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Assessment of hematology laboratory performance in the total testing process using quality indicators and sigma metrics in the northwest of Ethiopia: A cross-sectional study

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Abstract

Background and Aims: Assuring laboratory quality by minimizing the magnitude of errors is essential. Therefore, this study aimed to assess hematology laboratory performance in the total testing process using quality indicators and sigma metrics.

Methods: A cross-sectional study was conducted from April to June 2022. The study included a total of 13,546 samples. Data on included variables were collected using a checklist. Descriptive statistics were used to present the overall distribution of errors. Binary logistic regression models were applied. Furthermore, using a Sigma scale, the percentage of errors was converted to defects per million opportunities to assess laboratory performance. Finally, the defect per million opportunities was converted to a sigma value using a sigma calculator.

Results: Of the 13,546 samples and corresponding requests, the overall error rate was 123,296/474,234 (26%): 93,412/47,234 (19.7%) pre-analytical, 2364/474,234 (0.5%) analytical, and 27,520/474,234 (5.8%) post-analytical. Of the overall errors, 93,412/123,296 (75.8%), 2364/123,296 (1.9%), and 27,520/123,296 (22.3%) were pre-analytical, analytical, and post-analytical errors, respectively. The overall sigma value of the laboratory was 2.2. The sigma values of the pre-analytical, analytical, and post-analytical phases were 2.4, 4.1, and 3.1, respectively. The sample from the inpatient department and collected without adherence to the standard operating procedures (SOPs) had a significantly higher ($p < 0.05$) rejection rate as compared to the outpatient department and collected with adherence to SOPs, respectively. In addition, an association between prolonged turnaround times and manual recording, inpatient departments, and morning work shifts was observed.

Conclusion: The current study found that the overall performance of the laboratory was very poor (less than three sigma). Therefore, the hospital leadership should change the manual system of ordering tests and release of results to a computerized system and give need-based training for all professionals involved in hematology laboratory sample collection and processing.

KEYWORDS
hematology, laboratory, quality indicators, sigma metrics, testing process

1 | INTRODUCTION

In clinical medicine, improving the performance of laboratory services has a substantial role in providing accurate, precise, and timely results for patient care.[1] The studies showed that about 70% of clinical decisions regarding hospitalization, admission, prescription, and discharge are dependent upon laboratory results. As a result, ensuring the quality of laboratory services in the total testing process (TTP) is vital for the improvement of patient care.[2–4] The TTP encompasses the pre-analytical, analytical, and post-analytical phases of laboratory testing. Laboratory errors can occur at all phases.[5,6]

International Organizations for Standardization (ISO) defines errors as a failure of a planned action to be completed as intended.[7] Laboratory error is any defect or deviation of the result from the expected value.[8] In TTP, the pre-analytical error is the most prevalent, comprising, incorrect filling of the request form, incorrect labeling, sample clotting, hemolysis, insufficient volume, and the wrong blood-to-anticoagulant ratio.[9–11] Post-analytical error is the second most prevalent error, comprising, improper verification, delay in reporting, incorrect calculation, and critical results not reported. Analytical errors include pipetting errors, misinterpretation of results, the wrong procedure, incorrect standards, and calibration procedures.[12–15]

Quality indicators (QIs) and quality control (QC) programs are established to assure the quality of laboratory services by identifying defects alone. These parameters, however, are insufficient because they do not provide a direct and integrated assessment of test process performance in the laboratory.[2] Therefore, implementing another process improvement method like sigma metrics is critical to support or replace the existing QC mechanisms in the clinical laboratories.[16]

Sigma metrics are one of the tools to evaluate laboratory process performance in terms of defects per million opportunities (DPMO). The evaluation of laboratory errors out of one million tests rather than the frequency of defects out of 100% alone is more meaningful to improve the process.[17] Six sigma performance attainments require 3.4 DPMO, indicating the performance of the laboratory is world-class. The minimum acceptable sigma value for quality laboratory service is 3.[18] A lower sigma metrics value indicates higher errors, and many acceptable test results are falsely rejected, which makes it more difficult to use in the analysis of patient samples.[8]

According to available evidence, at least one laboratory error could occur between 214 and 8316 laboratory tests.[19] It causes around 6.4%–12% of inappropriate patient care, including death.[20] In addition, laboratory errors lead to delayed diagnosis, additional laboratory testing, incorrect treatment, increased healthcare costs, and minimized patient satisfaction.[21,22]

