Quality Assessment in the Laboratory: Errors in the Total Testing Process in the Clinical Chemistry Laboratory at University of Gondar Hospital, Northwest Ethiopia

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Abstract

Laboratory services have been described as the major processes contributing to safe patient care in the modern healthcare sector. However, occurrences of errors in the overall testing processes impair the clinical decision-making process. Such errors are supposed to be high in resource-poor countries, like Ethiopia. Therefore, this study was aimed to assess errors in the total testing process in the Clinical Chemistry Laboratory of University of Gondar Hospital. For this purpose, a cross-sectional study was conducted at the University of Gondar Hospital from February to March 2016. All the required data were collected using established quality indicators. Data were analyzed using SPSS version 20. Frequencies and cross tabulations were used to summarize descriptive statistics. A total of 3259 samples and corresponding laboratory request forms were received for analysis. Analysis of the overall distribution of errors reveals that 89.6% were pre-analytical errors, 2.6% were analytical, and 7.7% were post-analytical errors. Of the pre-analytical errors, incomplete request form filling was the most frequent error observed followed by sample rejection rate (3.8%). Analytical errors related to internal and external quality control exceeding the target range, (14.4%) and (51.4%) respectively were reported. Excessive Turnaround Time (TAT) and unreported critical value cases were major defects in the post-analytical phase of quality assurance. The study shows that relatively high frequency of errors, which alarms the importance of quality indicators to assess errors in the total testing process should improve the quality of healthcare services based on these findings using laboratory standards

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Keywords: Analytical errors; clinical laboratory; post-analytical errors; pre-analytical errors; Quality

1. Introduction

Laboratory services are the backbone of the modern healthcare sector (1). Diagnostic test results provide information that can be used to aid the patient, physician, and others in reaching decisions (2). The impact of laboratory testing in patient care contributes greater than 60% of medical decisions (3). However, the analysis performed in the laboratory is subjected to variance; hence, every clinical laboratory must have adequate procedures to assure the quality of the medical results reported. The quality of tests performed in laboratory, must allow clinicians to practice good medicine (4-6).

Quality in laboratory medicine is the guarantee that each and every step in the Total Testing Process (TTP) is correctly performed, thus ensuring valuable decision making and effective patient care (6). Errors can occur in any step of the process; these in turn directly lead to increased healthcare costs and decreased patient satisfaction. The impact of error during laboratory testing process can affect patient care in many ways, such as delay in reporting, unnecessary redraws, misdiagnosis, and improper treatment (7).

Evidence in recent decades proves that pre-, intra- and post-analytical processes are equally important for ensuring quality laboratory service. Thus, quality in clinical laboratories is assured by focusing on all analytical aspects. Studies show that the pre-analytical phase accounts for 46% to 68.2% of errors observed during the TTP compared to 13-32% in the analytical and 19-47% in the post-analytical phases. Pre-analytical and post-analytical errors combined account for 93% of the total errors encountered in the laboratory (8-10).

Evidence show that the risk of inappropriate care due to laboratory errors ranges from 6.4% to 12% and the incidence of further inappropriate investigations is much higher (19%) (11, 12). Poor laboratory performance that causes an error and delays in diagnosis and treatment is an obstacle to optimal patient care, particularly in high volume patient care areas such as University of Gondar (UOG) Hospital. Although a study was conducted in UOG hospital laboratory, it focused only on pre-analytical errors. It did not show errors occurring during the TTP. In addition, UOG Hospital laboratory

was recognized as a three-star level laboratory in the World Health Organization Regional Office for Africa accreditation system on November 18, 2011, its level has come down to one-star level on September 1, 2015 (13). It is a big issue that questions laboratory performance.

Identifying and evaluating errors in TTP is mandatory by using a quality indicator (14). The hypothesis of this study was an inspection of the TTP using quality indicator would enable identification of critical errors at any point of laboratory procedure. In addition, persistent evidence-based identification of laboratory performance through evaluation of pre-, intra-, and post-analytical errors that undermine laboratory quality status helps to put a new strategy to minimize and control errors, and improve processes. Therefore, the aim of this study was to assess errors in TTP in Clinical Chemistry laboratory of UOG Hospital.

