Clin. Lab. 2026;72:XXX-XXX

ORIGINAL ARTICLE

Application of Sigma Metric and TOPSIS Method to Comprehensively Analyze 15 Quality Indicators in Clinical Laboratory from 2019 Through 2024

Yuzhu Huang, Tingting Long, Siqing Mei, Pingan Zhang

Department of Clinical Laboratory, Institute of Translational Medicine, Renmin Hospital of Wuhan University, Wuhan, Hubei, P. R. China

SUMMARY

Background: **This study aimed to apply sigma metric and TOPSIS method to comprehensively analyze quality indicators from 2019 through 2024 and explore factors improving laboratory errors in the Department of Clinical Laboratory at the Renmin Hospital of Wuhan University.**

Methods: **Fifteen quality indicators (QIs) covering the total testing process were collected through the laboratory information system and manual statistics. After calculating the rates, they were converted into sigma values according to specific formula, and the turnaround time was expressed in minutes. The TOPSIS method was applied to comprehensively analyze the clinical laboratory medical quality in different years, specialties, and specimen types. Through sigma metric, the trend and quality difference of each indicator were analyzed year by year. TOPSIS method was used to rank the quality of different years, specialties, and specimen types and to identify quality problems and effective improvement measures.**

Results: **Due to Corona Virus Disease 2019 (COVID-19), the number of specimens in 2022 was the highest, while that in 2020 was the lowest, with blood specimens being the main type. The critical values notification and timely critical values notification were both 100% every year. The sigma values of all QIs were below six, among which the average sigma value of "incorrect sample type" was the highest, at 5.73. The average sigma value of "test covered by interlaboratory comparison" was the lowest, at 1.01. Comprehensive analysis revealed that the performance of QIs in 2024 ranked first. From 2019 through 2023, the rank of pre- and post-phase QIs was: 1) biochemistry, 2) immunity, 3) hematology, and 4) microbiology. In 2024, performance of immunity was the best. The sigma value of blood specimens was the highest among all sample types, and the average was above five.**

Conclusions: **Although the quality performance of QIs fluctuated year by year, it showed a trend of continuous improvement. The detailed analysis of quality indicators in different years, specialties, and sample types still was unsatisfactory. There, clinical laboratories should take targeted improvement measures according to the problems reflected in the QIs.**

(Clin. Lab. 2026;72:xx-xx. DOI: 10.7754/Clin.Lab.2025.250502)

Correspondence:
Pingan Zhang
Department of Clinical Laboratory
Institute of Translational Medicine
Renmin Hospital of Wuhan University
Wuhan, Hubei 430060
P. R. China
Phone: + 86 02788041911
Email: zhangpingan927@163.com

Manuscript accepted July 15, 2025

KEYWORDS

quality indicators, sigma metric, TOPSIS method, laboratory errors, quality improvement

INTRODUCTION

The application of quality indicators (QIs) in the medical field first originated from the clinical management of diseases [1]. Later, it was introduced into the clinical laboratory and gradually developed into an important

component of quality assessment and continuous improvement in healthcare systems. The definition of QIs in ISO 15189:2022 is "measure of the degree to which a large number of characteristics of an object fulfils requirements, which can measure how well an organization meets the needs and requirements of users and the quality of all operational processes" [2]. Total testing process (TTP) was traditionally divided into pre-analytical, analytical, and post-analytical phases. In recent years, scholars have also proposed to subdivide TTP into pre-pre-analytical, pre-analytical, analytical, post-analytical, and post-post-analytical phases [3,4]. Professor Plebani's research showed that errors coming from analytical phase only amounted to 7%, compared to 46 - 68% in the pre-pre-analytical phase, 3 - 5% in pre-analytical phase, 13 - 20% in post-analytical phase, and 25 - 46% in the post-post-analytical phase [5]. QIs can monitor processes out of analytical phase and identify laboratory errors effectively, thus helping clinical laboratories reduce the risk of error, improve the quality of service, and promote patients' safety.

Since 2008, the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) implemented a Model of Quality Indicators (MQI) for use in medical laboratories worldwide [6]. An order of priority has been assigned based on the importance of the specific indicators and difficulty in data collection. Because of the significant contributions made by WG-LEPS of IFCC in the work related to QIs, Chinese medical institutions have increasingly emphasized the role of quality indicators in risk management and error assessment in clinical laboratories over the past decade.

In 2015, in order to further strengthen medical quality management, standardize clinical diagnosis and treatment behaviors, and promote standardization and homogenization of medical services, General Office of National Health and Family Planning Commission of the People's Republic of China issued fifteen quality indicators of clinical laboratory; laboratories reported data through the official websites of provincial clinical testing centers. In 2020, National Health and Commission of the People's Republic of China incorporated the fifteen quality indicators into the accreditation standards for grading hospital review, further emphasizing the importance of quality indicators in China. Since 2025, China has been implementing a data-driven operation and management policy for secondary and tertiary hospitals, using fifteen QIs to monitor performance and realize real-time monitoring of quality indicators.

Sigma metric was developed from traditional quality management, which can link the mean and standard deviation of process with target values and specification boundaries. Sigma metric can indicate whether a process reaches the degree of customers' need [7]. Laboratories can calculate error rate of quality indicators, converting them to sigma level according to sigma calculation [8]. Six sigma means "first class quality", while three sigma is regarded as the minimum quality requirement. If the sigma of an indicator is below three, it means "unacceptable" [9]. ISO 15189:2022 indicates that sigma metric can be used to evaluate QIs [2].

Technique for Order Preference by Similarity to Ideal Solution (TOPSIS) was first proposed by Hwang and Yoon in 1981; it is a multi-criteria decision-making (MCDM) method that ranks alternatives based on their proximity to the ideal (best) and anti-ideal (worst) solutions [10]. TOPSIS method is a commonly-used method for multi-target decision analysis, and it can be used not only for evaluating economic efficiency and industrial decision-making but also for quality assessment in the medical and public health field [11]. Studies show that TOPSIS method can obtain objective ranking results in comprehensive quality analysis of the clinical laboratory [12].

For clinical laboratories, applying different statistical methods to analyze quality indicators over a number of years can help to identify problems and take targeted improvement measures. Based on this purpose, this study was designed to analyze fifteen quality indicators at the Department of Clinical Laboratory of Renmin Hospital of Wuhan University for six consecutive years, compare the utility of sigma metric and TOPSIS method for analyzing QIs, identify laboratory errors in TTP, and propose improvement measures.

