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ORIGINAL ARTICLE

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

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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.**

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Supplementary Material

Table S1. Definition and formula of fifteen quality indicators.

Quality indicators	Metric type	Formula	Explanatory note
Pre-analytical phase			
Incorrect sample type	Performance metric	Percentage of: Number of samples of wrong or inappropriate sample matrix (e.g., whole blood instead of plasma)/Total number of samples	
Incorrect sample container	Performance metric	Percentage of: Number of samples collected in wrong container/Total number of samples	
Incorrect fill level	Performance metric	Percentage of: Number of samples with insufficient sample volume/Total number of samples	Insufficient = when the sample volume is less than that requested independently for the possibility to perform the test. It has to measure the incorrect collection (volume inferior to that defined), independently of collected volume (50% or 80% or 90%). Samples of pediatric patients have to be excluded
Anticoagulant samples clotted	Performance metric	Percentage of: Number of samples clotted/Total number of samples with an anticoagulant checked of clots	Checked samples = all samples verified for clots have to be included (hematology, coagulation clinical chemistry, etc.)
Blood culture contamination	Performance metric	Number of contaminated blood culture samples/Total number of blood culture samples	
Pre-examination TAT	Performance metric	The median of time from sample collection to sample receipt (min)	TAT = turn-around time
Intra-analytical phase			
Intra-laboratory TAT	Performance metric	The median of time from sample receipt to results reporting (min)	
Tests covered by IQC	Presence metric	Percentage of: Number of tests with IQC/Total number of tests in the menu	IQC: Internal Quality Control
Unacceptable performances in IQC	Performance metric	Percentage of: Number of tests with coefficient of variation (CV)% higher than defined limits/Total number of tests with CV% known	
Tests covered by an EQA-PT control	Presence metric	Percentage of: Number of tests with EQA-PT control/Total number of tests available in an EQA-PT provider	EQA: External Quality Assessment; PT: Proficiency Testing
Unacceptable performances in EQA-PT schemes	Performance metric	Percentage of: Number of unacceptable performances in EQA-PT schemes, per year/Total number of performances in EQA schemes, per year	
Tests covered by inter-laboratory comparison	Presence metric	Percentage of: Number of tests with inter-laboratory comparison/Total number of tests without EQA-PT control	In China, when there are quantitative tests in the laboratory that have not participated in the EQA/PT scheme, they must be compared with other laboratories of the same hospital level or those recognized by CNAS, who use the same reagent band

Table S1. Definition and formula of fifteen quality indicators (continued).

Quality indicators	Metric type	Formula	Explanatory note
Post-analytical phase			
Incorrect laboratory reports	**Performance metric**	**Percentage of: Number of rectified reports by laboratory after the release/Total number of released reports**	**For example: Reports could be rectified for erroneous results or inappropriate/missed interpretative comment or wrong patient details, etc**
Notification of critical results	**Performance metric**	**Percentage of: Number of critical values of inpatients and outpatients notified (from result validation to result communication to clinicians)/Total number of critical values need to communicate**	**Critical results = results that are "extremely" abnormal and are considered life threatening, because they may be associated with a significant dangerous event unless a medical action is promptly established**
Timely critical value notification	**Performance metric**	**Percentage of: Number of critical values notified within a consensually agreed time (from result validation to result communication to the clinician)/Total number of critical values need to communicate**	**Consensually agreed time = time established by laboratory in which the critical result has to be effectively reported to the clinicians**