JOURNAL OF INTERNATIONAL CRISIS AND RISK COMMUNICATION RESEARCH
ISSN: 2576-0017
2024, VOL 7, NO S12

Evaluation of the performance of the hematology laboratory during the entire testing procedure utilizing sigma metrics and quality indicators in Saudi Arabia 2024

Abdualziz Fahaid Al-Hassan[1], Mubarakah Hilil Mohammed Alnfaiey[2], Ismaeel Yahya Ismaeel Mathkoor[3], Meshal Thaar Alotaibi[4], Maryam Ayyadah Alanazi[5], Eyad Zinulabdeen Oqab[6], Nawaaf Obedallah Azez Al Sheikh[7], Khalil Said Mohammad Alzahrani[8], Majed Saeed Ahmed alghamdi[8], Ayman Hamdan Abbas Aljilani[8], Fahad Saad Alsoufy[9]

1Laboratory Specialist, Prince Mohammed bin Abdulaziz Hospital - Riyadh, Saudi Arabi.
2laboratory specialist, Laboratory and blood bank at Prince Mishari Hospital in Baljurashi, Saudi Arabi.
3Laboratory specialist, Samtah general hospital, Saudi Arabi.
4laboratory technician, Khuraiman Health Center, Saudi Arabi.
5Lab technician, Department of laboratory and Blood bank Prince Mohammed Bin Abdulaziz , Saudi Arabi. Hospital, Saudi Arabi.
6Lab Specialst, Alnoor Hospital, Saudi Arabi.
7Laboratory specialist, Primary health care center in Umm Al-Jarm, Saudi Arabi.
8Technician-Laboratory, King Fahad Hospital albah, Saudi Arabi.
9Medical Technologist, King Fahad Hospital albah, Saudi Arabi.

Abstract:
Background: In clinical laboratory, the performance of the hematology analyzer should be checked routinely to ensure the desired quality. Clinical laboratories are dynamic and complex organizations that have a critical role in patient diagnosis, treatment, and management. It is crucial to ensure laboratory quality by reducing the extent of errors. Therefore, **this study aimed:** To evaluate hematology laboratory performance in the entire testing procedure utilizing sigma metrics and quality indicators in Saudi Arabia. **Methods:** A cross-sectional study was conducted from January to March 2024. The study included a total of 645 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. Additionally, we evaluate laboratory performance by employing a Sigma scale and calculating the percentage of mistakes. **Results:** The overall error rate was (26%): (19.7%) pre-analytical, (0.5%) analytical, and (5.8%) post-analytical. Of the overall errors, (75.8%), (1.9%), and (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. Furthermore, a correlation was seen between manual recording, inpatient departments, and morning work shifts and longer turnaround times. **Conclusion:** Based on the current study, the laboratory's performance was very poor (less than three sigma). Thus, the hospital administration should switch from a manual system of ordering tests and releasing results to a computerized system and provide need-based training to all

personnel engaged in the collecting and processing of hematological laboratory samples.

Keywords: Hematology, Laboratory, Quality Indicators, Sigma Metrics, Testing Procedure

Introduction:

Clinical laboratories are complicated and dynamic facilities that play a vital part in the diagnosis, management, and treatment of patients [(1)]. Standardized and harmonized testing methods are essential in clinical medicine to provide accurate, rapid, and exact results [(2)]. This enhances clinical judgment and permits strict adherence to existing guidelines. However, it can be difficult to harmonize and standardize the total testing process (TTP) [(2)]. Pre- and post-analytical phases are more likely to have laboratory flaws than the analytical phase, according to studies [(1, 2)]. Automation and sophisticated lab technology have decreased the frequency of errors during the analytical stage [(3)].

Additionally, the implementation of quality control mechanisms like external quality assurance (EQA) and internal quality control (IQC) has reduced the frequency of faults in the analytical phase [(4)]. However, the desired improvement in comparison to a comparable reference technique has not been realized through the use of quality control, automation, or advanced technology. Therefore, it is crucial to evaluate the analytical performance of hematology analyzers utilizing thorough and direct evaluation tools like sigma metrics [(2, 5)].

Sigma metrics are commonly used methods for assessing summarized processes. In the 1980s, the Motorola Company first suggested it for use in industry. Later on, it was also used in clinical laboratories as a tool for performance evaluation [(4, 6)]. Sigma metrics measure how far a given process deviates from internationally recognized standards [(7, 8)]. Evaluation of a laboratory's analytical performance in terms of sigma metrics is more significant than evaluation of the quantity of defects alone since the laboratory optimizes its IQC plan based on the sigma metrics value, determining the quantity and frequency of IQCs required for clinical purposes [(6, 8)].

