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ORIGINAL RESEARCH

Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia

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Background: Laboratory diagnostic service is an integral part of modern health care service. Quality of laboratory result helps for proper patient care. However, occurrences of clinical laboratory errors impair clinical decision-making process. Such errors are supposed to high in resource-poor countries like Ethiopia. Laboratory errors in any level of the process have an influence on total patient care, which might include misdiagnosis and mismanagement.

Objective: To determine types and frequency of errors in diagnostic laboratories among selected hospitals in East Wollega Zone, Oromia, Ethiopia.

Methods: Hospital-based cross-sectional study was conducted at diagnostic laboratories of selected hospitals in Wollega, West Ethiopia, from November 2020 to February 2021; to assess errors in laboratory procedures. Nekemte Specialized Referral Hospital, Wollega University Referral Hospital, Arjo Hospital, and Shambu Hospital have been chosen. All the required data were collected using established check list.

Results: The frequency and types of errors in the pre-analytical, analytical, and post-analytical phases were assessed in this study. Overall, 1124 (58.5%) laboratory errors were detected, of which 807 (71.8%) were pre-analytical, 85 (7.6%) analytical, 232 (20.6%) post-analytical errors.

Conclusion: Based on our findings pre-analytical and post-analytical errors occurred more frequently as compared to analytical errors and most of them are preventable errors and the increased pre-analytical errors indicates contribution of other health professionals. In general our study suggests the need for provision of trainings and supervisions for the staffs involved and coordinated activities to deliver quality services that meets the customer needs.

Keywords: laboratory errors, pre-analytical, analytical, post-analytical errors, total testing process

Introduction

Laboratory diagnostics is a rapidly expanding field that contributes significantly to clinical decision making by assisting in disease prevention, diagnosis, and therapy monitoring. Quality and safety in diagnostic testing, on the other hand, are critical to achieving the objective of high quality and safe healthcare, with no other disciplines playing such an important role in the patient safety solution as laboratory medicine.[1]

In clinical laboratories, there are three testing processes: pre-analytical, analytical, and post-analytical phases, which are referred to collectively as the total testing process (TTP). According to definition by ISO 15189:2007, Pre-analytical components are defined as steps beginning with the clinician's request and including the examination requisition, patient preparation, collection of the primary sample, transportation to and inside the laboratory, and ending when the analytical examination procedure begins.

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Post-analytical components are defined as processes that occur after the examination, including systematic review, formatting and interpretation,authorization for release, reporting and transmission of results, and storage of examination samples.[2]

Laboratory error is defined as "any defect from ordering tests through reporting results, as well as appropriately interpreting and reacting to them".[3] An error in the clinical laboratory may occur during the pre-analytical, analytical, or post-analytical phases; this entire process is impossible to perform error-free.[4] Any laboratory analysis strives to reduce uncertainty and estimate their magnitude to an acceptable degree.[5] Errors can occur at any stage and result in an inaccurate report production, which can have an impact on patient care such as misdiagnosis and incorrect treatment.[1] The most common errors impacting laboratory test findings occur in the pre-analytical phase (46–68.2% of total errors) and post-analytical phase (18.5–47% of total errors), with less (7–13% of total errors) occurring in the analytical phase.[1,3,6]

Modern technologies have turned laboratory diagnoses from a labor-intensive service to nearly fully automated operations, facilitating a corresponding reduction in workforce. Despite all of the automation, findings from many research clearly demonstrated that the laboratory remains a source of errors, which can lead to improper patient care decisions. Despite numerous studies aimed at improving analytical quality, faults in the laboratory testing process persist.[7]

Efforts to improve laboratory capacity and quality systems in resource-poor nations are meager, and access to reliable lab testing in many countries, including Ethiopia, remains limited. This leads to delayed diagnosis, misdiagnosis, and ineffective treatment, which increases morbidity and mortality.[8] According to official data, laboratory results influence 60–70% of clinical decisions about hospitalization, discharge, and medications.[4,7] Evidence showed that, the risk of improper care owing to laboratory errors ranges from 6.4% to 12%, with the likelihood of additional inappropriate investigations being substantially higher (19%).[9,10]