MATERIALS AND METHODS

Subjects

The data of fifteen quality indicators came from the Department of Clinical Laboratory of Renmin Hospital of Wuhan University from 2019 through 2024. The fifteen quality indicators issued by General Office of National Health and Family Planning Commission of the People's Republic of China include six pre-analytical phase QIs, six analytical phase QIs, and three post-analytical phase QIs. Specific definition and calculation formula are shown in Supplementary Table 1 [13,14]. For the convenience of subsequent statistical analysis, according to the essence of the fifteen quality indicators, this study divided them into two major categories: presence metric and performance metric.

Methods

In this study, pre-examination turnaround time (TAT) and intra-laboratory TAT were expressed in minutes, while others were expressed in sigma metric after being calculated as the error of rate. Laboratory information system (LIS) was used to collect relative data in real time. As for the turn-around time, the median time was calculated by LIS for the outpatients and inpatients. "Tests covered by internal quality control (IQC)", "unacceptable performances in IQC", "tests covered by an external quality assessment (EQA)-proficiency testing (PT) control", "unacceptable performances in EQA-PT schemes", and "tests covered by inter-laboratory com-

parison" were counted manually according to the prescribed definitions and formulas. These manually-collected quality indicators were calculated by two trained laboratory personnel for double-checking. All of the fifteen QIs were reviewed by a dedicated person and a quality supervisor every month and re-reviewed every year.

This study used sigma metric to quantify quality indicators and assess the quality and trend of each indicator. TOPSIS method helps to comprehensively evaluate and analyze the medical quality of a clinical laboratory in different years, different specialties, and different specimen types, which further helps rank quality level and finding quality problems and effective improvement. The analysis for the different years covered all fifteen quality indicators; that for different specialties only involved four QIs: "incorrect sample type", "incorrect sample container", "incorrect fill level," and "incorrect laboratory reports". As for the different specimen types, three QIs were counted: "incorrect sample type", "incorrect sample container", and "incorrect fill level".

Statistics

The sigma level can be conversed by the defects per million opportunities (DPMO). The DPMO equals to the number of defects/total number of opportunities * 1,000,000. In clinical laboratory, DPMO means error rate, the number of defects is the numerator of each indicator in Supplementary Table 1, while total number of opportunities is the denominator of each indicator. There exists a certain computational relationship between sigma metric and DPMO, while the DPMO corresponding to six sigma is 3.4 and to three sigma is 66,087. Therefore, sigma level can be calculated by certain software if the DPMO is known. Sigma level can indicate whether the improvement measures taken by laboratories are effective. When the improvement measures are effective, the error rate of quality indicators decreases and sigma value increases. The better the quality, the higher the sigma value.

The principle of TOPSIS is to find out the optimal scheme and the worst scheme of the finite scheme found from the normalized original data matrix. Then, through the distance between the evaluation object and the optimal scheme and the distance between the evaluation object and the worst scheme, the proximity is obtained, which is used as the basis for comprehensive evaluation. The detailed calculation principle of TOPSIS method has seven steps:

Step 1: Construct the decision matrix.

The first step is to define a decision matrix X(x_{ij}); rows represent different research subjects or research plans, while columns represent different indicators.

Step 2: Normalize the decision matrix.

The second step aims to convert the decision matrix X into a normalized matrix r = [r_{ij}] to eliminate the dimensional influence among different indicators.

Step 3: Construct the weighted normalized matrix.

This step uses entropy method to calculate weights w_j and assigns weights wj to the normalized matrix r = [r_{ij}] (where $\sum_{j=1}^{N} wj = 1$) and calculates the weighted matrix V = [v_{ij}], $v_{ij} = w_j \cdot r_{ij}$. N represents the number of indicators.

Step 4: Calculate the positive ideal solution (A^+) and negative ideal solution (A^-).

A^+ = the best value of each indicator; A^- = the worst value of each indicator.

Step 5: Calculate distance from the positive ideal solution (D^+) and distance from the negative ideal solution (D^-).

Step 6: Calculate the proximity of each indicator to the ideal solution.

$Ci = \frac{Di^-}{Di^+ + Di^-}$ $C_i \in [0,1]$

Step 7: Rank.

The final step ranks indicators according to Ci. The higher Ci of the indicator, the better the performance. All descriptive statistical analysis was performed on Minitab Software (Minitab Statistical Software for Windows, Chinese Version 19, Pennsylvania State University, USA) and Microsoft Excel 2021 software (Microsoft Inc., Redmond, Washington, DC, USA). Sigma value was calculated on a website named "Sigma Level Online Calculation and Conversion" (https://ucourse.org/sigma-level/). TOPSIS was performed on SPSSAU Software (www.spssau.net).

RESULTS

The numbers of specimens from 2019 through 2024 were 4,112,122, 3,065,554, 4,508,489, 9,667,248, 4,870,586, and 5,033,294, with blood specimen constituting the vast majority, as shown in Figure 1. On January 22, 2020, as for the outbreak of COVID-19, the People's Government of Hubei Province had issued a notice on strengthening the prevention and control of COVID-19. Under the influence of the COVID-19, the number of patients in hospitals had decreased sharply, and the number of specimens had also sharply declined in 2020. Subsequently, China had continuously optimized and refined its epidemic prevention and control measures and went through the exploration stage of regular prevention and control, the stage of precise prevention and control, and the stage of dynamic zero-COVID. As a result, the number of specimens gradually increased and reached its peak in 2022. After 2022, with the effective multi-faceted policies adopted by China, hospitals gradually resumed their regular working mode, and the number of specimens also returned to a normal and steady growth pattern.

Figure 2 shows the distribution of specimens from 2019 through 2024 in different professional groups. The professional groups with the highest to lowest number of specimens were biochemistry, hematology, immunity, and microbiology.

Table 1. The results of fifteen quality indicators were calculated by year.

