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Assessment of the pre-analytical phase errors in the clinical laboratory at Tripoli University Hospital

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ABSTRACT

The pre-analytical stage is the commonest source of laboratory errors. Errors in this stage can lead to a misdiagnosis, mismanagement, and represent serious harm to patients. Clinical laboratories use many different methods to reduce errors and improve quality, including assessment of pre-analytical phase errors that would result in improved quality of health care services. The purpose of this study was to determine the prevalence of pre-analytical phase errors in a clinical laboratory at Tripoli University Hospital, Libya. A descriptive cross-sectional study was conducted from March to May 2021 at the clinical laboratory of Tripoli University Hospital, involving 400 laboratory request forms and blood containers. Data was collected using an international standard checklist, and further analyzed using SPSS. Findings reveled that date of request and sex of the patients were present in all collected forms. However, physician's full name was missing in 80% of the request forms. No clinical details were provided in 79% of the forms. The doctor's signature was absent on 57% of the request forms. A bout 50% of the samples delivered in the laboratory did not contain the recommended volume of blood and 50% samples were hemolyzed. Besides, laboratory personals were not adhered with the standardized handling and transportation methods according to the International Organization of Standardization. Continuous educational action is needed for all lab staff involved in laboratory testing to improve the quality of the pre-analytical phase of the total testing process.

Keywords: Blood specimens, Clinical laboratory, Pre-analytical errors, Request form.

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INTRODUCTION

Laboratory errors can occur at any stage in the laboratory testing process, which requires to be monitored and controlled [1]. These medical errors captured a considerable attention and necessitate an urgent action to avert any undesirable consequences of medical outcomes, that could affect patient safety [2,3].

In clinical diagnostic laboratories, the process of laboratory testing is merely divided into three phases; pre-analytical, analytical, and post-analytical phases, according to the International Organization for Standardization (ISO).The pre-analytical phase is the primary phase before the beginning with the laboratory analysis. It involves the registration of clients, specimen collection and transportation. The second phase compromised of sample analysis, result examines, and technical validation. The third step involves the post-analytical phase, which includes result drafting, approval, and revealing to the doctor [4]. Laboratory errors might occur at any of these three phases, nevertheless the frequency of laboratory errors reported mostly in the pre-analytical phase [5].

Earlier studies reported that errors in results from laboratory testing were mostly recorded in the pre-analytical phase. Due to that, data accuracy, reliability and quality are influenced by this stage [6,8]. Inappropriate pre-analytical procedures of patient preparation, specimen handling, sample transportation, sample preparation, and sample storage making the reliability of the results doubtful.

It has been shown, from the literature, that maximum errors occur during the pre-analytical phase were about 61.9%,comparing to 15% and 23.1%, in analytical and post-analytical phases; respectively [9]. Errors in the pre-analytical phase had reported to commonly grows to be obvious subsequently at the analytical and post-analytical phases [10]. patient's safety and medical diagnosis improvements are depending on a currency of laboratory results, and that 70% of medical diagnostic decisions rely on the accuracy of laboratory tests [11].

It cannot be denied that laboratory errors play a significant role in the overall risk of error in healthcare [12]. Moreover, it is important to assess pre-analytical errors to define ways to reduce or eliminate laboratory errors that consider potentially significant on a patient's health, to improve the quality of laboratory analysis and reduce harm to patients [13]. Therefore, this study aims to assess and determine errors that occurs in the pre-analytical phase at the clinical laboratory of Tripoli University Hospital.

MATERIALS AND METHODS

Data settings and approval

A descriptive study was carried out from March to May 2021 with the aim of evaluating and analyzing pre-analytical errors occurred at the clinical laboratory of Tripoli University Hospital, using a simple random sampling strategy. This study was approved by the research committee of the Faculty of Medical Technology, University of Tripoli, Libya (No. Med-RCC-012).