Despite the fact that automation, standardization, and technical advancements have considerably increased the analytical reliability of laboratory tests, laboratory errors occur in every procedure. In Wollega, Ethiopia, there is a paucity of data on laboratory errors. As a result, the current study intends to fill this gap by generating data on the types and frequency of pre-, analytical-, and post-analytical errors, as well as analyzing their distribution among study settings. This study provides data on errors in the overall testing process in clinical laboratories and identifies errors that have an impact on the quality of the laboratory service. As a result, errors found can be prevented from repeating, resulting in improved laboratory quality.

Materials and Methods

Study Settings

Hospital-based cross-sectional study was conducted at diagnostic laboratories of selected hospitals in Wollega, West Ethiopia, from November 2020 to February 2021; to assess errors in laboratory procedures. Nekemte Specialized Referral Hospital, Wollega University Referral Hospital, Arjo Hospital, and Shambu Hospital have been chosen. All blood samples received with their request form ordered for Hematology, Clinical Chemistry, Serology and Immunohematology Unit during the study period were included in this study. The research was carried out on processes at the pre-, intra-, and post-analytical stages. The research comprised requests for hematology, immunohematology, serology, and clinical chemistry tests using venous blood samples (whole blood, plasma/serum sample). In each hospital, there are a number of automations merely carrying out of analytical run where the other laboratory processes are manual types.

Data Collection Tools and Technique

Process inspection sheets were developed to aid in the assessment of pre-, intra-, and post-analytical errors for Hematology, Immunohematology, Serology, and Clinical Chemistry Unit tests at Nekemte Specialized Referral Hospital, Wollega University Referral Hospital, JimmaArjo Hospital, and Shambu Hospital. Inspection sheets are created based on a study of similar research in the literatures.[1,3,11,12] This study had the participation of three investigators. Data was collected in the Hematology, Immunohematology, Serology and Clinical Chemistry section during routine hours

each day in the study period. The data collection process was continuously monitored and reviewed by the lead investigator to guarantee the completeness and consistency of the collected data.

Data Management and Analysis

The checklist was pre-tested to ensure the clarity, acceptability, and consistency of the structured inspection sheets. Before collecting the actual data, the necessary corrections were made. Close follow-up was done by the principal investigator. The filled checklists were collected after consistency and completeness was checked. The data was checked for completeness and entered into EPI info version 3.5.3 and transferred to Statistical Package for the Social Sciences (SPSS) version 20 (IBM Corporation, New York, United States) for analysis. Frequencies, and cross tabulations were used to summarize descriptive statistics.

Ethics Approval and Consent to Participate

Wollega University Institute of Health Sciences Research and Ethical Review Committee provided ethical approval. The postgraduate and research coordinator, Wollega University, wrote permission letters to the individual hospital, and the hospital CEO/medical director forwarded the letters to the hospital laboratory manager for cooperation and participation. All data was maintained with confidentiality. Detectable errors were linked to the responsible personnel for better patient management and quality improvement purpose.

Results

A total of 1465 request forms were gathered from different departments found in hospitals in Wollega Zones: 379, 472, 377, and 237 from Arjo, Nekemte, Shambu, and Wollega University Referral hospitals, respectively. Laboratory professionals 1261 (86.1%) and other health professionals 204 (13.9%) collected blood samples for this investigation. A total of 1922 laboratory tests were ordered from the request forms, including 935 hematology tests, 354 clinical chemistry tests, 131 CD4 testing, 296 immunohematology tests, and 206 serology tests. 73 (5.2%) of the total blood samples obtained were rejected, while 1392 (94.8%) were accepted. Table 1 shows the reasons for the blood samples being rejected.