In the TTP, pre-analytical errors account for 46%–68.2%, followed by post-analytical errors (19%–47%) and analytical errors (13%–2%).[23,24] In African countries, the magnitude of laboratory errors is higher than on other continents because of inadequate healthcare infrastructure, low-trained employees, poor management systems, terrible control devices, shortages of equipment, weak government policies, and demotivated workers. Consequently, achieving sustainable laboratory performance has major hindrances.[1,25]

According to the ISO 15189 report, the performance of many African laboratories is still below standard, and the quality of their services is poor.[26] Similarly, the majority of clinical laboratories in Ethiopia are not yet accredited, and their quality is below standard. But still, laboratory errors received little attention.[26,27] As a result, strengthening laboratory service through periodic assessment of the frequency of errors and sigma metrics performance level in all phases of TTP is essential to providing quality laboratory service. However, in Ethiopia and the study area, there is no adequate data that shows the overall magnitude of errors and the sigma metrics performance level of the hematology laboratory. Therefore, this study tried to assess the overall magnitude of errors and sigma metrics performance level of the hematology laboratory in TTP at the University of Gondar Comprehensive Specialized Hospital.

2 | MATERIALS AND METHODS

2.1 | Study design, period, and setting

A cross-sectional study was conducted from April to June 2022 at the University of Gondar Comprehensive Specialized Hospital Hematology Laboratory. The hospital is located 738 km away from the capital city of Ethiopia, Addis Ababa.[28] The hospital provides medical services for more than 7 million people in its catchment area and the nearby zones. The hospital has nine separate laboratory sections, including a hematology laboratory. On an annual basis, approximately 70,000 samples are collected and analyzed in the laboratory. The laboratory has been involved in the stepwise laboratory quality improvement process toward accreditation (SLIPTA) by the Ethiopian National Accreditation Office, but its performance has not been satisfactory.

2.2 | Inclusion and exclusion criteria

All blood sample collectors, laboratory professionals at the hematology unit, hematological samples and test requests, and daily internal quality control (IQC) data of hematology tests were included. However, tests requested with samples for nonroutine hematology tests such as pleural, synovial, cerebrospinal, and peritoneal fluids were excluded.

2.3 | Variables

Sigma metric performance level and the frequency of errors were dependent variables. Sample collection site, work shift, educational level, system of recording, clinic or ward, sex, age, work experience, laboratory quality management system (LQMS) training, and adherence to SOP of professionals were independent variables.

2.4 | Study definitions

Pre-analytical errors: any defect or mistake that will occur before sample analysis.

Analytical errors: any defect or mistake that occurs while testing or analysis.

Post-analytical errors: any defect or mistake that occurs after analysis or testing.

Total error/overall error: all errors that can occur during the TTP.

Critical values: results that exceed or below the reference range and need immediate medical attention.

Hemolysis is defined as in vitro or vivo destruction of RBCs that cause visibly red plasma in a tube of ethyl diamine tetra acetic acid anticoagulated settled blood.

Clotted sample: can defined as plasma in solid form that may clog the analyzer probe.

Sufficient sample: can be defined as the volume of sample collected less than 2 mL for CBC and erythrocyte sedimentation rat (ESR) analysis and hematocrit (HCT) tube filled less than 1/3 of its length for HCT measurement.

Sample delayed: the sample left at room temperature greater than 4 h without analysis for CBC, ESR, and HCT, and greater than 4 h without preparing smear and subsequently fixing the smear for peripheral morphology (PM).

Wrong sample storage: delayed sample not stored as policy.

Turnaround time is defined as the interval between the time of sample collection and the report released to the physicians.

Sample collector: a laboratory or other health professional who is assigned to collect clinical Hematology blood specimens.

Work shift is defined as a period when the clinical Hematology Laboratory is fully functional. It has two shifts, each will comprised of 4:30 h (first shift from 8.00 a.m. to 12:30 p.m. and second shift from 12.31 p.m. to 17:00 p.m.).

Sigma Metrics is the maximum number of standard deviation (SD) closest to the tolerance limit from the mean of the assay.

Unacceptable overall performance: the average sigma value was less than or equal to 3. Acceptable overall performance: the average sigma value was greater than 3.