A sigma value of three is the lowest that can be used in the process [(9, 10)]. Higher faults are indicated by lower sigma metrics values, and many valid test findings are mistakenly excluded, making them more challenging to apply when analyzing patient samples. Conversely, fewer flaws and fewer wrongly rejected acceptable test results are indicated by higher sigma metrics values [(10, 11)]. One tool used to conduct a full blood count (CBC) test is a hematology analyzer. It is employed in blood cell counting, hemoglobin measurement, hematocrit measurement, and blood cell index computation. In order to produce high-quality test results, the laboratory must make sure that instrument performance is sufficient [(4, 12)].

Research from various regions indicates that the hematology analyzer's sigma level varies for typical hematological parameters. For example, the studies done in India [(13)], Indonesia [(14)], Pakistan [(15)], Peru [(16)], Romania [(17)], Turkey [(18)], and the United States [(19)] showed poor to world-class sigma values for common hematological parameters.

Therefore, it is crucial to provide quality laboratory service by enhancing laboratory service by regular evaluation of the frequency of errors and sigma metrics

performance level in all TTP phases. Unfortunately, there is insufficient information available in Saudi Arabia regarding the overall size of mistakes and the hematology laboratory's performance level as measured by sigma metrics. So, this study aimed to evaluate the overall magnitude of errors and sigma metrics performance level of the hematology laboratory in total testing process at Hospital in Makkah, Saudia Arabia.

Methods

A cross-sectional study was conducted from January to March 2024 at the Hospital Hematology Laboratory in Makkah, Saudia Arabia. 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 non-routine hematology tests such as pleural, synovial, cerebrospinal, and peritoneal fluids were excluded. 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.

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 anti-coagulated settled blood. ***Clotted sample***: can define 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 three. ***Acceptable overall performance***: the average sigma value was greater than three.

During the study period, 645 blood samples with their corresponding request were evaluated by six 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 [(20-24)]. 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.

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.

After checking its completeness manually, the data were entered into Epi data version 3.1 and exported to SPSS version 28 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 $\chi 2$ 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.

Ethical approval was obtained from the Ethical Review Committee. 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.

Results

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

Table (1) Frequency of errors and sigma metrics levels on hematology laboratory request forms

Variables	Missed information %	Not missed information %	Sigma value
Appropriate and authorized requests	80.3	19.7	<3
MRN	0.5	99.5	4.1
Patient age	1.5	98.5	3.7
Patient sex	1.5	98.5	3.7
Signature of the physician	94.7	5.3	<3
Clinical history of the patient	99.99	0.01	<3
Patients address	99	1.0	<3
Name of sender address/ward	50.5	6700/49.5	<3
Date of test ordered	71.4	28.5	<3
Name of test ordered	0/0	100	>6
Time of sample collection	13,235/97.7	2.3	<3
Handwriting legible	3310/24.4	75.6	<3
Total	51.8	48.2	<3

Abbreviations: MRN, medical record number; %, percentage.

Table (2) shows the frequency of errors and the sigma metrics levels of the pre-analytical phase related to specimen quality, collection, preparation, storage, and transportation. The frequencies of hemolyzed, wrongly labeled, clotted, and insufficient samples were (1.8%), (1.8%), (1.56%), and (0.15%), respectively, 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 (0.8%) and (0.41%), with a sigma value of 4.1 for each. From the total opportunities for pre-analytical QIs (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) Frequency errors and sigma metrics levels of hematology laboratory in pre-analytical phases related to specimen quality, collection, preparation, storage, and transportation

Variables	Yes %	No %	Sigma value
Hemolyzed samples	1.8	98.2	3.6
Clotted samples	1.56	98.44	3.7
Insufficient volume	0.15	99.85	4.5
Incorrect containers	0.002	99.98	5
Incorrectly labeled specimens	1.8	98.2	3.6