Pre-Analytical, Analytical and Post-Analytical Errors

Out of 1465 evaluated laboratory request papers, physician name, patient clinical data, and physician signature were missed in 739 (50.8%), 644 (43.96%), and 624 (42.6%) respectively, as depicted in Table 2.

Overall, 1124 (58.5%) laboratory errors were detected, with 807 (71.8%) pre-analytical errors, 85 (7.6%) analytical errors, and 232 (20.6%) post-analytical errors. Table 3 shows the Pre-analytical, analytical and post-analytical percent of errors occurred within laboratory.

Table 1 Reasons for Rejection of Blood Samples Collected from Arjo, Nekemte, Shambu, and Wollega University Referral Hospitals, Wollega, Ethiopia (n=73)

Reasons of Rejections	Frequency	Percentages
Hemolyzed	8	11
Lipemic	3	4.1
Clotted	16	21.9
Unlabeled/Mislabeled	14	19.2
Inappropriate Test Order	3	4.1
Insufficient Volume	17	23.3
Sample without Request Paper	12	16.4

Table 2 Total Pre-Analytical Errors Observed on Laboratory Request Forms Collected from Arjo, Nekemte, Shambu, and Wollega University Referral Hospitals, Wollega, Ethiopia

S. No	Variables	Frequency	Percentages
1	Request paper not accompanied with the sample	18	1.2
2	Patient's name missed	7	0.5
3	Patient identification or card number missed	336	22.9
4	Patient sex un-identified	123	8.4
5	Patient age not written	116	7.9
6	Physician name not written	739	50.4
7	The requesting physician not signed	624	42.6
8	Patient clinical data missed	644	43.96
9	Test ordered not marked	43	2.9
10	Date of request not marked	263	17.95

Table 3 Pre-Analytical, Analytical and Post-Analytical Percent of Errors in Laboratory at Arjo, Nekemte, Shambu, and Wollega University Referral Hospitals, Wollega, Ethiopia (n=1124)

Pre-Analytical	N (%)	Analytical	N (%)	Post-Analytical	N (%)
Hemolyzed	8 (0.7)	Equipment malfunction	5 (0.4)	Result lost	1 (0.09)
Lipemic	3 (0.3)	Reagent expired	2 (0.2)	Critical result not communicated	25 (2.2)
Clotted	16 (1.4)	Sample mix-up	11 (0.9)	Delay in results reporting	206 (18.3)
Unlabeled/mislabeled	14 (1.2)	Sample lost	7 (0.6)		
Inappropriate test order	3 (0.3)	QC incompatibility	29 (2.6)		
Insufficient volume	17 (1.5)	Protocol/SOP not followed	31 (2.8)		
Sample without request paper	12 (1.1)				
Time of collection not written	422 (37.5)				
Date of collection not written	312 (27.8)				
Total	807 (71.8)	Total	85 (7.6)	Total	232 (20.6)

Abbreviations: QC, quality control; SOP, standard operating procedure.

Discussion

Any laboratory error, at any stage of the process, has an impact on patient care. To know its type and magnitude, we have assessed general laboratory errors manifested at each selected public hospital. In these hospitals, there are fully-automated machines in the analytical testing phase, which makes the error rate lower comparably, whereas in pre-analytical and post-analytical testing phases, majority of tests are manual-based, thus why errors dominated here.

This study looked at the frequency and types of errors in the pre-analytical, analytical, and post-analytical phases. Pre-analytical errors (71.8%) were with the highest frequency in our study, which is comparable with a study conducted in Ethiopia by Tadesse et al,[5] where pre-analytical errors (75.5%) were with the highest frequency, and another study from India[13] also found that pre-analytical errors account for 77.7% of total errors.