Data collection

An international standard pre-analytical checklist was used to collect data from Laboratory Request Forms (LRF), sample containers, and observation of biological specimens. Data was prospectively obtained through qualified clinical laboratory technicians during their duty work, and were checked for completeness by the principal investigator. All lab technicians voluntarily participated in the current study after signing a consent form. Data regarding the type of errors, missing data on patient identification (ID), date of birth, gender, clinical diagnosis, physician's name, date of request, and physician's signature were collected from about 400 laboratory request forms. Errors collected from blood containers such as; missing data on patient identification (ID), patient age, gender, date of sampling, time of sampling, and sample hemolysis, were also collected. Any visual hemolysis or lipemia were considered as sample errors, and were subsequently recoded.

Data analysis

The collected data were analyzed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA), and were presented as counts and percentages.

RESULTS

Out of all the required information on LRFs (n=400), only the date test was requested. Patient gender was present on all LRFs. The name of the physician, patient's clinical details, clinical diagnosis, and physician's signature were not provided on 332 (82.0%), 316 (79.0%), 240 (60.0%), and 228 (57.0%) of LRFs respectively. While, patient's full names were not found on 80 (20.0%) of the request forms, and age was missing on 88 (22.0%) of LRFs (Table 1).

Regarding errors on sample containers, the current results revealed missed data of 392 (98.0%) about gender, 388 (97.0%) regarding age, and 188 (47.0%)

about sampling date. While, patient's name was absent on 4 (1.0%) sample containers (Table 1).

Table 1. Frequency of errors linked with LRF and sample container

Variables of requests form	Frequency	Percentage %
Clinical details	316	79.0%
Requesting Physician's full name	332	82.0%
Clinicaldiagnosis	240	60.0%
Physician's signature	228	57.0%
Patients' full names	80	20.0%
Age (Years)	88	22.0%
Variables of sample container	**Frequency**	**Percentage %**
Time of sampling	400	100.0%
Gender of patient	392	98.0%
Age of patient	388	97.0%
Date of sampling	188	47.0%
Patients' full names	4	1.0%

Regarding errors on blood specimens, sample hemolysis and insufficient volume of blood were the most commonly observed pre-analytical errors on 200 (50.0%) of total samples, followed by 140 (35.0%) improper container, 100 (25.0%) clotted samples, 88 (22.0%) delay in sample transport, and 40 (10.0%) lipemic samples (Table 2).

Table 2. t-CT and chest radiography compliance

Variables	Frequency	Percentage
Insufficient volume of specimen	200	50.0%
Hemolyzed sample	200	50.0%
Inappropriate container	140	35.0%
Clotted sample	100	25.0%
Delay in sample transport	88	22.0%
Lipemic sample	40	10.0%

DISCUSSION

The primary goal of the study was to determine the frequency of pre-analytical errors that could affect the performance in the overall testing procedure. The current analysis of LRF data revealed that, only the reference gender and date test request appeared on all of the examined LRFs, dissimilar findings were reported in previous studies in India and Ghana [14, 15]. On the other hand, major pre-analytical errors (82.0%) were noticed in lab requesting forms about missing the physician's name, followed by 79.0% of missed clinical information. These findings were in agreement with results from study conducted in Ethiopia, which exhibited 17.9% and 22.5% missed information of physician name and clinical information, respectively [16]. Besides, the clinical diagnosis was not mentioned in 60.0% of the lab request forms. This was comparable to earlier study conducted in North India, which reported 61.6% missed information concerning the diagnosis in request forms [17]. Extraneous and unneeded tests are performed when clinical information (diagnosis) is lacking or uncertain.

Patient's names were recorded in almost all sample containers, whereas 97%, 98%, and 47% of ages, genders, and date of sampling, were missed; respectively. Recording the age and sex of the patient in the laboratory request form and sample container is important for correct interpretation of results, as the reference range of the tests are different for different age groups and sex. Incorrect or insufficient information in the test request or on the test tube label are major source of pre-analytical errors [18,19].

Generally, erroneous requests and labels are responsible for more than two-thirds of all rejected samples in clinical laboratories. In addition, several other investigations have confirmed that test requests can be clinically significant cause of errors [20,24]. In this study, laboratory request forms and sample containers did not carry all the required information regarding patient and sample details. This could be due to an overabundance of patients, as well as a lack of medical staff awareness of the relevance of the essential information in the appropriate processing of samples and transmission of reports. These details about patient's characteristics, such as age, gender, physiological conditions pregnancy and menopause details, used medications, and suspected diagnoses, are required to avoid unnecessary test repetitions in the event of dissimilar results that cannot be evaluated due to a lack of information.