2.5 | Data collection procedure

During the study period, 13,546 blood samples with their corresponding request were evaluated by eight data collectors to collect all necessary information. The data were collected by a pre-tested checklist to evaluate errors in the TTP of the hematology laboratory. The checklist was prepared based on QIs from guidelines and previous studies.[9,10,29–31] All the data collectors were laboratory professionals with training in LQMS. They were trained on how to collect all the necessary data for the assessment of all phases of testing based on QIs.

The laboratory test request forms' completeness was assessed prospectively by six data collectors assigned to sample collection sections. The two data collectors assigned to the hematology sections evaluated pre-analytical variables specifically related to specimen quality, analytical variables, and post-analytical variables. Furthermore, qualitative data were collected based on key informant face-to-face interviews to assess factors related to blood sample collectors and hematology laboratory professionals by the data collector assigned at the sample collection site. Moreover, other factors, such as the sample collection site and adherence to the SOP and system recording, were collected at both the sample collection and analysis sections through direct observation.

2.6 | Data quality control

Data quality was assured using a pre-tested checklist. It was used to ensure the feasibility and validity of study tools. In addition, the quality of the data was assured with a close follow-up of the completeness of the checklist on the spot by the data collectors at each phase of the testing process. A supervisor provided feedback and took corrective action on a daily basis during the data collection process. In addition, the completeness and clarity of the collected data were checked carefully and regularly by the principal investigator.

2.7 | Data analysis and interpretation

After checking its completeness manually, the data were entered into Epidata version 3.1 and exported to SPSS version 20 for analysis. Descriptive statistics such as frequency and percentage were used to present the general information of the study and the distribution of errors in the hematology laboratory. A two-sided χ^2 test was used to test the presence of association between categorical data. The simple and multivariate logistic regression model was used to estimate the crude odds ratio (COR) and adjusted odds ratio (AOR), respectively. Variance inflation factors were used before the analysis of multivariate logistic regression model. The Hosmer and Lemeshow goodness test was applied to assess the fitness of the model. The statistical significance level was set p value to 0.05 and 95% CI for all statistical analyses. Moreover, to measure the performance of the laboratory using the Sigma scale, defect rates were calculated at 100%, followed by conversion to the DPMO. Finally, the obtained DPMO values were converted to the corresponding sigma metrics value using a sigma calculator.

2.8 | Ethical consideration

Ethical approval was obtained from the Ethical Review Committee of the School of Biomedical and Laboratory Sciences, College of Medicine and Health Science, the University of Gondar (ref. no. SBLS/182/2014). Before data collection began, the permission was obtained from all the concerned bodies of the hospital. Besides, before collecting data used to assess associated factors from blood specimen collectors written informed consent was obtained. Detectable errors were linked to the responsible bodies for better patient management and quality improvement purposes by maintaining confidentiality.

3 | RESULTS

3.1 | General information of the study

During the study period, a total of 13,546 tests were requested: CBC (11,398), ESR (1508), HCT (555), and PM (85). Of the total tests requested, 9003 (66.5%) were from the OPD (outpatient department) and 2092/13,546 (15.4%) were from the IPD (inpatient department), but in the remaining requests, the name of sender was not specified on the request paper. Out of the total samples requested during the study period, 10,252/13,546 (75.7%) were requested during the morning work shift, while 3294/13,546 (24.3%) were requested during the afternoon work shift. From the total samples assessed, 12,825/13,546 (94.7%) were recorded by the laboratory information system (LIS), while 721/13,546 (5.3%) were recorded manually. In the study settings, blood samples were collected by both laboratory professionals and nonlaboratory health professionals. All nonlaboratory health professionals were untrained in laboratory quality management.

3.2 | The frequency of errors and the sigma metrics level of the pre-analytical phase related to missed information on laboratory requests

From the total of 13,546 hematology laboratory test requests evaluated, the lowest frequency of request incompleteness was detected in name of test ordered 0/13,546 (0%), medical record number (MRN) 66/13,546 (0.5%), patients' age 205/13,546 (1.5%), and patients' sex 197/13,546 (1.5%). On the other hand, the highest frequency of request incompleteness was detected in patients' clinical data 13,543/13,546 (99.99%) and patients' addresses 13,417/13,546 (99%). The sigma values for MRN, the patient's age, and sex were 4.1, 3.7, and 3.7, respectively (Table 1).

3.3 | The frequency of errors and the sigma metrics levels of the pre-analytical phase related to specimen quality, collection, preparation, storage, and transportation

In this study, the frequencies of hemolyzed, wrongly labeled, clotted, and insufficient samples were 246/13,546 (1.8%), 246/13,546 (1.8%), 212/13,546 (1.56%), and 20/13,546 (0.15%), respectively,

TABLE 1 Frequency of errors and sigma metrics levels on hematology laboratory request forms at the University of Gondar Comprehensive Specialized Hospital, northwest Ethiopia, 2022.

