Texila International Journal of Public Health
ISSN: 2520-3134
DOI: 10.21522/TIJPH.2013.11.02.Art002

Effect of Pre-Analytical Errors in Laboratory Testing Facilities: the Way Forward

Ofaka, Cordelia Enyanwu[1*], Nafarnda Wesley Daniel[2], Sonika, Raj Goel[1, 2]
[1]*Department of Public Health, Texila American University, Guyana, South America*
[2]*Department of Veterinary Public Health and Preventive Medicine, University of Abuja, Nigeria*

Abstract

Pre-analytical errors contribute a significant proportion of errors of all major sources of mistakes made in laboratory testing processes and are responsible for several patient safety risks. It contributes to wrong therapeutic interventions, irrelevant follow up laboratory investigations and diagnostic delays, which impact negatively on the economy and laboratory effectiveness of health services. Pre-analytical phase is directly related to the procedure of specimen collection and is mostly out of the direct control of the laboratory; further, most pre-analytical errors are related to human factors. The aim of the study is to determine the nature and the occurrence of pre-analytical errors and recommendations on possible measures to reduce these errors. A total of 300 specimens were randomly sampled from a study population of 600 patients and analyzed for pre-analytical errors. One hundred and eighty-four (184) samples were found unsuitable for further processing accounting for 1.9% of all samples analyzed for pre-analytical errors and sample rejection. Rejections were due to following reasons: hemolysis 21.7 % (40) wrong tubes 19 % (35); clotted blood 17% (32); inappropriate timing of collection 15.7% (29); mislabeled specimens 15.2% (28); insufficient specimen quantity 6.5 % (12) and lipemic specimens 4.3% (8). The overall percentage of rejection was 1.9% and the substantial numbers of the rejected specimens were re-tested. Efforts aimed to reduce the rates of rejected samples can improve the quality of laboratory-based health care response.

Keywords: *Error, Laboratory, Pre-analytical, Rejection, Specimen.*

Introduction

Pre-analytical errors contribute a significant proportion of errors in laboratory processes and contribute to several patient safety risks. The most reported types of pre-analytical error are missing sample and/or test request, wrong or missing identification, contamination from infusion route, hemolysis, clotted and insufficient samples, incorrect containers, erroneous blood to anticoagulant ratio etc. It contributes to incorrect therapeutic interventions, irrelevant follow up laboratory investigations and diagnostic delays, each of which impact on laboratory effectiveness and economic resources wastage [1-3]. It is important that laboratory quality management systems consider the impact of pre-analytical processes in such areas as identification and control of non-conformances, continual improvement, internal audit, and quality indicators. Previous studies have shown that there are wide variations in definition, repertoire, and collection methods for pre-analytical quality indicators. “Other measures for avoiding pre-analytical errors that have proven successful are never accept an unlabeled sample. Never allow unlabeled or mislabeled samples to be relabeled if recollection is

Received: 23.07.2022 ***Accepted: 12.09.2022*** ***Published on: 30.06.2023***
****Corresponding Author: ofakacordelia09@gmail.com***

feasible." "Document relabeling must be approved by an attending physician and the head, laboratory services, with results footnoted [4-6].

Currently, pre-analytical diagnostic errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from mistakes and problems in patient preparation, sample collection, sample transportation, sample preparation, and sample storage. However, while it has been reported that the pre-analytical phase is error-prone, only recently has it been demonstrated that most errors occur in the 'pre-pre-analytical phase'. This comprises the initial procedures of the testing process performed by healthcare personnel outside the laboratory walls and outside the direct control of the clinicians. Quality improvement and indicators (QIs) should therefore cover all steps in the pre-analytical phase, from test requesting to sample storage [7-9].

Pre-analytical errors (PAEs) are errors which occur prior to the analytical stage in the total testing process (TTP) and can occur both before and after receipt of specimens in the laboratory. PAEs contribute to several patient safety risks, including inappropriate or incorrect therapeutic interventions, unnecessary follow-up investigations and diagnostic delays, each of which impact on the clinical efficiency and economic resources of laboratory services [10, 11].

The current lack of attention to extra-laboratory factors points to the multitude of errors that continue to occur in the pre-analytical phase [8, 12]. The achievement of a consensus by a Technical Committee of the International Organization for Standardization (ISO/TC 212) on a comprehensive definition of errors in laboratory testing was therefore a milestone, in that it encourages a patient-centered approach and emphasizes the need to evaluate all steps of the testing process, whether they fall under the direct control of laboratory personnel.