2. Methods and materials

2.1.Study area

The study was conducted at UOG Hospital laboratory. Gondar town is located 738 km far from Addis Ababa, the capital city of Ethiopia. The town has around nine government health centers and one University Hospital. The Hospital is a tertiary level teaching Hospital that provides health services for more than 5 million inhabitants in Northwest Ethiopia. UOG Hospital has diagnostic laboratory service like Clinical Chemistry, Hematology, Microbiology, Parasitology, Serology, Urinalysis and Emergency laboratories that plays important role in teaching, research and community service. The laboratory has equipped automated instruments in the Clinical Chemistry section, such as Mind ray - BS 120 Auto Chemistry Analyzer, mini *VIDAS*® automated immunoassay, and Roche Diagnostics AVL 9180 Series Electrolyte Analyzers. Previously there was Laboratory Information System (LIS). However, the LIS service was non-functional during the study period. Clinical Chemistry performs a large number of tests. These include lipid profile tests, kidney function tests, liver function tests, electrolyte profile tests, hormonal analysis, cancer markers detection, measurement of glucose and troponin. Approximately on average 120 samples run per day. These tests are manipulated in Clinical Chemistry with 4 Medical laboratory Scientists and 2 Clinical Chemists.

2.2 Study Design and Period

A cross-sectional study was conducted from February 1 to March 30, 2016, to assess errors in TTP in Clinical Chemistry laboratory of UOG Hospital.

2.2.1 Sample Size and Sampling Technique

The study included all test requests that were referred to Clinical Chemistry tests at the UOG Hospital during the study period. The total sample size of the study was the total number of requests ordered to Clinical Chemistry tests during the study period. All test requests ordered to Clinical Chemistry tests taking into account venous blood sample were included using consecutive sampling technique.

2.2.2 Data Collection Methods and Processes

Process inspection sheets were formulated to help in the evaluation of pre-, intra- and post-analytical errors for Clinical Chemistry tests at UOG Hospital. Inspection sheets were based upon the International Federation of Clinical Chemistry (IFCC) approved quality indicators (14) and literature review of similar studies (9, 15-18). Nine investigators participated in this study. Training was given to all investigators. Data were collected in the Clinical Chemistry section during routine hours each day in the study period. The principal investigator has closely followed and checked the data collection process to ensure the completeness and consistency of the collected data.

2.2. Inclusion and Exclusion Criteria Inclusion criteria

The study was conducted on processes at pre-, intra-, and post-analytical phases. Requests which were ordered for Clinical Chemistry tests taking into account venous blood sample (serum sample) were included in the study.

2.2.1. Exclusion Criteria

Urine and other body fluids such as serous fluid, synovial fluid, and cerebrospinal fluid were not included in this study. Moreover, only test requests ordered for Clinical Chemistry tests were included. Those requested analyses for Hematology, Coagulation, Serology, Urinalysis, Emergency laboratory, and Microbiology were not included in this study.

2.3. Data Management and Quality Control

Pre-test of the checklist was done to check clarity, acceptability, and consistency of the structured inspection sheets. A necessary correction was taken before the actual data collected. The data collection, in accordance with quality indicators was checked by senior laboratory technologist and principal investigator. Close follow up has been done by the principal investigator. The filled checklist was collected to check consistency and completeness.

2.4 Data Analysis and Interpretation

The data were checked for completeness and entered EPI info version 3.5.3 then transferred to Statistical Package for the Social Sciences (SPSS) version 20 (IBM Corporation, New York, United States) for analysis. Independent t-test, frequencies, and cross tabulations were used to summarize descriptive statistics.

2.5 Ethical Clearance

Ethical clearance was taken from Research and Ethical Review Committee of School of Biomedical and Laboratory Sciences, UOG. Permission letter was secured from both medical director of the Hospital and diagnostic coordinator of UOG Hospital. All data obtained were kept confidential by using codes instead of any personal identifier. Detectable errors were linked to the responsible personnel for better patient management and quality improvement purpose.

3. Results

According to this study, 3259 blood samples and their request papers were inspected. Out of which 2287 (70.1%) were from outpatient department (OPD) and 972(29.8%) were from Inpatient Department (IPD).