Variables	Missed information Number/%	Not missed information Number/%	Total/%	DPMO	Sigma value
Appropriate and authorized requests	10,884/80.3	2662/19.7	13,546/100	803,484	<3
MRN	66/0.5	13,480/99.5	13,546/100	4872	4.1
Patient age	205/1.5	13,341/98.5	13,546/100	15,134	3.7
Patient sex	197/1.5	13,349/98.5	13,546/100	14,543	3.7
Signature of the physician	12,823/94.7	723/5.3	13,546/100	946,626	<3
Clinical history of the patient	13,543/99.99	3/0.01	13,546/100	999,999	<3
Patients address	13,417/99	129/1.0	13,546/100	990,477	<3
Name of sender address/ward	6846/50.5	6700/49.5	13,546/100	505,389	<3
Date of test ordered	9674/71.4	3872/28.5	13,546/100	714,159	<3
Name of test ordered	0/0	13,546/100	13,546/100	0	>6
Time of sample collection	13,235/97.7	311/2.3	13,546/100	97,704	<3
Handwriting legible	3310/24.4	10,236/75.6	13,546/100	244,353	<3
Total	84,200/51.8	78,352/48.2	162,552/100	517,988	<3

Abbreviations: DPMO, defect per million opportunities; MRN, medical record number; %, percentage.

with a sigma value of sample hemolyzed, wrongly labeled, clotted, and insufficient were 3.6, 3.6, 3.7, and 4.5, respectively. In addition, the frequency of the test requests lost and samples lost was 82/13,546 (0.8%) and 56/13,546 (0.41%), with a sigma value of 4.1 for each. From the total opportunities for pre-analytical QIs (n = 343,891), 93,412 (27.2%) pre-analytical errors were observed. The overall pre-analytical sigma metrics levels out of the total pre-analytical QIs were less than 3 (Table 2).

3.4 | The frequency of errors and sigma metrics levels of analytical phase

In the current study, none of the nonlinear and questionable test results were released after retesting and morphology verification. Furthermore, of the 63 IQCs expected daily, all were performed and were within acceptable ranges. In addition, 12/63 (15.2%) of preventive maintenance was not performed as expected. Of the total QIs (n = 21,277) assessed in the analytical phase, 2364/21,277 (11.1%) analytical errors were observed. The sigma value for nonlinear results and questionable results that were released without retesting and checking by morphology was less than 3. Furthermore, the sigma values for IQC passed and IQC performed as expected were greater than 3. The overall sigma value of the analytical phase of the QIs assessed was 2.8 (Table 3).

3.5 | The frequency of errors and sigma metrics performance level of post-analytical phase

Among the post-analytical QIs evaluated (n = 109,066), none of the critical test results were communicated to physicians, and samples were retained as per policy. Almost all 12,318/12,384 (99.9%) test results were not verified and signed by authorized personnel. In addition, 1027/10,372 (10.3%) results were released outside of the expected TAT. Of the total post-analytical phase QIs (n = 109,066), post-analytical errors were identified in 27,520/109,066 (25.2%). The sigma values for lack of critical result communication with physicians, result release without verification, and prolonged TAT were less than 3. The mean sigma value for the post-analytical phase out of QIs assessed for the post-analytical phase was less than 3 (Table 4).

TABLE 2 Frequency errors and sigma metrics levels of hematology laboratory in pre-analytical phases related to specimen quality, collection, preparation, storage, and transportation, University of Gondar Comprehensive Specialized Hospital, northwest, Ethiopia, 2022.