Errors due to analytical problems have been significantly reduced over time, but there is evidence that, particularly for immunoassays, interference may have a serious impact on patients. A description of the most frequent and risky pre-analytical errors and advice on practical steps for measuring and reducing the risk of errors is stated in this study [13-15]. Many mistakes in the Total Testing Process are called "laboratory errors", although these may be due to poor communication, action taken by others involved in the testing process (e.g., physicians, nurses, and phlebotomists), or poorly designed processes, all of which are beyond the laboratory's control [16]. Likewise, there is evidence that laboratory information is only partially utilized. A recent document from the International Organization for Standardization (ISO) recommends a new, broader definition of the term 'laboratory error' and a classification of errors according to different criteria [16, 17]. In a modern approach to total quality, centered on patients' needs and satisfaction, the risk of errors and mistakes in pre-examination steps must be minimized to guarantee the total quality of laboratory services.

Methodology

This is a prospective case study on pre-analytical error in public health laboratories: the impact and reduction. This study was carried out at a tertiary institution, Wuse, General Hospital, Abuja. The sample size is a total of 300 randomly sampled and analyzed within the period of January 2022 to March 2021. These samples were collected by trained phlebotomists. Questionnaire sample size is 10% 0f 300 which is 30 questionnaires as the sample size of questionnaires. Information on questionnaires includes General laboratory error related information at the preliminary phase of laboratory analysis. The quality indicators questions for assessment of errors at the preliminary phase. Study respondent selection criteria were by age which is between

the ages of 20-30 years old. Data was collected using the study tools which are the questionnaires and interviews [17, 18].

Methodology assessed test request forms, specimen's collection procedures for both in-patient and out-patient (patient and specimen identification, specimen containers, labeling, transportation, storage, and documentation), screening, identification of types and frequencies of pre-analytical errors form part of methodology [7, 12, 19]. All the above was used to generate data. The data was analyzed, and analysis of result was statistical and presented tables. All procedures were featured in the final report writing. The data collection process was also done through quantitative and qualitative information gathering on specific pre-analytical error variables. Research questions were answered, hypothesis tested, and outcomes were evaluated. Quantitative data analysis was by regression analysis whereby two variables were examined and compared. Qualitative analysis combined content analysis to measure content changes over time and across media, discourse and narrative analysis were used to explore conversations in their social context [17, 18, 20]. Hence, data analysis was by metrics, facts and figures with the representation of analytics in tables and charts to illustrate data generated and trends in pre-analytical errors. Statistical analysis was by Null hypothesis or alternate hypothesis to test whether hypothesis is true and the use of the Chi-square test. A P- value of less than 0.05 was considered statistically significant.

Methodology gathered information, physical screening of pre-analytical processes and materials, use of interviews and Questionnaires to correspond with staff and respondents on the techniques. Assessment and screening of test request forms, specimen collection procedures, specimen identification, specimen containers, labeling, transportation, storage, and documentation [3, 21], the information was assembled and organized to generate data. The data collected was analyzed, and interpretations of results were presented both in statistical, narrative, graphs, and tables. The data collection process was also done through quantitative and qualitative information gathering on specific pre-analytical error variables [4, 9]. Research questions were answered, hypothesis tested, and outcomes were evaluated. Quantitative data analysis was by regression analysis whereby two variables were examined and compared. Qualitative analysis combined content analysis to measure content changes over time and across media, discourse and narrative analysis were used to explore conversations in their social context. Hence, data analysis was by metrics, facts and figures with the representation of analytics in tables and charts to illustrate data generated and trends in pre-analytical errors. Screening and checks on pre-analytical errors and Questionnaires as study tool was administered to respondents and the following result was obtained.

Results

A total of 300 specimens from the outpatient department and in-house patients were analyzed for pre-analytical errors within the period of January 2021 to March 2021. It is assumed that out of these; 184 samples were found unsuitable for further processing. This accounted for 1.9% of all samples collected in the laboratory and pre-analytical errors were responsible for these samples to be rejected over a period of 3 months. Rejections arose because of the following reasons: 21.7% (40) were rejected due to hemolysis; 19% (35) were blood collected in wrong tubes; 17% (32) were clotted blood; 15.7% (29) had inappropriate timing of collection; 15.2% (28) were mislabeled specimens; 6.5% (12) had insufficient specimen quantity and 4.3% (8) were lipemic specimens. Misidentification of patients was 9.23% (17). Appropriateness of test request on number of requests with clinical question were one hundred and sixteen (116) accounting for 38.66% of total samples. The