Quality indicators	Year						Average
	2019	2020	2021	2022	2023	2024	
Represented as σ							
Incorrect sample type	5.65	5.74	5.90	5.80	5.63	5.63	5.73
Incorrect sample container	5.20	5.12	5.29	5.73	5.50	5.62	5.41
Incorrect fill level	5.03	5.18	5.31	5.28	5.28	5.32	5.23
Anticoagulant samples clotted	4.65	4.75	4.88	4.82	4.88	4.87	4.80
Blood culture contamination	3.73	3.70	3.76	3.87	3.96	3.90	3.82
Tests covered by IQC	4.14	4.20	4.20	4.34	4.55	-	4.29
Unacceptable performances in IQC	3.82	3.93	4.08	4.14	4.08	4.03	4.01
Tests covered by an EQA-PT control	3.11	3.57	3.51	2.87	4.25	3.89	3.53
Unacceptable performances in EQA-PT schemes	3.46	3.57	4.22	3.81	3.54	3.77	3.73
Tests covered by inter-laboratory comparison	0.70	0.36	0.68	1.38	1.33	1.58	1.01
Incorrect laboratory reports	4.39	4.37	4.38	4.66	4.41	4.46	4.45
Represented as min (median)							
Pre-examination TAT (outpatient)	17	19	20	36	21	17	22
Pre-examination TAT (inpatient)	63	60	60	63	70	67	64
Intra-laboratory TAT (outpatient)	45	78	114	143	40	53	79
Intra-laboratory TAT (inpatient)	144	125	124	107	108	105	119
Represented as %							
Critical values notification	100%	100%	100%	100%	100%	100%	100%
Timely critical values notification	100%	100%	100%	100%	100%	100%	100%

The rate of "tests covered by IQC" in 2024 was 100%, which could not be conversed in sigma value.

Table 2. Analysis of QIs in different years by TOPSIS.

Year	Positive ideal solution distance D^+	Negative ideal solution distance D^-	Relative proximity (Ci)	Rank
2019	0.378	0.408	0.519	3
2020	0.579	0.197	0.254	6
2021	0.525	0.192	0.268	5
2022	0.454	0.423	0.482	4
2023	0.134	0.581	0.812	2
2024	0.137	0.603	0.815	1

Descriptive analysis of QIs in different years

The annual comprehensive statistic of all fifteen quality indicators is shown in Table 1. The turn-around time is expressed in minutes, while the critical values notification and timely critical values notification are expressed in percentages. Others were converted into the sigma value by being calculated as rate first. The analysis found that the sigma value of all the quality indicators was below six. For "incorrect sample type", "incorrect sample container", and "incorrect fill level", "incorrect sample type" showed the best quality level with the highest sigma value, and all the three QIs had sigma value above five. For the QI "anticoagulant samples clotted", the sigma value was below five over the course of six years. The main problem laid in the coagulation samples, which were the first tubes of blood collected except for blood culture. When the blood flows out poorly, clots easily form. The sigma value of blood cul-

Table 3. The analysis of QIs of different professional groups by TOPSIS method.

Year	Group	Positive ideal solution distance D^+	Negative ideal solution distance D^-	Relative proximity (*Ci*)	Rank
2019	Hematology	0.719	0.005	0.007	3
	Biochemistry	0.058	0.663	0.920	1
	Immunity	0.068	0.714	0.913	2
2020	Hematology	0.650	0.076	0.104	3
	Biochemistry	0.006	0.656	0.990	1
	Immunity	0.149	0.622	0.807	2
2021	Hematology	0.733	0.010	0.013	3
	Biochemistry	0.009	0.733	0.988	1
	Immunity	0.182	0.562	0.756	2
2022	Hematology	0.216	0.466	0.683	3
	Biochemistry	0.041	0.651	0.941	1
	Immunity	0.086	0.598	0.874	2
	Microbiology	0.645	0.069	0.096	4
2023	Hematology	0.348	0.461	0.570	3
	Biochemistry	0.046	0.780	0.945	1
	Immunity	0.194	0.600	0.756	2
	Microbiology	0.780	0.066	0.078	4
2024	Hematology	0.306	0.335	0.523	3
	Biochemistry	0.109	0.543	0.832	1
	Immunity	0.173	0.447	0.721	2
	Microbiology	0.587	0.006	0.010	4

Table 4. The annual performance of QIs by different professional groups.

Professional group	Group	Positive ideal solution distance D^+	Negative ideal solution distance D^-	Relative proximity (*Ci*)	Rank
Hematology	2019	0.324	0.072	0.181	6
	2020	0.342	0.135	0.283	5
	2021	0.309	0.158	0.339	4
	2022	0.154	0.341	0.690	3
	2023	0.115	0.321	0.737	2
	2024	0.080	0.339	0.809	1
Biochemistry	2019	0.262	0.103	0.282	6
	2020	0.152	0.178	0.539	4
	2021	0.124	0.196	0.613	2
	2022	0.160	0.154	0.489	5
	2023	0.125	0.238	0.655	1
	2024	0.150	0.18.	0.549	4
Immunity	2019	0.299	0.036	0.107	6
	2020	0.304	0.081	0.211	5
	2021	0.200	0.128	0.390	4
	2022	0.156	0.266	0.631	3
	2023	0.122	0.245	0.667	2
	2024	0.106	0.235	0.689	1
Microbiology	2022	0.072	0.308	0.811	2
	2023	0.023	0.352	0.939	1
	2024	0.351	0.056	0.138	3

Table 5. The analysis of QIs of different specimen types by TOPSIS method.

Specimen type	Group	Positive ideal solution distance D^+	Negative ideal solution distance D^-	Relative proximity (*Ci*)	Rank
Blood Specimens	2019	0.292	0.018	0.059	6
	2020	0.287	0.020	0.064	5
	2021	0.097	0.200	0.674	4
	2022	0.050	0.280	0.848	2
	2023	0.071	0.227	0.761	3
	2024	0.031	0.276	0.900	1
Body fluid specimens	2019	0.272	0.138	0.337	5
	2020	0.326	0.127	0.280	6
	2021	0.233	0.292	0.556	2
	2022	0.293	0.228	0.438	4
	2023	0.229	0.242	0.513	3
	2024	0.215	0.294	0.578	1
Other specimens	2019	0.459	0.157	0.254	5
	2020	0.360	0.300	0.454	3
	2021	0.221	0.329	0.598	2
	2022	0.134	0.465	0.777	1
	2023	0.418	0.134	0.243	6
	2024	0.372	0.187	0.335	4

Others specimens: It refers to feces, respiratory tract (sputum, alveolar lavage fluid, nasopharyngeal swab), bone marrow, and tissue samples in our laboratory.