In the present study, findings regarding blood specimens revealed that 50% of both hemolyzed sample and insufficient volume were the most common pre-analytical errors leading to specimen rejection in the clinical lab at this research. This was comparable to previous study done in Turkey where insufficient volume was the most common errors with 48.8% [25], and less prevalence from study conducted by Goswami et al., which reported 81% hemolyzed specimens that caused specimen rejection [26].

The current results also reported 35% of inappropriate containers, which was less than the

reported rate of 57% from previous Indian study [27]. Another frequent pre-analytical error encountered is clotted samples, which was reported in 25% of all collected samples. The most prevalent cause of samples clotting is inappropriate mixing of samples immediately after collection, which may had occurred in the present study, as some clotted samples are easy to detect compared to micro-clots. This error was previously reported as the most common factor with an incidence ranging from 43.8% to 55.8% [28,30]. Additionally, the transportation of biological samples must be done as quickly as possible to the laboratory by taking all precautions to avoid contamination [31]. In the current study, delay in sample transport was reported to be 22.0%. Transport delays may result from in adequate number of lab staff and lack of their awareness.

The pre-analytical variables such as patient preparation, drug consumption, and tourniquet application was not included, which was considered as limitation of this study.

CONCLUSION

The current findings reported the presence of errors in the pre-analytical phase which could be of concern to patient safety. Continuous evaluation of the pre-analytical phase, causes of error, and corrective measures should be taken to make this phase error-free. To improve the quality of services, physicians and laboratory workers should collaborate more closely together. Incomplete request forms and samples should be rejected, and laboratory technicians should be educated on established guidelines.

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REFERENCES

1. Lopis M, Alvarez V, Martínez-Brú C, Gómez R, Barba N, Ibarz M, Cortés M, Ventura M, Alsina MJ. Quality assurance in the preanalytical phase. Applications and experiences of quality control. IntechOpen.2011:704.doi: 10.5772/15854.
2. Dean B. Learning from prescribing errors. Qual Saf Health Care 2002;11;258–60.
3. Hawkins R. Managing the pre- and post-analytical phases of the total testing process. Ann Lab Med. 2012;32(1):5-16. doi: 10.3343/alm.2012.32.1.5.
4. Carayon P, Wood KE. Patient safety - the role of human factors and systems engineering. Stud Health Technol Inform. 2010;153:23-46.
5. Plebani M. Exploring the iceberg of errors in laboratory medicine. Clin Chim Acta. 2009;404(1):16–23.
6. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clinical chemistry. 2007;53(7):1338-42.
7. Lewandrowski K, Baron J, Dighe A. Utilization management in the clinical laboratory: an introduction and overview. InUtilization management in the clinical laboratory and other ancillary services 2017 (pp. 7-29). Springer, Cham.
8. Astion ML, Shojania KG, Hamill TR, Kim S, Ng VL. Classifying laboratory incident reports to identify problems that jeopardize patient safety. Am J Clin Pathol. 2003;120(1):18-26. doi: 10.1309/8EXC-CM6Y-R1TH-UBAF.
9. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clin Chem 2007;53:1338-42.
10. Rachna A, Sujata C, Neelam C, Renu G, Ishita P, Chandra BT. Role of Intervention on Laboratory Performance: Evaluation of Quality Indicators in a Tertiary Care Hospital. Ind J ClinBiochem. 2012; 27: 61–68. doi: 10.1007/s12291-011-0182-7.
11. M'Antonia L, Virtudes A, Cecilia MB, Rubén G, Núria B, Mercè I, Mariano C, MontserratV, M'Jesús A. Quality Assurance in the Preanalytical Phase, Applications and Experiences of Quality Control, Prof. Ognyan Ivanov (Ed.). 2011. ISBN: 978-953-307-236-4.
12. Lippi G,PlebaniM, ŠimundićA. Quality in laboratory diagnostics: From theory to practice. Biochem Med. 2010;20:126-130.
13. Lippi G, Bassi A, Brocco G. Preanalytic error tracking in a laboratory medicine department: results of a 1-year experience. Clin Chem 2006; 52:1442-4.
14. Neelam C, Sarbjeet K, Rachna A, Neeraj KS. Effect of PreAnalytical Errors on Quality of Laboratory Medicine at a Neuropsychiatry Institute in North India. Ind J Clin Biochem. 2011; 26: 46–49. doi: 10.1007/s12291-010-0082-2.
15. Olayemi E, Asiamah-Broni R. Evaluation of request forms submitted to the haematology laboratory in a Ghanaian tertiary hospital. Pan Afr Med J. 2011;8:33. doi: 10.4314/pamj.v8i1.71148.
16. Wondimagegn MW, Yallew WW, Anijajo TT. Assessment of Pre-Analytical Error on Blood