Variables	Yes Number/%	No Number/%	Total (N/%)	DPMO	Sigma value
Hemolyzed samples	246/1.8	13,300/98.2	13,546/100	18,160	3.6
Clotted samples	212/1.56	13,334/98.44	13,546/100	15,650	3.7
Insufficient volume	20/0.15	13,526/99.85	13,546/100	1476	4.5
Incorrect containers	4/0.002	13,542/99.98	13,546/100	296	5
Incorrectly labeled specimens	246/1.8	13,300/98.2	13,546/100	18,160	3.6
Delayed samples	14/0.1	13,532/99.9	13,546/100	1034	4.6
Wrong sample transportation	28/0.2	13,518/98.8	13,546/100	2067	4.4
Sample lost	56/0.41	13,490/99.2	13,546/100	4134	4.2
Requests lost	82/0.6	13,464/99.4	13,546/100	6053	4.1
Unacceptable quality smears	20/23.5	65/76.5	85/100	235,294	<3
Wrong sample storage	14/100	0/0	14/100	1,000,000	<3
Blood mixed with anticoagulant improperly	823/7.4	10,262/92.6	11,085/100	74,244	3
Improperly sealed capillary tube	37/6.7	518/93.3	555/100	66,667	3.1
Incorrect anticoagulant-to-blood ratio	5186/38.3	8360/61.7	13,546/100	382,844	<3
Patients identified improperly	1216/11	9869/89	11,085/100	90,909	<3
Incorrect tourniquet application time	965/8.8	9954/91.2	10,919/100	88,378	<3
Blood unmixed before analysis	43/0.35	12,093/99.65	12,136/100	3543	4.2
Total	9212/5	172,127/95	181,339/100	50,323	3.2
Grand total pre-analytical errors	93,412/27.2	250,479/72.8	343,891/100	271,633	<3

Abbreviations: DPMO, defect per million opportunities; N, total frequency; %, percentage.

TABLE 3 The frequency of errors and the sigma metrics levels of the hematology laboratory in the analytical phase at the University of Gondar Comprehensive Specialized Hospital, Northwest Ethiopia, 2022.

Variables	Yes (N/%)	No (N/%)	Total (N/%)	DPMO	Sigma value
IQC results failed	0	63/100	63/100	0	>6
Daily IQC not performed	0/0	63/100	63/100	0	>6
Preventive maintenance not performed	12/15.2	67/84.8	79/100	151,899	<3
Equipment mal-functionality observed	3/4.8	60/95.2	63/100	47,619	3.2
Reference range unavailable for parameters	0/0	24/100	24/100	0	>6
Electric power inconsistency during analysis	598/5.3	10,621/94.7	11,219/100	53,302	3.2
Nonlinear results released without retesting	9/100	0/0	9/100	1,000,000	<3
Reagents expired	3/4.8	60/95.2	63/100	47,619	3.2
Inappropriate reagent storage condition	0/0	63/100	63/10	0	>6
Improperly filled ESR tube	66/4.9	1290/95.1	1356/100	48673	3.2
Position of ESR tube wrong	10/0.7	1346/99.3	1356/100	7375	4.0
Delay in ESR results reading	0/0	1356/100	1356/100	0	>6
ESR samples analyzed at wrong temperature	0/0	1356/100	1356/100	0	>6
Questionable results were not retested	776/100	0/0	776/100	1,000,000	<3
Critical results were not checked by PM	776/100	0/0	776/100	1,000,000	<3
HCT tube leaked	41/8.2	459/91.8	500/100	82,000	<3
HCT tube broken	8/1.4	547/98.6	555/100	14,414	3.7
Speed of centrifuge adjusted improperly	0/0	439/100	439/100	0	>6
Time of centrifuge adjusted improperly	0/0	439/100	439/100	0	>6
HCT results measured incorrectly	10/2.3	429/97.7	439/100	22,779	3.5
Smears not air-dried	0/0	55/100	55/100	0	>6
Incorrect preparation of working solution for PM	2/3.2	61/96.3	63/100	31,746	3.4
Smears stained at incorrect time	40/72.7	15/27.3	55/100	727,273	<3
Incorrectly washed smears	6/10.9	49/89.1	55/100	109,091	<3
Incorrectly examined smears	4/7.3	51/92.7	55/100	72,727	3.0
Total	2364/11.1	18,913/88.9	21,277/100	111,106	<3

Abbreviations: DPMO, defect per million opportunities; ESR, erythrocyte sedimentation rat; HCT, hematocrit; IQC, internal quality control; N, total frequency; PM, peripheral morphology; %, percentage.

3.6 | The overall prevalence of errors and performance levels by sigma metrics in hematology laboratory

Of the total QIs assessed in this study ($n = 474,234$), the total hematology laboratory errors observed were 123,296/474,234 (26%). Of these, the frequencies of 93,412/123,296 (74.8%), 2364/123,296 (1.9%), and 27,520/123,296 (22.3%) were detected in the pre-analytical, analytical, and post-analytical phases, respectively. The overall sigma value of the hematology laboratory was 2.2 (DPMO = 259,990). The mean sigma values for pre-analytical, analytical, and post-analytical phases out of the total QIs assessed were 2.4, 4.1, and 3.1, respectively (Table 5).