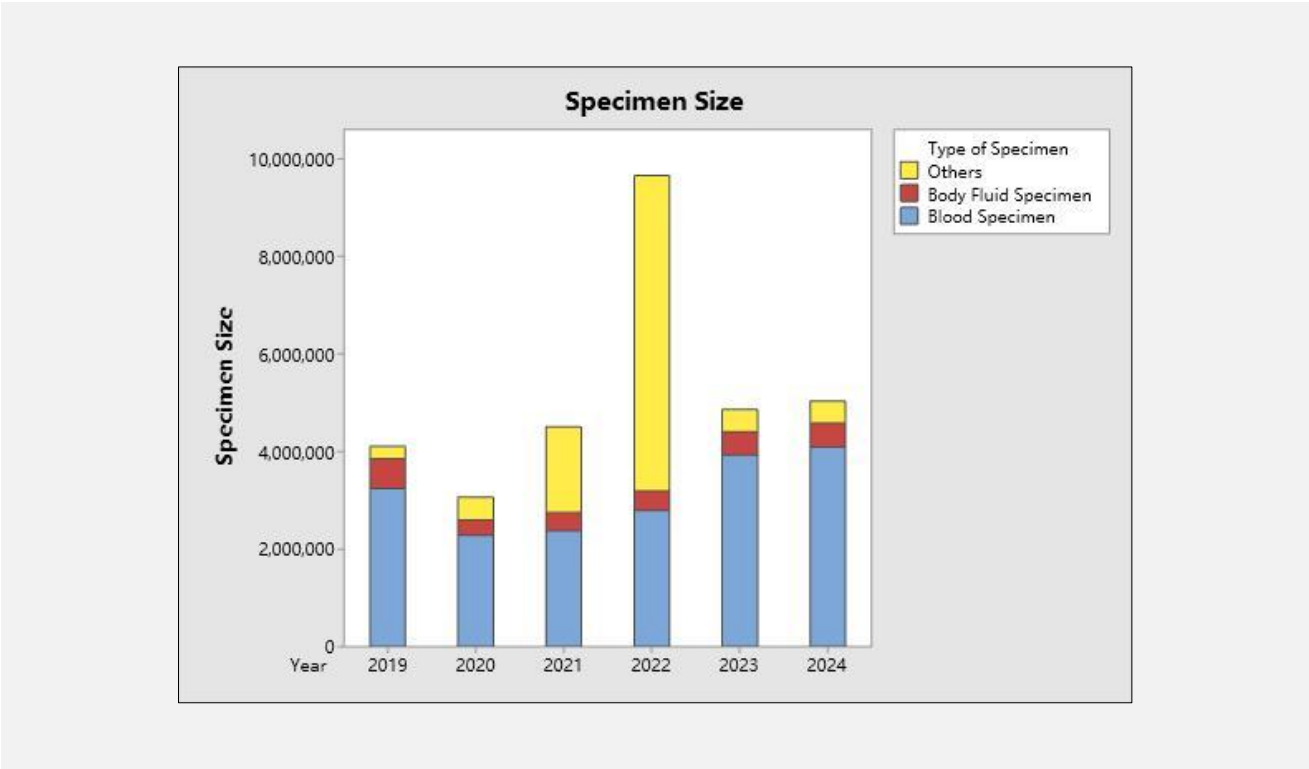

Figure 1. Distribution of different specimen types from 2019 through 2024.

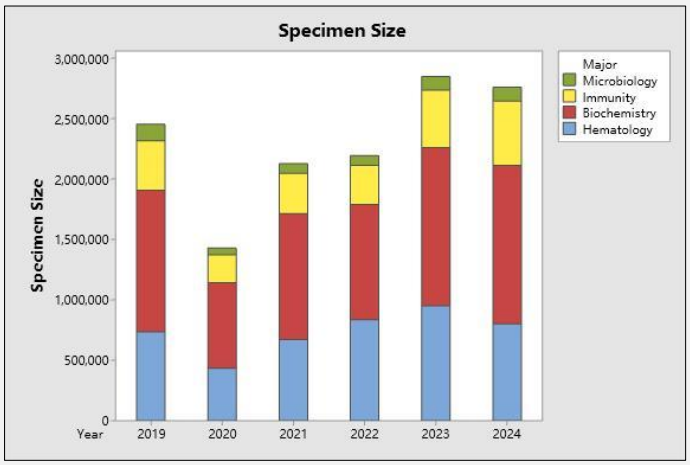

Figure 2. Distribution of specimens of different professional groups from 2019 through 2024.