Variables	Yes %	No %	Sigma value
Delayed samples	0.1	99.9	4.6
Wrong sample transportation	0.2	98.8	4.4
Sample lost	0.41	99.2	4.2
Requests lost	0.6	99.4	4.1
Unacceptable quality smears	23.5	76.5	<3
Wrong sample storage	100	0	<3
Blood mixed with anticoagulant improperly	7.4	92.6	3
Improperly sealed capillary tube	6.7	93.3	3.1
Incorrect anticoagulant-to-blood ratio	38.3	61.7	<3
Patients identified improperly	11	89	<3
Incorrect tourniquet application time	8.8	91.2	<3
Blood unmixed before analysis	0.35	99.65	4.2
Total	5	95	3.2
Grand total pre-analytical errors	27.2	72.8	<3

Table (3) shows the frequency of errors and sigma metrics levels of analytical phase. (15.2%) of preventive maintenance was not performed as expected. Of the total QIs assessed in the analytical phase, (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): The frequency of errors and the sigma metrics levels of the hematology laboratory in the analytical phase

Variables	Yes (%)	No (%)	Sigma value
IQC results failed	0	100	>6
Daily IQC not performed	0	100	>6
Preventive maintenance not performed	15.2	84.8	<3
Equipment mal-functionality observed	4.8	95.2	3.2
Reference range unavailable for parameters	0	100	>6

Variables	Yes (%)	No (%)	Sigma value
Electric power inconsistency during analysis	5.3	94.7	3.2
Nonlinear results released without retesting	100	0	<3
Reagents expired	4.8	95.2	3.2
Inappropriate reagent storage condition	0	100	>6
Improperly filled ESR tube	4.9	95.1	3.2
Position of ESR tube wrong	0.7	99.3	4.0
Delay in ESR results reading	0	100	>6
ESR samples analyzed at wrong temperature	0	100	>6
Questionable results were not retested	100	0	<3
Critical results were not checked by PM	100	0	<3
HCT tube leaked	8.2	91.8	<3
HCT tube broken	1.4	98.6	3.7
Speed of centrifuge adjusted improperly	0	100	>6
Time of centrifuge adjusted improperly	0	100	>6
HCT results measured incorrectly	2.3	97.7	3.5
Smears not air-dried	0/0	100	>6
Incorrect preparation of working solution for PM	3.2	96.3	3.4
Smears stained at incorrect time	72.7	27.3	<3
Incorrectly washed smears	10.9	89.1	<3
Incorrectly examined smears	7.3	92.7	3.0
Total	11.1	88.9	<3

Abbreviations: ESR, erythrocyte sedimentation rat; HCT, hematocrit; IQC, internal quality control; PM, peripheral morphology; %, percentage.

Table (4) shows the frequency of errors and sigma metrics performance level of post-analytical phase. Among the post-analytical QIs evaluated, none of the critical test results were communicated to physicians, and samples were retained as per policy. Almost all (99.9%) test results were not verified and signed by authorized personnel. In addition, (10.3%) results were released outside of the expected TAT. Of the total post-analytical phase QIs, post-analytical errors were identified in (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): The frequency of errors and sigma metrics level of the hematology laboratory in the post-analytical phase

Variables	Yes %	No %	Sigma value
Critical values were not communicated to physician immediately	100	0/0	<3
Results released without result verification	99.9	0.01	<3
Test results unrecorded	2.3	97.9	3.5
Results released without TAT	10.3	89.7	<3
Results reported without standard unit	4	96	3.3
Samples were not retained/stored as the policy	100	0	<3
Laboratory results lost	2.3	97.7	3.5
Results reported with incorrect standard unit	0.7	99.3	4
Results reported without reference range	1.2	98.8	3.8
Results reported by unauthorized personnel	0.53	99.4	4.1
Total	25.2	74.8	2.2

Abbreviations: TAT, turnaround time.

Table (5) shows the overall prevalence of errors and performance levels by sigma metrics in hematology laboratory. The total hematology laboratory errors observed were (26%). Of these, the frequencies of (74.8%), (1.9%), and (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. 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): Hematology laboratory errors

	Errors % With in	Errors % Out of	Sigma
Variables	phases	total QI	value
Pre-analytical	74.8%	19.7%	2.4
Analytical	1.9%	0.5%	4.1
Post-analytical	22.3%	5.8%	3.1
Total	100	27.52	2.2

Abbreviations: QI, quality indicator; %, percentage.

Table (6) shows the he 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): Bivariate and multivariate logistic regression analysis of prolonged TAT (in minutes) and explanatory variables in the hematology laboratory

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

Table (7): Bivariate and multivariate logistic regression analysis of sample rejection and explanatory variables in the hematology laboratory

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.