Specimens Referred for CD4 and Haematology Tests in Central Oromiya, Ethiopia. American Journal of Laboratory Medicine. 2016;1(3):58-64.

17. Chhillar N, Khurana S, Agarwal R, Singh NK. Effect of pre-analytical errors on quality of laboratory medicine at a neuropsychiatry institute in North India. Indian Journal of Clinical Biochemistry. 2011;26(1):46-9.
18. Galloway M, Woods R, Whitehead S, et al. An audit of error rates in a UK district hospital transfusion laboratory. Transfus Med 1999;9:199-203.
19. Murphy MF, Stearn BE, Dzik WH. Current performance of patient sample collection in the UK. Transfus Med 2004;14:113-21.
20. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clin Chem 2007;53:1338-42.
21. Wiwanitkit V. Types and frequency of preanalytical mistakes in the first Thai ISO 9002:1994 certified clinical laboratory, a 6 - month monitoring. BMC Clin Pathol2001;1:5.
22. Wagar EA, Tamashiro L, Yasin B, et al. Patient safety in the clinical laboratory: alongitudinal analysis of specimen identification errors. Arch Pathol Lab Med 2006;130:1662-8.
23. Dale JC, Novis DA. Outpatient phlebotomy success and reasons for specimen rejection. Arch Pathol Lab Med 2002;126:416-9.
24. Kirchner MJ, Funes VA, Adzet CB, Clar MV, Escuer MI, Girona JM, Barellas RM, Alsina CP, Aguilá CR, Isern GT, Navarro CV. Quality indicators and specifications for key processes in clinical laboratories: a preliminary experience. Clin Chem Lab Med. 2007;45(5):672-7. doi: 10.1515/CCLM.2007.122.
25. Cakirca G. The evaluation of error types and turnaround time of preanalytical phase in biochemistry and hematology laboratories. Iranian journal of pathology. 2018;13(2):173.
26. Goswami B, Singh B, Chawla R, Mallika V. Evaluation of errors in a clinical laboratory: a one-year experience. Clin Chem Lab Med. 2010;48(1):63-6.
27. Begum F. A study of pre-analytical errors in a hospital based clinical biochemistry laboratory and formulation of measures for correction. Age. 2014;758:6-18.
28. Guimaraes AC, Wolfart M, Brisolara ML, Dani C. Causes of rejection of blood samples handled in the clinical laboratory of a University Hospital in Porto Alegre. Clin Biochem. 2012;45(1-2):123-6.
29. Sinici Lay I, Pinar A, Akbiyik F. Classification of reasons for rejection of biological specimensbased on pre-preanalytical processes to identify quality indicators at a university hospital clinical laboratory in Turkey. Clin Biochem. 2014;47(12):1002-5.
30. Bhat V, Tiwari M, Chavan P, Kelkar R. Analysis of laboratory sample rejections in the pre-analytical stage at an oncology center. Clin Chim Acta. 2012;413(15-16):1203-6.
31. Duchassaing D. Phase pré-analytiqueenbiochimie: processus de maîtrise de la qualité. Revue Française des Laboratoires. 1999 Nov 1;1999(317):27-34.