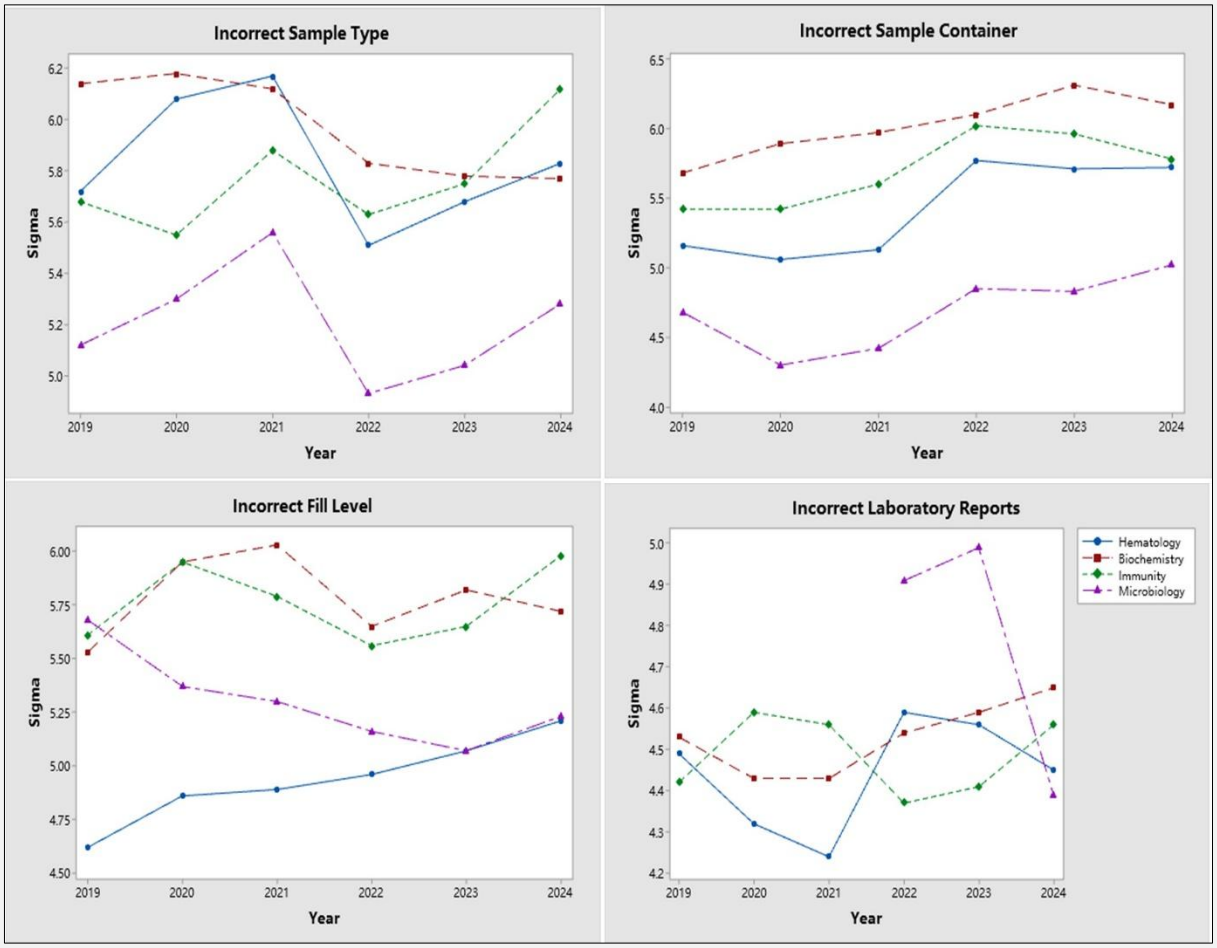

Figure 3. The time sequence diagram of sigma value of quality indicators for different professional groups.

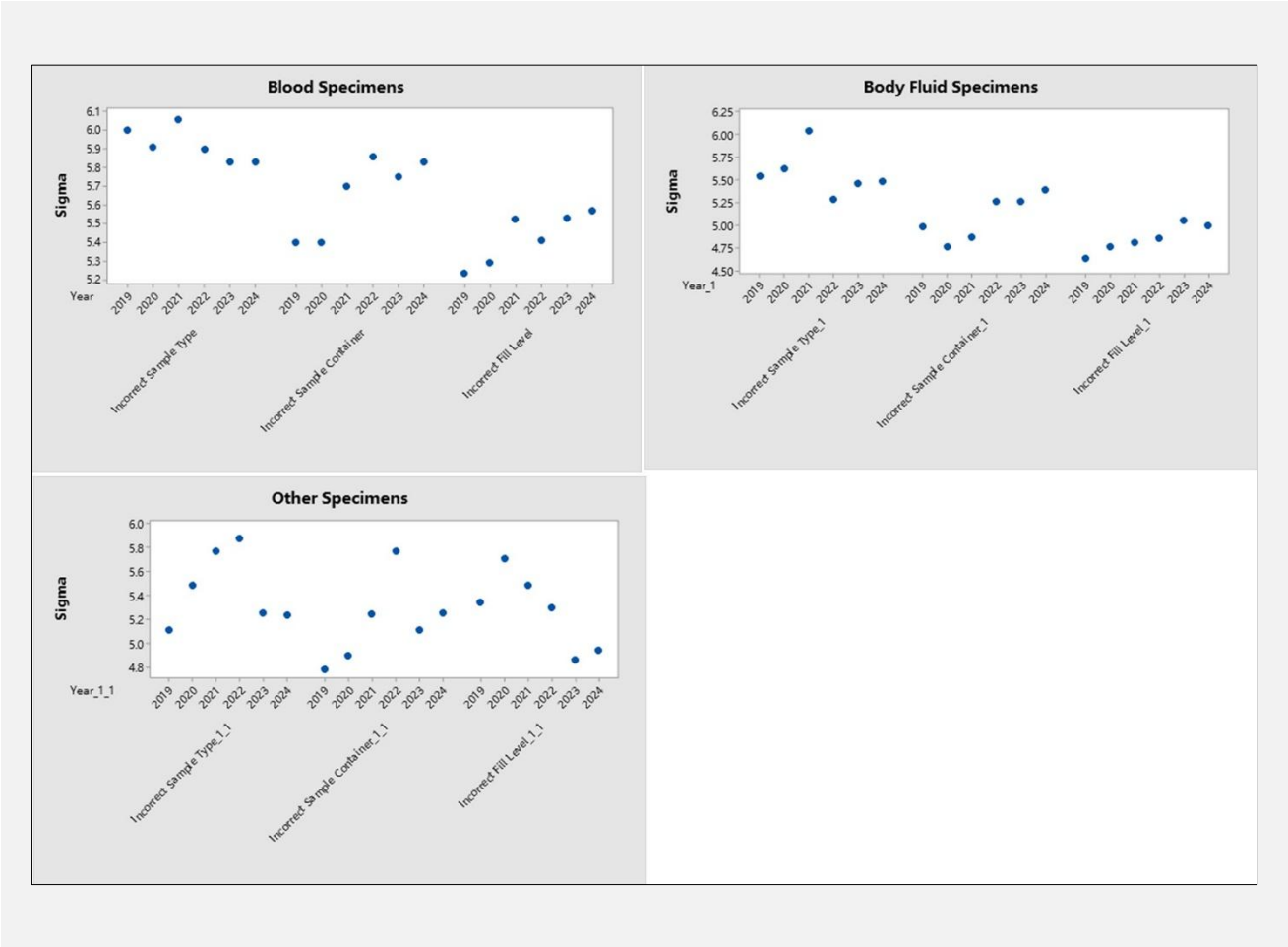

Figure 4. The pre-analytical phase quality indicators of different specimen types.

ture contamination was the lowest among pre-analytical phase QIs, as we had been taking many targeted improvement measures, including questionnaires, training, and customized reports.