number of appropriate tests with respect to the clinical question were one hundred and thirteen (113) accounting for 37.66% of total samples. The number of requests without physician's identification was twelve (12) which accounted for 6.58% of total samples. The number of unintelligible requests was fifteen (15) accounting for 8.15% of the total sample. The number of requests with errors concerning test input was twelve (12) accounting for 6.52% of total samples. The number of samples lost/not received was twenty-two (22) and 11.95% of total samples. Numbers of samples collected in inappropriate containers were thirty-five (35), accounting for 19.02% of total sample, samples with insufficient volumes were 8 which is 4.34%, samples with inadequate sample-anticoagulant ratio were nine (9) which is 4.89%, samples damaged in transport were 13 which is 7.06%, improperly labeled samples were twelve (12) which is 6.58%, and numbers of improperly stored samples were twenty-four (24) accounting for 13.04% of total samples.

In conclusion, of all the samples received in the laboratory, the overall percentage of rejection was 1.9%. Substantial numbers of specimens undergo repeated testing because of pre-analytical error of rejection. Efforts aimed to reduce the rates of rejected samples can improve the quality of laboratory testing processes.

Discussion

Misuse of laboratory services through inappropriate laboratory test request is currently placed under scrutiny worldwide due to its impact, total costs, and the inherent increased risk of medical errors and injury. One major and important source of pre-analytical error is incorrect and incomplete information on the test request and labels which have been found in two thirds of all rejected samples in the laboratory [22, 23]. Several other studies confirm that test requests can be a clinically important source of errors. Paper-based test requests are risky as they can be incompletely filled, placed in the wrong collection box, or simply be lost. Incomplete laboratory requests forms are rarely rejected at the service point and in many instances the reception staff in the laboratory may not know the significance of the missing data. Specific missing information included the physician's name, misidentification of patient and requested tests. Appropriate laboratory tests requisition was 38.66% of total samples and inappropriate test requisition was 61.34%. Inappropriate test requisition varies from 11% to 50% for general biochemistry and hematology tests, 5% to 95% for urine screens and microbiology, and 17.4% to 55% for cardiac enzymes and thyroid tests. Correct patient identification is the most important task in all medical procedures, therefore efforts to ensure compliance with standardized identification routines should be prioritized. Mistakes in patient identification before specimen collection are responsible for up to 25% of all pre-analytical errors while critical patient identification errors occur in approximately 5 out of 300 tests requested. Mistakes in patient identification often occur during manual tasks which can be avoided using electronic technologies like barcodes, radiofrequency identification and wristbands. Wristbands have patient's name and identification number, and sometimes also have a barcode. Studies have reported error rates of 0.3– 11% for identification wristbands mostly comprising of missing or incomplete wristbands, and wrong wristband on the patient. Labeling of specimen containers should always be done immediately before sample collection while labeling them after sample collection increases the risk of the specimen collection from the wrong patient. Mislabeling is 6.58% responsible for almost 50% of all identification errors. Proper sample collection is an important part of good laboratory practice and improper collection can lead to delays in reporting, unnecessary re-draws/re- tests, decreased customer satisfaction, increased costs, incorrect diagnosis / treatment, injury and occasionally

death. Studies have shown the importance of checking for specimen adequacy as a critical factor in test result accuracy and usefulness. Samples that are missing, coagulated, hemolysed, insufficient or wrong due to inappropriate specimen collection and handling account for a large percentage of pre-analytical mistakes. Insufficient volume is a major factor leading to rejection of samples. The main reason for this anomaly is the ignorance of the phlebotomist, difficult sampling as in pediatric patients, debilitated cases, those on chemotherapy and those with difficult to localize veins. Insufficient samples constituted the most frequent cause of test rejection in a study done in the out–patients department. Incorrect phlebotomy practices are also one of the main reasons behind pre- analytical errors which occur due to lack of knowledge or heavy workload. Ideal phlebotomy practices should be adopted by all health care workers [2, 3]. Lipemic samples are often seen following collection after heavy meals or due to pre - existing metabolic disorder (hyper lipo proteinemias). Some of these errors can be avoided by collecting samples after an overnight fast or by mentioning the metabolic disorder in the requisition slip. Fat interferes with optical reading of the instrument and can affect electrolyte values. Too many lipemic samples are often due to non-dissemination of information regarding patient preparation by the clinicians, non-compliance and/or miscomprehension by the patient. It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection. Haemolysis of samples occurs when blood is forced through a fine needle, shaking the tubes vigorously, and centrifuging the sample specimens before clotting. Haemolysis accounts for most rejections in specimens received in the laboratory. The introduction of vacuum tubes along with the closed system of blood collection has made blood collection efficient and easy. But lack of staff training engaged in phlebotomy is an impediment for expediting sample collection and transport. Red top vacationers without any anticoagulant should not be shaken after the sample has been collected, and vacationers for plasma should be gently inverted a few times so the anticoagulant mixes with the blood. Freezing and thawing of blood specimens also causes massive haemolysis. A study reported that over 95% of the haemolysed samples were due to incorrect sampling procedure or transportation.

Haemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of potassium, aspartate aminotransferase (AST) and lactate dehydrogenase (LDH) [3, 5]. Transport delays to the laboratory can give rise to clinically important errors if transport conditions are not optimized. The specimen preparation steps contribute to approximately 19% of the overall cost of analyzing a single specimen and are time-consuming (57.37% of time spent in producing result). Being infectious, manual handling of samples is a well-recognized hazard to laboratory staff. Patient identification is probably the most important task in sample collection and error in this crucial step could have mild to life threatening consequences. Therefore, efforts to ensure compliance with standard identification procedures should be prioritized. Similarly wrong container labeling could also result in mild to severe life-threatening consequences. Other important sources of pre-analytical error not related to human mistakes include medications, which can cause errors through analytical (in vitro) or biological (in vivo) effects. Biological variation is the major source of variation for certain analyses. It consists of two parts i.e., intra-individual part (normal variation of analyzed substance in everyone) or inter- individual part (normal variation of the analyzed substance between individuals) [13, 24]. Other patient-related physical variables such as stress, diet and exercise can also affect test results. The laboratory should establish rejection criteria and

follow them closely. It is sometimes difficult to reject a sample, but it must be remembered that a poor sample will give poor results. Management should regularly review the number of rejected samples and reasons for rejections by conducting audit and training on sample collection and revising written procedures for sample management as and when needed. Always record the reason for rejection in the logbook and include all pertinent information. Frequency of errors and nature of occurrence should be documented and serve as a guide or point of reference to management of pre-analytical errors [4-6]. Promptly inform the authorized person that the sample is unsuitable for testing and request a fresh sample. Retain the rejected sample till decision is finalized and, in some circumstances, it may be necessary to proceed with the testing of a sample that is not optimal [2, 9, 20]. In conclusion, laboratory workers need to adopt a holistic approach towards laboratory diagnosis and function in close coordination with the clinicians to provide effective diagnostic services to the patients [14, 15].

In conclusion, adoption of quality control, not merely in the analytical processes, and regular appraisal and audits, but in all phases of diagnostic process is necessary to safeguard patient interests and to deliver quality services. The concept of total quality management encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians to reduce or eliminate the errors that may arise during the various steps. The promotion of ideal phlebotomy practices and sample transport procedures is a pre-requisite for the efficacy of laboratory functioning. The dependence on accurate laboratory results for diagnostics makes it mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis because of faulty reporting. The practice of keeping a record of the errors at all stages of analysis and then devising corrective strategies for their prevention can gradually free a laboratory from such errors.

Conclusion

From the findings of this research study, it is evidently established that effect of pre-analytical errors in testing facilities could be attributed to several reasons and negatively affect the economy of the nation, the hospital and laboratory, diminish confidence in healthcare services, tarnish the good name of the testing facility and the nation at large. It has a very bad effect on laboratory test results, patient care, and treatment and should not be overlooked. However, emphasis was made that adequate training professionally and continuous knowledge acquisition should be given to medical laboratory Scientists and Health workers to overcome the effect of pre-analytical errors inside and outside the laboratory.

Acknowledgement

I take this opportunity to thank Texila America University, my school faculty supervisor, Sonika Raj Goel who took their time to edit the article write-up. My immense gratitude goes to my local guide, Prof. Welsely Daniel Nafarnda of University of Abuja, Nigeria for accepting me as an external PhD research candidate irrespective of his tight schedule. My appreciation goes to my school mentor Ms Jesna Merlyn of Texila American University, Guyana, South America, who greatly contributed to the success of my schoolwork. My special thanks go to the CMDs Wuse General Hospital, Abuja and staff for their cooperation and support during the research work. I extend my sincere thanks to all Texila American University Coordinators, and everyone that contributed to the completion of this article. You are highly acknowledged.