3.7 | The factors associated with prolonged TAT and sample rejection

With regard to TAT, the bivariate logistic regression model shows that the first work shift (8.00 a.m. to 12:30 p.m.), addresses of patients (IPD), and manual recording system were statistically associated with the prolonged TAT as compared to the second work shift, OPD (outpatient department) and. Similarly, the multivariate logistic analysis affirmed that first shift, IPD, and manual system recording were significant predictors of prolonged TAT (Table 6). With regard to sample rejection, the bivariate logistic regression model shows that patient addresses (IPD) and lack of adherence to SOP were statistically associated with specimen rejection. Likely, the

TABLE 4 The frequency of errors and sigma metrics level of the hematology laboratory in the post-analytical phase at the University of Gondar Comprehensive Specialized Hospital, Northwest Ethiopia, 2022.

Variables	Yes Frequency/%	No Frequency/%	Total/%	DPMO	Sigma value
Critical values were not communicated to physician immediately	173/100	0/0	173/100	1,000,000	<3
Results released without result verification	12,356/99.9	2/0.01	12,358/100	999,831	<3
Test results unrecorded	291/2.3	12,310/97.9	12,601/100	23,093	3.5
Results released without TAT	1027/10.3	9345/89.7	10,372/100	103,748	<3
Results reported without standard unit	480/4	11,395/96	11,875/100	40,421	3.3
Samples were not retained/stored as the policy	12,611/100	0/0	12,611/100	1,000,000	<3
Laboratory results lost	291/2.3	12,310/97.7	12,601/100	23,093	3.5
Results reported with incorrect standard unit	83/0.7	11,792/99.3	11,875/100	6989	4
Results reported without reference range	142/1.2	12,074/98.8	12,216/100	12,172	3.8
Results reported by unauthorized personnel	66/0.53	12,318/99.4	12,384/100	5329	4.1
Total	27,520/25.2	81,546/74.8	109,066/100	252,324	2.2

Abbreviations: DPMO, defects per million opportunities; TAT, turnaround time.

TABLE 5 Total hematology laboratory errors at the University of Gondar, Comprehensive Specialized Hospital, Northwest Ethiopia, 2022.

Variables	Errors			% With in phases	% Out of total QI	DPMO	Sigma value
	Yes	No	Total				
Pre-analytical	93,412	250,479	343,891	74.8%	19.7%	196,974	2.4
Analytical	2364	18,913	21,277	1.9%	0.5%	4985	4.1
Post-analytical	27,520	81,546	109,066	22.3%	5.8%	58,030	3.1
Total	123,296	350,938	474,234	100	27.52	259,990	2.2

Abbreviations: DPMO, defect per million opportunities; QI, quality indicator; %, percentage.

TABLE 6 Bivariate and multivariate logistic regression analysis of prolonged TAT (in minutes) and explanatory variables in the hematology laboratory at the University of Gondar Comprehensive Specialized Hospital, Northwest Ethiopia, 2022.

Variable		COR (95% CI)	AOR (95% CI)	*p* Value
Work shift	First	3.85 (3.054–4.85)	4.36 (3.425–5.561)	<0.001
	Second	Ref	Ref	
Ward	IPD	3.9 (2.04–7.48)	1.9 (1.6–2.3)	<0.001
	Unknown	2.6 (2.21–2.95)	0.5 (0.24–0.82)	0.03
	OPD	Ref	Ref	
System of recording	Manual	12 (9.9–14.6)	11.2 (9.08–13.88)	<0.001
	LIS	Ref	Ref	
Lack of adherence to SOP	Yes	2.1 (1.85–2.44)	1.6 (1.42–1.9)	<0.001
	No	Ref	Ref	

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; COR, crude odds ratio; IPD, Inpatient Department; LIS, Laboratory Information System; OPD, Outpatient Department; Ref, reference; SOP, standard operating procedure.

TABLE 7 Bivariate and multivariate logistic regression analysis of sample rejection and explanatory variables in the hematology laboratory at the University of Gondar Comprehensive Specialized Hospital, Northwest Ethiopia, 2022.