"Tests covered by IQC", "unacceptable performances in IQC", and "incorrect laboratory reports" had sigma value between four and five. The sigma value of "tests covered by an EQA-PT control" and "unacceptable performance in EQA-PT schemes" was between three and four, indicating plenty of room for improvement. The worst performance was seen in "tests covered by inter-laboratory comparison"; the average of sigma value was 1.01, which was unacceptable. The reason for inter-laboratory comparison showing the worst performance was that for manual items or self-built items it was difficult to find laboratories to compare them, and some laboratories were unwilling to compare them considering the cost.

As for TAT, for both outpatients and inpatients, there was little fluctuation in pre-examination TAT over the course of six years, while the biggest fluctuation was seen in intra-laboratory TAT for outpatients. The rate of critical values notification and timely critical values notification was 100% every year, which is related to the thorough reporting and processing mechanism of critical values in our laboratory and hospital. When the laboratory issues the critical values reports, it will automatically notify the clinic to deal with the critical values through the link between the laboratory information system and hospital information system. The clinicians shall deal with the critical values within the specified times.

Comprehensive analysis of QIs in different years by TOPSIS

Comprehensive analysis by TOPSIS method showed that the total testing process QIs of 2024 had the best performance with the highest C_i, ranking first, followed by those of 2023. There were several quality indicators that had the highest sigma value in 2024, such as "incorrect fill level", "tests covered by IQC", "tests covered by inter-laboratory comparison", and pre-examination TAT (outpatient). The ranking analysis results by TOPSIS showed that the COVID-19 pandemic had a

certain impact on laboratory quality, as the overall quality ranking was the worst in 2020; after that, there was an upward trend year by year. Compared with sigma metric, TOPSIS method focuses more on integrity.

Analysis of the pre-analytical and post-analytical quality indicators according to professional groups

The time sequence diagram of sigma value of quality indicators for different professional groups is shown in Figure 3. Although biochemistry had the best performance on "incorrect sample type", the ratio increased year by year while sigma decreased on the whole. As for "incorrect sample container", the sigma value of biochemistry was the highest, and all the professional groups performed the best in 2022. The sigma value of "incorrect fill level" of hematology was the lowest; the main problem were the coagulation samples. The coagulation samples need to be collected by filling up the tube to ensure the ratio of blood sample to sodium citrate anticoagulant is 9:1. If the blood is insufficient, the ratio will be less, which may lead to incorrect test results. Therefore, the professional hematology group had been improving this problem in continuous communication and training with clinicians, which made the sigma value increase year by year. Microbiology performed the worst in "incorrect sample type" and "incorrect sample container", as the clinicians and nurses were not familiar with the types and containers of samples during the sampling process. Microbiology performed the best in "incorrect laboratory reports" from 2019 through 2023 with the hierarchical reporting system, while the sigma level dropped sharply in 2024, because several new employees were hired in that year.

TOPSIS method was used to make a comprehensive analysis of the pre-analytical and post-analytical phase QIs of different professional groups. The analysis included two parts. The first part evaluated the performance of each group annually. The results are shown in Table 3. The second part evaluated the annual performance by professional groups, which is shown in Table 4. Since there were no incorrect reports for microbiology in 2019 - 2021, only three professional groups were involved in statistics. The performance of the pre- and post-analytical phase QIs from 2019 through 2023 was ranked: 1) biochemistry, 2) immunity, 3) hematology, and 4) microbiology. In 2024, immunity had the best performance, surpassing biochemistry, and the rank of other professional groups remained. The result for hematology remained low over the time period; the main problems lied in the "incorrect sample container" and "incorrect fill level".

The main specimen types of hematology included ethylenediaminetetraacetic acid (EDTA) anticoagulant whole blood specimen, citrate anticoagulant blood specimen, urine, stool, and leucorrhea. Compared with biochemistry and immunity, there were more types of specimens and manual testing which were collected by patients and clinicians. Therefore, it was necessary to train them on how to collect specimens correctly. The abovementioned reasons could explain why hematology remained low on the rate of "incorrect sample type" between 2019 and 2024. The rate of "incorrect sample container" mainly derived from patients using incorrect containers to collect urine or stool, while the rate of "incorrect fill level" resulted from insufficient volume of coagulation specimens collected.

In terms of each group, the overall rank of hematology and immunity showed an upward trend, indicating a trend of continuous improvement. Biochemistry and microbiology fluctuated greatly. As can be seen in Figure 3, the main quality problems in biochemistry were "incorrect samples type" and "incorrect fill level". In 2024, the overall quality of microbiology significantly declined, mainly due to a sharp increase of the rate of "incorrect laboratory reports". At the end of 2023, experienced senior staff in microbiology retired, junior staff entered, and personnel rotation was carried out in our laboratory, resulting in insufficient capabilities and experience in the personnel issued reports. Ultimately, that led to a significant decrease in quality of microbiology in 2024.

Analysis of pre-analytical quality indicators according to specimen type

The pre-analytical phase quality indicators of different specimen types are shown in Figure 4. The sigma values of the blood specimens were all above five, making them the best performing among all specimen types. The main issue with blood specimens lied in the "incorrect fill level", which had the lowest sigma value. The pre-analytical phase QIs of body fluid specimens showed an upward trend in sigma values from 2022 through 2024, but the rates of "incorrect sample container" and "incorrect fill level" remained the primary areas of improvement. Although the sigma values of other types of specimens were all above 4.8, they all showed an initial upward trend followed by a sharp decline. The sigma values in the last two years were lower than those in 2019, indicating that the performance of pre-analytical phase quality indicators was not as good as before.

Table 5 showed the performance and ranking of the pre-analytical quality indicators of all types of specimens in each year. The performance of blood specimens and body fluid specimens of six years had the best performance in 2024. As for other specimens, the performance of 2023 was the best. When TOPSIS method has a small number of evaluation items, the advantages of sigma metric will be highlighted, which can indicate specific improvement measures. For example, according to the results of Figure 4 and Table 5, laboratory can determine QIs that need to be improved for each specimen type based on sigma level.

DISCUSSION

This study aimed to comprehensively analyze and assess fifteen six-year quality indicators issued by National Health Commission of the People's Republic of China by sigma metric and TOPSIS method and find potential trend and quality risks in total testing process.