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 by Tadesse et al., (2018) [24] 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 by Sakyi et al., (2015) [25], Pothula et al., (2017) [26], Kale et al., (2014) [27], Aadil et al., (2020) [20],[9] Abdollahi et al., (2014) [28],[4] and Sadiq et al., (2014) [29] [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.

On the contrary, the overall frequency of errors in this study is lower than studies conducted by Ambachew et al., (2018) [30] and Tola et al., (2022) [31] 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 by Ambachew et al., (2018) [30] Tadesse et al., (2018) [24] Tola et al., (2022) [31] Sakyi et al., (2015) [25], Pothula et al., (2017) [26], Kale et al., (2014) [27], Aadil et al., (2020) [20], Abdollahi et al., (2014) [28], and Sadiq et al., (2014) [29] 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 by Sadiq et al., (2014) [29] and Kale et al., (2014) [27], (5.5%). 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 by Najat et al., (2017) [33]. 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 by Tola et al., (2022) [31] (3.5%). However, it is lower than a study done by Ambachew et al., (2018) [30] (16.6%). 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 by Tola et al., (2022) [31] (12.8%) and Ambachew et al., (2018) [30] (9.3%).

The magnitude of error reported in the analytical phase was 11.1%, which is higher than a study done by Teshome et al., (2021) [32] (3.5%). However, it is lower than a study done by Ambachew et al., (2018) [30]. 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 by Teshome et al., (2021) [32] (12.8%)[37] and by Ambachew et al., (2018) [30].

Conclusion:

According to the study's findings, the TTP had a greater rate of hematological laboratory mistakes. The pre-analytical and post-analytical phases of testing were where the majority of the errors were recorded. The hematological laboratory's total sigma metric performance fell short of the minimal requirement (less than three sigma values). As a result, the hospital administration should prevent any disruptions to the laboratory information system right away and develop a computerized system that can only be finished if all required information has been recorded during test ordering and result release. As a result, the majority of faults happened before and after the analysis; the defect rate was much reduced by ordering tests and providing results via an electronic system.

References

1. Ahmed El-Neanaey W, Mahmoud AbdEllatif N, Abdel Haleem Abo Elwafa R. Evaluation of sigma metric approach for monitoring the performance of automated analyzers in hematology unit of Alexandria Main University Hospital. *Int J Lab Hematol*. 2021;43(6):1388–1393. doi:10.1111/ijlh.13660
2. Charuruks N. Sigma metrics across the total testing process. *Clin Lab Med*. 2017;37(1):97–117. doi:10.1016/j.cll.2016.09.009
3. Chaudhuri S, Das A, Das SK, Saha T. Evaluation of performance in the pre-analytical phase of a clinical biochemistry laboratory in a Tertiary Medical College Hospital. *AJMS*. 2022;13(6):62–67.
4. Fuadi R. Using six sigma to evaluate analytical performance of hematology analyzer. *Indones J Clin Pathol Med Lab*. 2019;25(2):165–169. doi:10.24293/ijcpml.v25i2.1375
5. Levey S, Jennings ER. The use of control charts in the clinical laboratory. *Am J Clin Pathol*. 1950;20(11):1059–1066. doi:10.1093/ajcp/20.11_ts.1059
6. Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, Morgan T. Evaluating laboratory performance on quality indicators with the six sigma scale. *Arch Pathol Lab Med*. 2020;124(4):516–519. doi:10.5858/2000-124-0516-ELPOQI
7. Gupta M, Ranapurwala M, Kansara K, Chhatriwala M. Application of sigma metrics in haematology laboratory. *Int J Clin Diag Pathol*. 2022;5(2):21–25. doi:10.33545/pathol.2022.v5.i2a.467
8. Westgard S, Westgard Q. Six sigma metric analysis for analytical testing

processes. *Abott Lab MS*. 2019;9(5):4–256.