Variable		COR (95% CI)	AOR (95% CI)	*p* Value
Work shift	First	1.1 (0.9–1.24)	1 (0.9–1.22)	0.63
Second	Ref	Ref		
Ward	IPD	1.5 (1.2–1.76)	2.4 (2.07–2.87)	<0.001
	Unknown	3.3 (2.8–3.87)	2.2 (1.88–2.64)	<0.001
	OPD	Ref	Ref	
Lack of adherence to SOP	Yes	6.3 (5.2–7.64)	5.7 (4.67–6.89)	<0.001
	No	Ref	Ref	

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; COR, crude odds ratio; IPD, Inpatient Department; LIS, Laboratory Information System; OPD, Outpatient Department; Ref, reference; SOP, standard operating procedure.

multivariate logistic analysis revealed the presence of an independent association between IPD and lack of adherence to SOP with sample rejection (Table 7).

4 | DISCUSSION

The findings of the current study indicate that errors have occurred in all stages of TTP, with an overall prevalence of 26%. The finding is comparable with the study conducted in Addis Ababa, Ethiopia[31] with an overall error rate of 28.5%. The high frequency of error rate in the study area may be due to inconsistent adherence to standardized protocols. In addition, it may be related to poor LIS, poor infrastructure, and poor management. The overall rate of errors may be reduced by using easy procedures such as establishing strong policies to follow protocols, avoiding interruption of LIS, giving training for professionals, using appropriate technology, and monitoring QI routinely.

In comparison to other studies, the overall error rate of our laboratory is higher than the studies conducted in Anokye, Ghana,[32] Al-Assah, Saudi Arabia,[33] Aurangabad, India,[34] Teerthanker Mahaveer, India,[9] Imam, Iran,[4] and Lahore, Pakistan[35] that report error rates between 0.17% and 6.3%. The occurrence of this discordance might be due to the variability of QIs and the system of ordering of the tests. Hence, those studies included less compressive QI and ordering all tests using the electronic system compared to the current study, the error rate may be reduced in the place. In addition, the discordance may be related to sample size; those studies used a relatively large sample size (minimum 97,618 samples) compared with the current study which may dilute the findings. On the contrary, the overall frequency of errors in this study is lower than studies conducted in Gondar, Ethiopia[23] and Wolega, Ethiopia[36] with defect rates of 36.8% and 58.2%, respectively. This discrepancy might be due to the smaller sample size, the inclusion of various working units in both studies, and the variability of the QIs included.

In this study, the most frequent errors were reported in the pre-analytical phase (75.8%), followed by the post-analytical phase (22.3%). This finding is supported by studies carried out in Gondar, Ethiopia,[23] Addis Ababa, Ethiopia,[31] Wolega, Ethiopia,[36] Anokye, Ghana,[32] Al-Assah, Saudi Arabia,[33] Aurangabad, India,[34] Teerthanker Mahaveer, India,[9] Imam, Iran,[4] and Lahore, Pakistan,[35] with the frequency of pre-analytical errors (65.1%–94.7%), analytical errors (2%–12.1%), and post-analytical errors (7.7%–25%) reported.

A higher pre-analytical error of 29.2% was reported in this study than in studies conducted in Pakistan (1.48%)[35] and Nepal (5.5%).[34] This higher error rate might be due to the inconsistent adherence to standardized protocols during patient preparation, sample collection, specimen acquisition, handling, and storage. In addition, professionals who give less attention to the pre-analytical phase than others might further aggravate the problem. On the other hand, a lower magnitude (39%) of pre-analytical error was reported in the study done in Iraq.[5] This discordance might be due to variations in the operational definition of variables, QIs, study period, and sample sizes.

The magnitude of error reported in the analytical phase was 11.1%, which is higher than a study done in Dessie, Ethiopia (3.5%).[36] However, it is lower than a study done in Gondar, Ethiopia (16.6%).[23] This variation might be due to differences in QIs, sample size, study period, professional skills, and equipment running the tests. In this study, the post-analytical error was 25.2%, which is higher than the studies done in Dessie, Ethiopia (12.8%)[36] and Gondar, Ethiopia (9.3%).[23]

The magnitude of error reported in the analytical phase was 11.1%, which is higher than a study done in Dessie, Ethiopia (3.5%).[37] However, it is lower than a study done in Gondar, Ethiopia (16.6%).[23] This variation might be due to differences in QIs, sample size, study period, professional skills, and equipment running the tests. In this study, the post-analytical error was 25.2%, which is higher than the studies done in Dessie, Ethiopia (12.8%)[37] and Gondar, Ethiopia (9.3%).[23]

In the assessment of laboratory performance using sigma metrics, the current study showed the overall performance of the hematology laboratory was poor (2.2 sigma value). The low performance of our laboratory might be due to a lack of adherence to SOP during pre-examination, examination, and post-examination

time, sample collection by non-laboratory health professionals, electrical fluctuation, and a weak result reporting system. Besides, poor infrastructure, low management support, lower staff motivation, and training gaps might contribute to poor adherence to six Sigma in our setting.[38] This may affect future laboratory accreditation through decreasing recognition. The hospital leadership should address the issue and improve all aspects of the laboratory.