The establishment of quality indicator system in clinical laboratory can help identify potential errors and improve performance [15]. Laboratories should conduct both internal and external evaluation systems of quality indicators to enhance and compare quality levels. Internal evaluation involves setting quality goals, implementing improvement measures when monitoring results of QIs fail to meet the requirements of quality goals, and verifying the effectiveness of improvement through monitoring QIs. External evaluation includes participating in external quality assessment programs and evaluating the quality systems based on performance among the clinical laboratories. The QIs cannot develop without advanced laboratory information system (LIS), which significantly improves the quality of QIs and ensures the reliability of the row data. In a cross-sectional study of QIs, Berta et al. found that the overall performance of their hematology laboratory was very poor, which was attributed to the manual system for ordering tests and releasing results [16]. Our laboratory has adopted LIS to replace manual methods for collecting QIs since 2022, which accounts for a sharp increase of overall quality analyzed by TOPSIS method in Table 2.

Currently, the MQI proposed by IFCC includes 53 measurements for 26 quality indicators, and a short-term sigma is calculated and included in the periodical report of External Quality Assessment Program (EQAP) provided by WG-LEPS in order to monitor variation in QI data in a controlled manner [17]. Sigma metrics not only help eliminate causes of errors in each laboratory but also act as a basis for establishing quality specification for QIs [18]. A higher short-term sigma level indicates that a process is less likely to generate problems [19]. Since 2008, WG-LEPS of the IFCC has made a lot of effort in regard of quality indicators and great contributions to the quantification, standardization, and formulation of performance specifications of QIs [20,21]. China has also been constantly developing and improving the relevant surveys on quality indicators and promoting their practical application following the guidance of IFCC.

National Center for Clinical Laboratories (NCCL) began to carry out external quality assessments of QIs in 2015. After a ten-year development, the calculation formula and reporting format of quality indicators have been continuously improved in China, and a relatively complete evaluation system for quality indicators has been established. The number of QIs has increased year by year. In 2024, laboratories participating in the EQAP of QIs were required to provide basic information about their hospital and laboratory. A total of eighteen mandatory reporting quality indicators and thirty-two optional reporting quality indicators had to be submitted through the information reporting website of the provincial clinical laboratory center. Provincial clinical laboratory center calculates sigma value of each QI, the number of laboratories, median, and quartiles. Participating laboratories can analyze the quality level of each QI in all laboratories across the whole country or the whole province. Sigma metric is a vital evaluation methodology to assess QIs for EQA organizers.

As for laboratories, all the QIs in EQAP proposed by WG-LEPS can be used to monitor quality level and potential trend by calculating sigma level. Our laboratory monitors fifty-one quality indicators, covering many aspects such as total testing process, the satisfaction of patients, cost-effectiveness, and so on. By calculating error rate and comparing with quality goals, we take targeted improvement measures for the poor performance of quality indicators and put forward higher quality target requirements for the better performance of QIs to achieve a higher level of quality. For example, the sigma value of quality indicator "tests covered by inter-laboratory comparison" remained the lowest over the course of the past six years. The original intention of this indicator was to monitor examination method performance using sample exchanges with other laboratories when an EQA program is either not available or not considered suitable [2]. At the beginning, our laboratory did not deem much importance to this indicator because it required a lot of time, energy, and effort. However, with the issue of detailed rules for the evaluation of grade hospitals and ISO15189:2022, the significance of this indicator for quality assessment was emphasized. Our laboratory then took improvement measures, including sorting out the items not participating in EQA, formulating comparison plans and schemes, and appointing dedicated personnel to supervise the implementation. As shown in Table 1, the sigma value of "tests covered by inter-laboratory comparison" in 2023 has nearly doubled compared to that in 2022.

Sigma metric is widely used to manage and monitor the performance of QIs. Swetha et al. used percentage variance and sigma metric to monitor QIs across the testing process, and made their final evaluation based on sigma metric [22]. Sigma metric analysis measures process performance quantitatively and provides opportunities for improvement in the process [23]. Error rate can be converted to sigma value, which can be used to trend analysis by comparing sigma value for consecutive years. However, sigma metric can only determine the quality level and trend of a single quality indicator, reflecting the quality of a certain process of TTP; it cannot indicate the quality level of the whole testing process. Moreover, the limitation of sigma value is that it does not allow assessment of what is the extent to which the error rate can be tolerated [24].

TOPSIS method makes up for the shortcoming of sigma metric. The advantages are that TOPSIS can integrate the results of all the QIs to analyze the overall quality

level, assess quality problems according to different groups from different angles, and reveal results simple and clear by ranking strategy.

Table 3 analyzed the quality performance of each group annually, which helped quality supervisors of clinical laboratory to identify which professional group had significant quality issues. For instance, if Table 3 showed that hematology had mediocre quality performance every year, then quality improvement measures should be made within this professional group. For pre-analytical quality improvement, our laboratory formed a professional physician team to provide training on sample collection precautions in clinical settings, and hospitals established a penalty mechanism for sample collection errors. For the high rate of "incorrect laboratory reports" of microbiology, our laboratory had been strengthening the new employee training and assessment and implanting job rotation within the professional group to increase personnel's familiarity with various microbiology specimens. Although Table 4 and Table 3 were the same set of data, they analyzed the quality indicators of different professional groups over the past six years from different perspectives. Table 4 shows annual performance of QIs by different years, which was helpful for professional group leaders or quality supervisors within the group to analyze quality trends. As was shown in Table 4, both hematology and immunology showed an increasing trend in quality performance, indicating that the quality improvement measures taken within the groups were effective and could be continued. However, the biochemistry group showed a fluctuating state, which might be related to new items. After in-depth analysis, it was found that in the year of quality decline, new urine-related items were launched in biochemistry. The main quality issues were related to improper sample collection, such as that patients provided random urine instead of 24-hour urine, or contamination of urine iodine specimens with iodine solution from fingers which had pressured on collection point, leading to a false increase in iodine levels in the urine.

The drawback of TOPSIS method is that it still needs to be combined with sigma metric for it to determine specific quality risk; it may ignore quality problems if used alone. For example, even though Table 2 shows that QIs in 2020 exhibited the worst performance, we still need to check which quality indicator performed well and which one performed bad according to sigma value. Therefore, the combined application of sigma metric and TOPSIS method can identify quality risks, make effective improvement measures, and identify multi-year quality trends to determine whether the improvement measures are effective. In addition, TOPSIS method requires data standardization, as each quality indicator has different directions and ranges. Sigma metric, on the other hand, can eliminate the dimensional differences of each quality indicator and be the best statistical basis for TOPSIS method for QIs. Combined use of sigma metric and TOPSIS method is not only suitable for laboratories but also for EQA organizers to comprehensively compare the quality levels of participating laboratories in different years, different regions, and different grades of hospitals.

