the physician and further follow up [7].

2. LITERATURE SURVEY

Any defect from ordering experiments to reporting and analysis of findings is known as a laboratory mistake. The consequences of errors at any level can lead to delayed results, repeated visits, multiple avoidable pricks, incorrect results leading to incorrect or delayed diagnosis and treatment [8]. Patient care quality is compromised, adding to the overall cost, patient dissatisfaction, even having lethal repercussions. Over the last few decades; the face of lab errors has seen a significant decrease in the analytical phase of sample processing. This is a product of laboratory policies and procedures that ensure quality outcomes by properly recorded calibration and analyses [9]. This has been easier than the other phases as the number of factors, whether it be manpower or infrastructure, are easy to identify, locate and rectify. This, however, is not as easy before and after a sample reaches and leaves the laboratory, respectively. Currently, available data shows that the methodological steps before and after are more likely to be a mistake [10]. A proper assessment of all sources of errors, be it in any phase, is essential to ensure quality health care delivery. It is a responsibility that has to be shared amongst every person involved starting from the patient coming prepared for a sample and the doctor interpreting a report [11].

3. METHODS

3.1 Pre-Analytical Errors

The responsibility of achieving quality and credibility is not solely based upon the performance of the clinical laboratory. On the contrary, it has been observed that 46 to 68.2 % of errors are attributable to pre-analytical before a sample even reaches an auto analyzer. Irrespective of the stage where a mistake happens to protect the validity of the result, the laboratory is the important element and much more necessary to minimize the pre-analytical process of laboratory medicine. Any healthcare professional involved in the ordering and collecting investigations is an integral component of result generation [12]. Any errors in this phase due to miscommunication or any other reason are known as Pre-analytical errors. This can occur when ordering tests with respect to the patient and test identification during sample collection concerning a patient, specimen, and container selection. Other causes of errors include the labelling of tubes, the transport of specimens, or specimens' receipt in the laboratory.

3.2 Common Problems

3.2.1 Ordering investigations

Physicians should make an aware and conscious choice before ordering a test, keeping in mind the relevance for correct diagnosis and also the irrelevance of tests that may not add to the already available knowledge. This decreases unnecessary and unjustifiable costs and inconvenience for the patient. The means of ordering such tests also determine the types of errors.

3.2.2 Incomplete laboratory request forms

Legibility and completeness of the form are important to ensure correct tests are analyzed. Certain information on the Laboratory requisition

forms is essential for the laboratory and even the treating physician to interpret a result. A very common example is age. The absence of an exact age can make it difficult to define a reference range and thereby hinder the interpretation of whether the result is age-appropriate or needs to be further evaluated for any error source. Similar is the case for the period of gestation in pregnancy for tests like beta-HCG and TSH.

3.2.3 Patient preparation

Certain tests require certain conditions to be followed by the patient. A few examples would be to adhere to fasting or eating guidelines of certain tests like lipid profile and Oral Glucose Tolerance Test, respectively. Follow steps for a 24-hour collection or urine sample, or timing of collecting urine sample after dosage of a drug, etc [13]. In this case, the responsibility of providing the correct guidelines or information may differ based on the setup of a hospital or laboratory. This needs to be addressed to ensure that a reliable result is generated in the end since an error at this phase makes the following steps of analysis and interpretation irrelevant, even if performed to perfection.

3.2.4 Specimen collection (potential outcomes of collection errors)

Incorrect phlebotomy practices and patient information can lead to an inadequate quantity of sample collection, lexemic or haemolysed samples making their further processing difficult or impossible and unreliable results.

3.2.5 Wrong patient-specimen identification/wrong labelling of the containers

This Pre-analytical error is more common than one would expect, with mislabelling accounting for 50% of the errors in identification. This usually occurs under the scenario of high throughput hospitals dealing in constraint workforce and infrastructure. Patient identification errors before sample collection account for up to 25% of all Pre-analytical errors [14]. It can lead to patients being diagnosed and treated based on a sample from another patient. If not identified or correlated, outcomes can be catastrophic.

3.2.6 Transportation

The conditions and time between sample collection and analysis are enough to affect certain analyses' values.

3.2.7 Errors in specimen preparation

The time spent processing the sample, including centrifugation speed and temperature, light exposure, and aliquot preparation, are critical considerations that must be weighed before the study is carried out. The best situation for stocking samples is critical. The time it was processed and how it was stored, frozen or thawed have both led to certain modifications based on analysis and have an effect on the analysis outcome. Not properly processing a specimen before the test or substances which interfere with test performance may affect analysis results [15].