3.1 Parameters on the Test Request Form

The information provided on each request form was examined. Only 3 (0.09 %) requisition papers have been found to have complete data (a requested paper containing all the necessary information) the rest did not contain full information that they were supposed to contain. Indicators of patient information such as clinical data 3226 (99%) were not filled on the test request form. However, patient's name, sex, age and hospital number were relatively more mentioned. The name 1262 (38.7%) and the exact address 60 (1.8%) of the requesting physicians were not specified on the test request

form. Sample quality indicators on test request form, time of collection (99.3%), and date of sampling (40.1%) were missed on test request form (Table 1).

Table 1: Frequency Of Missed Data on Routinely Submitted Test Request Forms in Clinical Chemistry Laboratory at UOG Hospital from February tTo March 2016, Northwest Ethiopia

Data type	OPD N(%)	IPD N(%) n=972	Total N(%)	Sig. (2-tailed)
Patient name	0 (0.0)	0 (0.0)	0 (0.0)	
Hospital number	1 (0.04)	3 (0.3)	4 (0.1)	0.048
Patient sex	13 (0.6)	5 (0.5)	18 (0.6)	0.849
Patient age	14 (0.6)	5 (0.5)	19 (0.6)	0.737
Physician name	1006 (44.0)	256 (26.3)	1262 (38.7)	0.000
Patient clinical	2269 (99.2)	957 (98.5)	3226 (99.0)	0.049
Patient location	32 (1.4)	28 (2.9)	60 (1.8)	0.000
Date of sampling	1072 (46.9)	235 (24.2)	1307 (40.1)	0.000
Test ordered	1 (0.04)	0 (0.0)	1 (0.03)	0.515
Time of sampling	2281 (99.7)	956 (98.4)	3237 (99.3)	0.000
Over all incomplete request form	2286 (99.9)	970 (99.8)	3256 (99.9)	0.160

Note: *IPD: Inpatient Department, OPD: Out Patient Department, UOG: University of Gondar*

3.1. Sample Quality Indicators

The other observation made during the study period was an assessment of sample quality. Of the total number, 3259 samples submitted to the laboratory for Clinical Chemistry tests, 123 (3.8%) were rejected. The most common reason for sample rejection was haemolysis, 41 (1.3%) followed by the request with no sample or sample with no request 39 (1.2%), and mislabeled 35 (1.1%) (Table 2).

Table 2: Type and Frequency of Reason for Sample Rejected in Clinical Chemistry Laboratory at UOG Hospital from February to March 2016, Northwest Ethiopia

Parameter	OPDN (%)	IPD N (%)	Total N (%) n=3259
Haemolysis	19 (0.6)	22 (0.7)	41 (1.3)
Lipemic sample	4 (0.1)	0 (0.0)	4 (0.1)

Parameter	OPDN (%)	IPD N (%)	Total N (%)n=3259
Insufficient volume of sample	0 (0.0)	2 (0.1)	2 (0.1)
Mislabeled	29 (0.9)	6 (0.2)	35 (1.1)
Sample with no request/request with no sample	28 (0.9)	11 (0.3)	39(1.2)
Test not ordered/inappropriate test	0 (0.0)	2 (0.1)	2 (0.1)
Total	80 (2.5)	43 (1.3)	123 (3.8)

Note: IPD: Inpatient Department, OPD: Out Patient Department, UOG: University of Gondar

3.2.Quality Indicators Covering the Analytical Phase

Unacceptable performances in External Quality Control (EQC) accounted 18 (51.4%), followed by non-conformity of Internal Quality Control (IQC) 81 (14.4%) (Table 3)

Table 3: Error Frequency of Analytical Phase in Clinical Chemistry Laboratory at UOG Hospital from February to March 2016, Northwest Ethiopia.