9. Sawalakhe P, Desmukh S, Lakhe R. Evaluating performance of testing laboratory using six sigma. *Int J Innov Eng Sci*. 2016;1(1):13–20.
10. Coskun A. Six sigma: projects and personal experiences. *BOD*. 2011;3(6):250 (12–18).
11. Aggarwal K, Patra S, Acharya V, Agrawal M, Mahapatra SK. Application of six sigma metrics and method decision charts in improvising clinical chemistry laboratory performance enhancement. *IJAM*. 2019;6(5):1.
12. Turgeon ML. *Clinical Hematology: Theory and Procedures*. Lippincott Williams & Wilkins; 2005.
13. Nagaraj RB, Ansari MKA, Shivanna BDM. Evaluation of quality control in clinical hematology laboratory by using six-sigma. *Ann Rom Soc Cell Biol*. 2021;25:20354–20359.
14. Hidayati L, Maradhona Y. Six sigma for evaluation of quality control in clinical laboratory. *Int J Public Health Sci*. 2018;5(4):144–150.
15. Shaikh MS, Moiz B. Analytical performance evaluation of a high-volume hematology laboratory utilizing sigma metrics as standard of excellence. *Int J Lab Hematol*. 2016;38(2):193–197. doi:10.1111/ijlh.12468
16. Moya-Salazar J, Pio-Dávila L. Critical systematic errors in the implementation and follow-up of performance in the hematology area: a prospective study. *Med Uni*. 2018;20(1):22–34.
17. Oprea OR, Hutanu A, Pavelea O, Kodori DR, Dobreanu M. Quality control strategy for automated CBC: a laboratory point of view deducted from an internal study organised in an emergency laboratory. *RRML*. 2020;28(1):19–27.
18. Ozdemir S, Ucar F. Determination of sigma metric based on various TEa sources for CBC parameters: the need for sigma metrics harmonizatio**n**. *Laboratoriums Medizin*. 2022;46(2):133–141.
19. Rishniw M, Pion PD. Evaluation of performance of veterinary in-clinic hematology analyzers. *VCP*. 2016;45(4):604–614.
20. 20Aadil S. Study of the errors in hematology laboratory in a tertiary care hospital. EJMCM. 2020;7(2):1366-1381.
21. 21Alavi N, Khan SH, Saadia A, Naeem T. Challenges in preanalytical phase of laboratory medicine: rate of blood sample nonconformity in a tertiary care hospital. EJIFCC. 2020;31(1):21-27.
22. Akande T. Assessment of extra-analytical phase: improving labora- tory service and patient safety. J Adv Med Med Res. 2018;26(6):1-5.
23. College of American Pathologists. In: Hematology, ed. Hematology and Coagulation Checklist. CAP; 2021.
24. 24Tadesse H, Desta K, Kinde S, Hassen F, Gize A. Errors in the Hematology Laboratory at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia. BMC Res Notes. 2018;11(1):420.

25. 25Sakyi A, Laing E, Ephraim R, Asibey O, Sadique O. Evaluation of analytical errors in a clinical chemistry laboratory: a 3 year experience. Ann Med Health Sci Res. 2015;5(1):8-12.
26. 26Pothula Y, Al-Marzooq YM, Salem R, Al-Jasem W, Al-Hajji A. A retrospective study of quality improvement in clinical biochemistry laboratory. Parameters. 2016;2017:2018.
27. 27Kale S, Gumber R, Mahajan M, Mulay S. Identifying errors involving clinical laboratory: a 1 year study. IJHR. 2014;4(8):48-53.
28. 28Abdollahi A, Saffar H, Saffar H. Types and frequency of errors during different phases of testing at a clinical medical laboratory of a teaching hospital in Tehran, Iran. N Am J Med Sci. 2014;6(5):224.
29. 29Sadiq F, Yasmeen F, Mumtaz A, et al. Frequency of errors in clinical laboratory practice. Iran J Pathol. 2014;9(1):45-49.
30. 30Ambachew S, Adane K, Worede A, et al. Errors in the total testing process in the clinical chemistry laboratory at the University of Gondar Hospital, Northwest Ethiopia. Ethiop J Health Sci. 2018;28(2):235-244.
31. 31Tola EK, Dabi YT, Dano GT. Assessment of types and frequency of errors in diagnostic laboratories among selected hospitals in East Wollega Zone, Oromia, Ethiopia. Pathol Lab Med Int. 2022;14:1-6.
32. 32Teshome M, Worede A, Asmelash D. Total clinical chemistry laboratory errors and evaluation of the analytical quality control using sigma metric for routine clinical chemistry tests. J Multidiscip Healthc. 2021;14(2):125-136.
33. 33Najat D. Prevalence of pre-analytical errors in Clinical Chemistry Diagnostic Labs in Sulaimani City of Iraqi Kurdistan. PLoS One. 2017;12(1):e0170211.