3.2.8 Limitations in reducing pre-analytical errors

A more significant pre-analytical error source is biological variance, not linked to an uncontrollable by human error. This variation can either be intra-individual, seen in the form of different results of the same patient, or inter-individual, the variation between two different individuals. Other factors like built, exercise, stress, dietary habits, lifestyle, chronic disease, and ongoing treatment are also capable of influencing results but are difficult to measure and account for and may vary drastically depending on the analysis.

3.3 Possible Resolutions

3.3.1 Computerized order entry system

An electronic system of ordering tests circumvents problems of legibility, misplacement, duplication, redundancy, and completeness of the information being conveyed to the laboratory. Access and availability of previous records provide better information for requesting a test, allowing better healthcare. Order sets will boost the effective test order more and limit the rate of redundant and/or unwanted orders.

Specific protocols and operating procedures (SOPs) goes a long way to introduce uniformity and reduce any confusion regarding procedures such as sample collection. These SOPs serve as reminders or help when in doubt and should be made by integrating CLSI guidelines for order of draw and manufacturer specifications.

3.3.2 Control of sample collection

The responsibility of sample collection varies from hospital to hospital. Control over the sample collection allows for better implementation and

corrective action. In case sample collection and processing units have independent control, good communication between the two is very important for maintaining quality.

3.3.3 Enhancing health care professional training

Although the process of sample collection its steps and how to avoid errors is well established. Adherence to the same is not always as efficient as the established protocols. Not always follow instructions for the collection of venous blood specimens. Training of new employees who may be involved in any process of the pre-analytical phase can help ensure compliance to guidelines**.**

3.3.4 Rejection criteria

Clinical laboratories should define basic requirements for exclusion of specimens and have access to them and closely monitor those participating in the processing of samples. This ensures that the sample is appropriate to enter the next stage of analysis. This reduces expenditure and decreases the turnaround time by timely informing the need for a fresh specimen rather than after the unsuccessful completion of the analytical phase. For this, flowcharts guiding how to deal with haemolysed, clotted and insufficient sample helps remove the ambiguity of the process. Automation can further remove the subjectivity of visual observation of such factors by measuring the haemolysis index.

3.3.5 Automation

Pre-analytical phase is also undergoing automation, thereby significantly reducing human errors. This involves the automatic preparation of a phlebotomy tray using specimen labellers and specimen management systems are combined with specimen management systems, Laboratory information systems, and Health maintenance information systems, further increase the efficiency of the entire process.

3.3.6 Monitoring quality indicators

Apart from establishing efficient systems and training programs, improvement can occur only if the effectiveness of these systems is continuously monitored with the help of quality indicators. A lab should be able to give feedback regarding the source, type, and magnitude of errors and recommend or devise corrective measures to combat the same. Monitoring serum indices, for example, is a way of monitoring sample collection quality or efficacy of remedial measures.

3.3.7 Communication

Errors can dramatically be reduced if the communication between the inter-lab departments such as clinical chemistry, microbiology, and pathology as well as physicians, nurses, and other healthcare workers is improved.

3.3.8 Product selection

Depending on the needs of the population being catered to, selection of products and maintenance of their supply and uniformity allow comparability of specimens received by a lab and their results.

4. ANALYTICAL ERRORS

In the analytical step of sample collection, the substitution of manual estimating techniques by automatic analyzers has considerably minimized errors. Internal quality control involves running samples with known values in order to make sure that the analyzing unit constituting of reagents and instrument is performing optimally. This was always a part of the analysis, and now external quality control has also gained ubiquitous acceptance, in which an unknown sample is analyzed and compared to global values achieved by lab all over the world enrolled in the program. This phase still has a certain area process that a lab can improve upon. This article aims to provide an idea as to what are the basic problems faced by a laboratory in general non-technical terms and how they can be resolved. A detailed explanation of achieving this would go beyond the scope of this article and steps difficult to accommodate. Nevertheless, analytical consistency is an important issue. Any of the following

4.1 Common Problems

4.1.1 Participation without action

Although the lab participates in quality programs, until and unless they use that information received as a result of participation to ensure quality, mere participation will not help improve analytical errors.

4.1.2 Reference ranges

While reporting results, laboratories should have well-established reference ranges based on physiological parameters such as age, the period of gestation in case of pregnancy, sex rather than ambiguous and general ones, as the interpreting physician will be treated based on these ranges provided.

4.1.3 Verify test performance

For any parameter that a lab is performing, its performance should be evaluated and verified with respect to its sensitivity, specificity, linearity, and precision.