	IQC N (%)	EQC N (%)	Total N (%)
Pass	481 (85.6)	17 (48.6)	498 (83.4)
Fail	81 (14.4)	18 (51.4)	99 (16.6)
Total	562 (100.0)	35 (100.0)	597 (100.0)

Note: IQC: Internal Quality Control, EQC: External Quality Control

Quality Indicators in the Post-Analytical Phase

In the post-analytical phase, 291 (9.3%) errors were observed. Excessive Turnaround Time (TAT), 270 (8.6%) contributed to the majority of post-analytical errors followed by unreported critical value cases, 15(0.48%). All critical value cases were not communicated to the concerned physician. Although this laboratory didn't have functional laboratory information system (LIS) currently, manual reporting accounted only 6 (0.2%) transcription errors (Table 4). Pre-analytical phase was found to be error prone process among the total errors (Table 5).

Table 4: Error Frequency Of Post-Analytical Phase In Clinical Chemistry Laboratory At UOG Hospital From February To March 2016, Northwest Ethiopia

Parameter	(n = 3136) Frequency (%)
Excessive TAT	270 (8.6)
Not informed critical result	15 (0.48)
Data transcription errors	6 (0.2)
Total	291 (9.3)

Note: TAT: turnaround time, UOG: University of Gondar

Table 5: Distribution of total testing process error frequency in the Clinical Chemistry laboratory at UOG Hospital from February to March 2016, Northwest Ethiopia

Phase	Error frequency (%)	Error frequency (%)
	A	B
Pre-analytical*^{6518}	3379 (51.8)	3379 (89.6)
Analytical*^{597}	99 (16.6)	99 (2.6)
Post-analytical*^{3136}	291 (9.3)	291 (7.7)
Total*^{10251}	3769 (36.8)	3769 (100)

Note: the asterisk (*) indicates denominator for each phase in the 'A' column
A: Error frequency in the pre-analytical, analytical, and post-analytical phases
B: Overall percent of errors in the three analytical phases

4. Discussion

In this study, errors in TTP in Clinical Chemistry laboratory were assessed based on IFCC quality indicators. Currently, there is lots of emphasis on managing TTP in clinical laboratories. This supports a quantitative basis for interested parties aiming to guarantee improvement and up to date performance in care and processes (14, 19).

Accordingly, 3259 request papers were submitted to the Clinical Chemistry laboratory. Pre-analytical errors associated with request form accounted 49.9% due to the omission of important data. Significantly, 3256 (99.9%) request papers were incomplete, lacking one or more of the required information. The only well-documented parameter appeared on all request forms in this study was the patient's name. This result was similar with the

finding in Ethiopia (18), Pakistan (20), and Ghana (21). This was not astonishing since it was very likely that the request would have been rejected if the patient's name was not mentioned. However, the name of the attending physician was omitted in 38.7% of test request forms observed. This figure was higher than a study conducted in Nigeria reported 19.8% (22). The rationale behind this figure could be attributed to lack of awareness and variability of physicians attending the patient on one site since most physicians visiting the patient were interns.

Besides, this study shows that clinical data (99%) and time of sampling (99.3%) were found to be incomplete on the request forms. This result is consistent with the previous study done in a similar setting in Ethiopia (18), the authors stated that clinical data (97.8%) and time of sampling (100%) have been missed. This result indicates no improvement after the previous report at similar setting in Ethiopia (18) which demands extra management effort to create awareness concerning the impact of incomplete test request form on the quality of patient care.

Moreover, 40.1% of the request forms observed did not state the date of sampling. This was comparable to the results obtained in a similar study conducted in Ghana (37.3%) (21). but it is higher than the results obtained in Nigeria (0.5%) (23). This variation could be attributed to the workload on physicians, attitudinal difference and negligence among physicians, lack of monitoring by the concerned body or improper orientation about the impact of incomplete test request form on the quality of patient care.

In our study, 3.8% samples were rejected for various reasons. This figure was lower than a study conducted in India (4.91%) (19), but it is higher than the rejection rate reported in Ethiopia (2.4%) (18), (1.4%) (24), Turkey (0.91%) (25) and USA (0.74%) (26). Moreover, high staff turnover, the periodic influx of students, frequent job rotation of phlebotomists, increased patient flow or poor quality management system, would be the main cause for increased sample rejection.

In this study, the most common frequent cause for sample rejection was haemolysis (33.3%) which is comparable in a study conducted in Ethiopia (24), Nigeria (27), and Spain (28) reported haemolysis as the main cause for sample rejection. Increased haemolysis observed from this study could be the

result of poor phlebotomy procedures or periodic influx of students in the institutions.