In the current study, the top 3 reason for sample rejection was insufficient volume (23.3%) followed by clotted sample (21.9%) and unlabeled/mislabeled specimen 19.2%. Another study done in Ethiopia[11] showed the most common frequent cause of sample rejection was hemolysis (33.3%) followed by a sample with no request/request with no sample which accounted for 31.7% and mislabeled samples (28.5%) in their study. These inconsistencies might be the result of a lack of proper patient orientation and sample collection preparation.

Physician names and signatures were missed in 739 (50.8%) and 624 (42.6%) of the 1465 request forms evaluated at the laboratory, respectively, which is lower than another study conducted in Ethiopia by Tadesse et al[14] where physician names and signatures were missed in 84.8% and 30.3%, respectively. Missed patient clinical data (644 (43.6%)) was the second most

common missing information from request forms in our study, which was lower than the previous study in Ethiopia,[11] but higher than a study in India, where physician names and signatures were missed in 13.1% and 13.4% of forms, respectively.[15]

In the current study, analytical errors account for 7.6%, which is lower than a large-scale study was done in Tehran, Iran where analytical errors contribute to 23.2% of the total errors that occurred in the laboratory.[4] The most frequently detected analytical errors were due to Protocol/SOP not followed by laboratory professionals, which contributes to 31 (2.8%) of total errors. Laboratories use SOPs for correct test selection, sample collection, and handling while standardized test terminology, and units of traceability to ISO standard 17511 are required to ensure equivalency of measurement results.[16]

Furthermore, failing to follow the Protocol/SOP has an effect on the outcomes and complicates patient treatment. Variations across laboratories in measurement standards, terminology, reporting formats, and interpretation of test results aggravate the difficulties of communicating and integrating clinical data.[17] Establishing and validating test methods performance criteria such as test accuracy, precision, sensitivity, specificity, and linearity are other areas where mistakes can arise during the analytical phase of laboratory testing. In our study, QC incompatibilities were the second most frequently detected analytical errors, accounting for 29 (2.6%) of total errors.

Several previous studies have proved laboratory errors occurred more in the pre-and post-analytical phase of TTP.[3,5,14] In line with this from the three types of errors, post-analytical errors were the second most common, contributing 232 (20.6%) of the total errors that occurred within the laboratory. Delays in results reporting were the most common post-analytical errors that occurred in our study and in 25 (2.2%) of cases critical results were not communicated. These errors can be prevented by giving regular trainings that can involve all stakeholders to increase their commitment for quality improvement, implementing laboratory information systems (LIS) that can minimize the manual works in the laboratories, frequent supervisions by regional laboratories, and improved quality assurance system will guarantee reduction in errors in laboratory.

Conclusion

The role of laboratory medicine is indispensable for the health care system. An error in any phase of the total testing process leads to improper patient care. Based on our findings pre-analytical and post-analytical errors occurred more frequently as compared to analytical errors and most of them are preventable errors and the increased pre-analytical errors indicates the contribution of other health professionals. From the analytical errors failure to follow standard operating procedures was the most common one which is not a hard task to apply for the professional but being unable to follow SOPs might result in misdiagnosis and in turn results in mismanagement of the patient. In general, our study suggests the need for the provision of training and supervision for the staff involved and coordinated activities to deliver quality services that meet the customer's needs.

Abbreviations

QC, quality control; SOP, standard operating procedure; SPSS, Statistical Package for the Social Sciences; TTP, total testing process.

Ethical Clearance

The Wollega University Institute of Health Sciences Research and Ethical Review Committee provided ethical approval. The postgraduate and research coordinator, Wollega University, wrote permission letters to the individual hospitals, and the hospital chief executive officer/medical director forwarded the letters to the hospital laboratory manager for cooperation and participation. All data was kept for confidentiality. Detectable errors were linked to the responsible personnel for better patient management and quality improvement purpose.

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Author Contributions

All authors made substantial contribution to the conception and design, acquisition of data, analysis and interpretation of data; took part in drafting, revising and critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted and are accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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