Conflict of Interest

No conflict of interest declared.

References

[1] Bowen RA, Hortin GL, Csako G, Otañez OH, Remaley AT. (2010) Impact of blood collection devices on clinical chemistry assays. *Clin Biochem*.; 43(1-2):4-25.

[2] McCall R, Tankersley C. Phlebotomy Essentials. 5th ed. Philadelphia, PA: Lippincott, Williams, and Wilkins, 2008:245.

[3] Favaloro EJ, Adcock DM, Lippi G. (2012) Preanalytical variables in coagulation testing associated with diagnostic errors in hemostasis. *Lab Med*.; 43(2):1-10.

[4] Validation and verification of tubes for venous and capillary blood specimen collection; approved guideline. CLSI document GP34-A. Wayne, PA: Clinical and Laboratory Standards Institute, 2012.

[5] Lippi G, Fostini R, Guidi GC. (2008). Quality improvement in laboratory medicine: extra-analytical issues. *Clin Chem Lab Med*.; 28(2):285-294.

[6] Arneson W, Brickell J. (2008). Clinical Chemistry: A Laboratory Perspective. Philadelphia, PA: FA Davis Company, :418.

[7] Wallin O, Söderberg J, Van Guelpen B, Stenlund H, Grankvist K & Brulin C. (2008) pre-analytical venous blood sampling practices demand improvement — A survey of test-request management, test-tube labelling, and information search procedures. Clin Chim Acta 391; 91-7

[8] Hawkins R. (2012). Managing the pre- and post-analytical phases of the total testing process. *Ann Lab Med*.; 32(1):5-16.

[9] Green SF. (2013). The cost of poor blood specimen quality and errors in pre-analytical processes. *Clin Biochem*.; 46(13):1175-1179.

[10] Plebani M. (2007). Laboratory errors: How to improve pre- and post-analytical phases *Biochemia Medica*. 2; 17(1):5-9

[11] Jiu T, The importance of pre-analytical phase in laboratory testing and diagnosis.

[12] Datta P. (2005). Resolving discordant specimens. *ADVANCE for Administrators of the Laboratory*.: 60.

[13] Plebani M. (2006). Errors in clinical laboratories or errors in laboratory medicine? *Clin Chem Lab Med*.; 44(6):750-759.

[14] Lippi G, Becan-McBride K, Behúlová D, Bowen RA, Church S, Delanghe J, et al. Preanalytical quality improvement: in quality we trust. *Clin Chem Lab Med*. 2013;51(1):229-241.

[15] Bonini P, Plebani M, Ceriotti F, Rubboli F, Errors in Laboratory Medicine. Clinical Chemistry, 48: 5691–698 (2002).

[16] Plebani M, Carraro P. (1997) Mistakes in a stat laboratory: Types and frequency. *Clin Chem*.; 43(8):1348-1351.

[17] Söderberg J, Brulin C, Grankvist K, Wallin O. (2009) Pre-analytical errors in primary healthcare: a questionnaire study of information search procedures, test request management and test tube labelling. *Clin Chem Lab Med*.; 47(2):195–201.

[18] Söderberg J, Wallin O, Grankvist K, Brulin C. (2010) Is the test result correct? A questionnaire study of blood collection practices in primary health care. *J Eval Clin Pract*.; 16(4):707–711.

[19] Plebani M. (2005) Exploring the iceberg of errors in laboratory medicine. *Clin Chim Acta*.; 404(1):16-23.

[20] Barak M, Jaschek R. (2013). A new and effective way for preventing preanalytical laboratory errors. *Clin Chem Lab Med*.; 50(4):1-4.

[21] Favaloro EJ, Adcock DM, Lippi G. (2012) Preanalytical variables in coagulation testing associated with diagnostic errors in hemostasis. *Lab Med*.; 43(2):1-10.

[22] Hollensead SC, Lockwood WB, Elin RJ, Errors in Pathology and Laboratory Medicine: Consequences and Prevention. Journal of Surgical Oncology 2004; 88:161–181.

[23] Jiu T, The importance of pre-analytical phase in laboratory testing and diagnosis.

[24] Hammerling J. (2012) A review of medical errors in laboratory diagnostics and where we are today. *Lab Med*.; 43(2):41-44.