Remarkably, the second frequent reason for sample rejection was a sample with no request which accounted 31.7%, which is higher than the result reported in Ethiopia (24). The same figure for mislabeled samples is 28.5% in the current study. This could be due to excessive patient load (disproportionate of patients to phlebotomists), the absence of functional LIS and pneumatic tube complicated proper labeling and delivery of samples with corresponding request forms. Loss of attention and poor communication between staffs might have further aggravated the problem.

In our study, a total of 16.6% analytical error is seen as compared to India report (5.07%) (19). Of which unacceptable performance in IQC accounted 14.4%, which could be due to the improper reconstitution of quality control (QC) material, inappropriate storage, instability of reagents or contamination or calibration drift. This figure (14.4%) was much higher than India (0.6%) non-conformity of QC (29). The difference could be attributed to the difference in the use of QC material, operator, type of machine, environmental condition, or implementation of quality assurance system.

Unsatisfactory evidence has been found from the external agency as part of the involvement of proficiency testing program which showed EQC exceeding the target range accounted 51.4%. It indicated a need to address shortcomings related to analytical process, which is much higher when compared to a report of Spain (0.8%) (30). Instability of the instrument due to fluctuation in electricity, lack of laboratory staff training about automation and quality management system, staff turnover or frequent changes of staffs without training could be attributed to the remarkable increment in the analytical errors.

In the current study, the frequency of errors in post-analytical phase was 9.3% almost triple than the India (3.2%) (29). Even though, the percentage of transcription error has contributed much in some literature (29), in this study, excessive TAT (8.6%) has contributed to the majority of post-analytical errors. Electrical fluctuation, shortage of distilled water and workload could be the cause for not reporting results within a specified time. Manual reporting of results accounted only 0.2% transcription errors. Since it is all

about the life of the human being, it does not mean that the result of this study is low.

Another important aspect of the post-analytical phase of the testing process was critical value reporting. On examination of critical value reporting, 15 (0.48%) critical value cases were observed almost double that of India's report (0.21%) (19), and none of them has been communicated to the concerned physician. Lack of functional LIS, poor awareness among laboratory staffs, missed parameter on the test request form such as patient address, attending physicians, and telephone complicated in difficulty to notify within the target time, failure to deliver a critical value notification within the indicated time could be life-threatening if the patient is left untreated. In fact, implementation of electronic LIS can improve the post-analytical phase. This might eliminate transcriptional errors and delay in results.

In general, the overall statistics shows that the error frequency was 89.6% in the pre-analytical phase, 2.6% in the analytical and 7.7% in the post-analytical phase. Results reported in Netherlands with a certain difference to this study show that the distribution of errors; pre-analytical 68.2%, analytical 13.3%, and post-analytical 18.5% (31). This variation is difficult to explain with regard to the relative frequency of errors observed in the different phases, being different in work complexity, in the implementation of quality management system and method of error detection. Similarly, the frequency of errors may differ from institution to institution and from time to time.

This study provides literature regarding the errors in the total testing process in clinical laboratories and points out errors in the TTP that affect the quality of the laboratory service. Therefore, errors detected can be prevented from recurring, thus; make better laboratory quality. As a limitation to this study, the whole story of errors in TTP cannot be addressed. Hence, further in-depth study to evaluate details of errors in TTP, including pre-pre-analytical phases such as sampling, sample transportation and the like, and post-post-analytical phases should be conducted. Another limitation was the inability to assess the impacts of laboratory errors on patient health and the entire healthcare system. These can be a possible area for future research.

To conclude, this study reported a high frequency of errors in the TTP. These indicate a need to address shortcomings related to each analytical process. Therefore, a continuous practice of assessing errors is mandatory to help in devising corrective strategies. This helps to improve laboratory performance and hence effective clinical decision-making process.

Acknowledgement
We are very grateful to the University of Gondar, College of Medicine and Health Sciences, School of Biomedical and Laboratory Sciences for logistic and financial support for this study. Our special thanks also go to University of Gondar Hospital laboratory staff members, especially Clinical Chemistry laboratory workers for their kind cooperation during data collection.

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