This study also had some limitations. It was a single-center research, aiming to introduce a new method to analyze quality indicators by combining sigma metric and TOPSIS method; one that laboratory professionals of other laboratories and EQA organizers could refer to. There were two quality indicators that reached 100% in each year, which were excluded from TOPSIS analysis to avoid weight deviation. The TOPSIS analysis in this study assigned weights using entropy weight method, which is objective; however, in order to avoid subjectivity, it did not consider the priority and impact on patients of each quality indicator. Other laboratories can form an expert team of QIs to evaluate the importance and priority of each indicator and assign weights using a more scientific way, both subjective and objective. Due to the space limitation of this manuscript, only a few indicators were taken as examples for in-depth analysis to demonstrate the value of combined application of sigma metric and TOPSIS method in finding potential trends and quality risks.

Acknowledgment:

The authors appreciate Shanghai Rui Mei Computer Technology Co., Ltd., for providing them with the laboratory information system to collect data. They also thank all patients at their hospital from 2019 through 2024 for allowing them to collect valid information on quality indicators.

Source of Support:

There was no source of support in the form of grants, equipment, or drugs.

Declaration of Interest:

There is no conflict of interest for any of the authors regarding the contents of the article. The authors declare that no competing financial interest exists; there was no involvement of company funding, and there were no sponsors for this article.

References:

1. Kohn LT, Corrigan J, Donaldson MS. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press 2001. https://nap.nationalacademies.org/read/10027/chapter/1

2. ISO 15189:2022. Medical laboratories-requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization 2022. https://www.iso.org/standard/76677.html

3. Laposata M, Dighe A. “Pre-pre” and “post-post” analytical error: high-incidence patient safety hazards involving the clinical laboratory. Clin Chem Lab Med 2007;45(6):712-9. (PMID: 17579522)

4. Stroobants AK, Goldschmidt HM, Plebani M. Error budget calculations in laboratory medicine: linking the concepts of biological variation and allowable medical errors. Clin Chim Acta 2003; 333(2):169-76. (PMID: 12849900)

5. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47(Pt2):101-10. (PMID: 19952034)

6. Sciacovelli, L, Plebani, M. The IFCC working group on laboratory errors and patient safety. Clin Chim Acta 2009;404(1): 79-85. (PMID: 19328194)

7. Shahangian S, Snyder SR. Laboratory medicine quality indicators: a review of the literature. Am J Clin Pathol 2009;131(3): 418-31. (PMID: 19228647)

8. Westgard JO. The Six Sigma Calculators. https://westgard.com/six-sigma-calculators.html

9. Westgard JO. Six sigma: quality, design and control. https://westgard.com/lessons/advanced-quality-management-six-sigma/lesson67.html

10. Hwang CL, Yoon K. Multiple Attribute Decision Making: Methods and Applications a State-of-the-Art Survey. Springer-Verlag 1981. https://link.springer.com/book/10.1007/978-3-642-48318-9

11. Mingshao X. TOPSIS method with objective weight based on attribute measure and its application. Mathematics in Economics 2010;27:1-7. https://api.semanticscholar.org/CorpusID:123712073

12. Wang Y, Ren L, Chen L, Sun Z. [A novel improved TOPSIS method and its application in medical science]. Zhong Nan Da Xue Xue Bao Yi Xue Ban 2013;38(2):196-201. (PMID: 23456068)

13. International Federation of Clinical Chemistry and Laboratory Medicine. Quality Indicators in Laboratory Medicine. http://crb.aopd.veneto.it/MqiWeb/Page_QualityIndicators.jsf

14. Duan M, Kang F, Zhao H, et al. Analysis and evaluation of the external quality assessment results of quality indicators in laboratory medicine all over China from 2015 to 2018. Clin Chem Lab Med 2019;57(6):812-21. (PMID: 30511924)

15. Plebani M, Astion ML, Barth JH, et al. Harmonization of quality indicators in laboratory medicine. A preliminary consensus. Clin Chem Lab Med 2014;52(7):951-8. (PMID: 24622792)

16. Berta DM, Grima M, Melku M, et al. 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. Health Sci Rep 2024;7(1):e1833. (PMID: 38264158)

17. 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 2000;124(4):516-9. (PMID: 10747306)

18. Li Y, Chen F, Chen X. The surveys on quality indicators for the total testing process in clinical laboratories of Fujian Province in China from 2018 to 2023. Clin Chem Lab Med 2024;63(1):118-28. (PMID: 38987249)

19. Sciacovelli L, Padoan A, Aita A, Basso D, Plebani M. Quality indicators in laboratory medicine: state-of-the-art, quality specifications and future strategies. Clin Chem Lab Med 2023;61(4):688-95. (PMID: 36660807)

20. Plebani M. Quality in laboratory medicine: 50 years on. Clin Biochem 2017;50(3):101-4. (PMID: 27760306)

21. Sciacovelli L, Lippi G, Sumarac Z, et al.; Working Group “Laboratory Errors and Patient Safety” of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Quality indicators in laboratory medicine: the status of the progress of IFCC working group “laboratory errors and patient safety” project. Clin Chem Lab Med 2017;55(3):348-57. (PMID: 27988505)

22. Swetha NK, Kusuma KS, Sahana KR, et al. Sigma metric analysis of quality indicators across the testing process as an effective tool for the evaluation of laboratory performance. Med J Armed Forces India 2023;79(Suppl 1): S150-S155. (PMID: 38144620)

23. Mukhopadhyay T, Shekhar S, Dagar VK, Mukhopadhyay AK. Characterization of pre-analytical errors using Six sigma metrics and process capability index in a clinical biochemistry laboratory. Int J Health Sci Res 2021;11(2):171-6. https://ijhsr.org/IJHSR_Vol.11_Issue.2_Feb2021/IJHSR023.pdf

24. Sciacovelli L, Aita A, Plebani M. Extra-analytical quality indicators and laboratory performances. Clin Biochem 2017;57(1):632-7. (PMID: 28347721)

Additional material can be found online at:
http://supplementary.clin-lab-publications.com/250502/