In the pre-analytical phase, the mean sigma value was beyond the acceptable limit (less than three sigma levels). The possible explanation for this lower performance may be due to lower experience, negligence, and less attention to the pre-analytical phase. On the other hand, the performance level of our laboratory in the analytical and post-analytical phases was good (4.1) and marginal (3.1). Even though, still, it is below world-class performance. The lower performance of the analytical phase might be related to the shortage of trained manpower, reagents, and proper preventive maintenance, the small sample size, and a lack of verification and awareness about critical value checking. The lower performance in post-analytical phases might be due to a lack of critical test results communication with physicians, test results verification, and release of results within established TAT. In addition, increased workload, weak laboratory policy implementation, a weak reporting system, a shortage of infrastructure, and electric power fluctuation might be other aggravating factors for the lower performance of the post-analytical phase.

In this study, the multivariate logistic analysis revealed that patients' addresses (IPD) and a lack of adherence to SOP were statistically associated with unsuitable samples. Lack of adherence to SOP increases the likelihood of sample rejection nearly six times more than adherence to SOP. This finding is supported by a study conducted in Kenya.[39] The poor adherence to SOP in our study setting may be due to low commitment among laboratory personnel, sample collection by non-laboratory health professionals, work overload, and weak supervision. Similarly, IPD aggravates the sample rejection rates nearly two times as much as OPD. This finding is supported by research conducted in Hawassa, Ethiopia,[40] Nepal,[41] and India.[34] The possible cause for the occurrence of unsuitable samples in IPD may be related to the specimen collectors, who are mainly untrained, nonlaboratory healthy professionals.

Besides, the current study showed that manual recording and the first work shift were statistically associated with prolonged TAT. This finding is supported by the study done in an Armed Forces hospital in Ethiopia.[42] Prolonged TAT on the first shift (morning) might be due to work overload and professional work fatigue. The reason for the prolonged TAT in IPD might be related to the distance between the sample collection site and the site of analysis.

5 | CONCLUSION AND RECOMMENDATION

This study concluded that there was a higher frequency of hematology laboratory errors in the TTP. Most of the errors were reported in the pre-analytical phase of testing, followed by the post-analytical phase. The overall sigma metric performance of the hematology laboratory was lower than the minimum specification (less than three sigma values). Therefore, the hospital leadership should immediately avoid interruption of the laboratory information system, and create a computerized system that only can be completed when all necessary data are entered during the ordering of tests and releasing the results. Hence, most of the errors occurred in the pre and post-analytic phases; ordering tests and releasing results by electronic system significantly minimized defect rate. Besides, the hospital leadership and laboratory director should immediately work together to mentorship and build the capacity of professionals working in the whole process of testing by organizing need-based training.

AUTHOR CONTRIBUTIONS

Dereje Mengesha Berta: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing—original draft; writing—review and editing. **Mekonnen Grima**: Formal analysis; investigation; methodology; project administration; supervision; writing—original draft; writing—review and editing. **Mulugeta Melku**: Formal analysis; investigation; methodology; project administration; supervision; writing—original draft; writing—review and editing. **Tiruneh Adane**: Formal analysis; investigation; methodology; supervision; writing—original draft; writing—review and editing. **Elias Chane**: Methodology; writing—original draft; writing—review and editing. **Bisrat Birke Teketelew**: Formal analysis; methodology; writing—original draft; writing—review and editing. **Aregawi Yalew**: Investigation; methodology; writing—original draft; writing—review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICAL STATEMENT

Ethical approval was obtained from the Ethical Review Committee of School of Biomedical and Laboratory Science, University of Gondar, according to the declaration of Helsinki. The corresponding author, Dereje Mengesha, had full access to all of the data in this study and took complete responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY STATEMENT

The lead author Dereje Mengesha affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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