4.1.4 Total allowable error

Defining the allowable error helps monitor and improve the analytical process.

4.2 Possible Resolutions

4.2.1 Automated analysis

Before the use of auto analyzers, reagents and samples were manually required to be pipette, the accuracy of which was heavily operator dependant. Certain estimations require the measurement of signals at particular times, and it is obvious that these lead to higher variability and errors. With the advance in automation, the manual error involved in carrying out these reactions has drastically reduced and is limited to manual programming of patient samples for required tests. Now automation has evolved a step further, wherewith the help of barcodes, this step of manual processing has also been circumvented drastically reducing missed, misidentified, misplaced, and incorrectly run tests. Steps requiring human intervention have now been reduced to a minimum.

4.2.2 Validation

Validation is an integral component before meeting any accreditation standards. This involves ensuring the validity and acceptability of a new program, instrument, and technique for a particular test.

4.2.3 Method verification

This involves verifying the reportable range, precision, analytical sensitivity, interferences, and accuracy, as provided by the test-specific kit insert. The process of achieving this verification should be well documented in the form of SOPs.

4.2.4 Reference range

The reference ranges used by a lab should be specific to the physiological conditions of the patients, such as age, sex, gestation in case of pregnancy, and these should be verified by running samples of healthy individuals.

4.2.5 Monitoring quality controls

A well developed and well-recorded curriculum must be established for.

4.2.6 Internal qc program

These quality checks are run on a daily basis to ensure the accuracy of the results of each run. Any malfunction as the levels of the instrument, reagent, or lab personnel can be identified.

4.2.7 External quality assurance program

These monthly checks comparing lab values with that of others helps detect any systematic errors and shift that may go unnoticed in the internal QC program. Reports once received from these programs should be investigated and resolved to prevent errors in clinical decisions. Inter Lab Comparison is another way a lab can assess and compare their performance with each other.

4.2.8 Allowable total error

This allows a lab to assess how stringent the Internal QC rules should be to limit random and systematic errors.

4.2.9 Peer review

This is an important factor that helps reduce error in the field of microbiology and pathology, where the variability of results due to subjective observation can be reduced.

5. POST-ANALYTICAL ERRORS

5.1 Common Problems

After a result is obtained, it has to reach the treating physician on time and unmodified to be of diagnostic and therapeutic utility. A wrong result is as bad as a late one, especially for critical values that, if not reported at the right time to the right physician, would delay lifesaving intervention.

5.2 Possible Resolutions

Automation has helped reduce these errors by directly transferring results in the Laboratory Information Systems. Linking the availability of critical values directly to the mobile of the healthcare provides has further reduced time to a notification.

6. RESULTS AND DISCUSSION

6.1 Limitations and Challenges to Lab Errors Improvement

With the advent of new and innovative technologies around automation, the ability to provide quality patient care and safety has improved significantly. There are still certain factors that put a limitation to the improvement that can be achieved.

6.1.1 Expansion

Labs are now emerging as larger organizations spread over even larger geographical areas. This expansion, together with the outsourcing of lab services, has become an area capable of increasing the sources of errors by making transportation a major factor of consideration. The conditions during transportation, the time required, and communication difficulties are some examples.

6.1.2 Economic constraints

High cost of automation is born with the concomitant reduction in laboratory staff, which, although minimal, with increased workloads starts affecting personal productivity again, becoming a source of error.

6.1.3 Point of care testing

In the pre-analytical process of accurate selection, POCT has a larger probability of mistakes.

7. CONCLUSION

A visit to the clinical laboratory, whether it is for a routine health workup or following a visit to a physician, has become a common affair that everyone is familiar with. Reducing pre-analytical, analysis- and post-analytical mistakes not only improves patients' trust in the system but also increases reporting doctors and helps minimize any excessive hospital and laboratory costs. Thus it is of interest to check all these errors in the total testing phase occurring in each laboratory and formulate corrective measures to avoid them. Scientific advancement has allowed morphed the manual and tedious analytical techniques to full automation, ensuring accuracy and speed, but there is a need to improve the communication between all healthcare professionals to improve on the errors occurring outside the confines of the laboratory. These errors are practically difficult to monitor, report and rectify, making the awareness of such mistakes even more important. This will help in increasing the awareness of the various steps and possible mistakes that can lead to fatal losses and thereby decrease the occurrence of laboratory errors more successfully.

CONSENT

It is not applicable.

ETHICAL APPROVAL

Ethical approval taken from Symbiosis Medical College for Women, Symbiosis International (Deemed University), Pune, Maharashtra, India

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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