Assessing clinical laboratory pre-analytical quality: evolution of sigma metrics across seven IFCC harmonized indicators in an International Laboratory Benchmarking Program

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BACKGROUND

Laboratories employ performance monitoring systems, with quality indicators (QI) playing a key role. Pre-analytical errors, responsible for up to 70% of laboratory errors, require continuous monitoring through QIs. Brazil's Laboratory Indicators Benchmarking Program, launched in 2006, includes 400 laboratories from 17 countries and 180 indicators, 42 of which focus on pre-analytical QIs.

AIM

To evaluate the performance of laboratories in this program, focusing on seven pre-analytical QIs harmonized by the IFCC WG-LEPS (Working Group on Laboratory Errors and Patient Safety).

METHODS

The study evaluated seven pre-analytical indicators: Sample Recollection, Sample Not Received due to Transport Error, Collection Error (Incorrect Sample and Container), Coagulated Samples, Hemolyzed Samples, and Patient Identification Error (misidentified requests). Median values for 2018 and 2023 global data were accessed, and performance was compared using sigma (σ) metrics for the 50th percentile to detect differences.

RESULTS

Analysis showed no significant differences between 2018 and 2023 for four of the seven pre-analytical indicators (Sample Not Received due to Transport Error σ >7.0 to >7.0, Incorrect Container σ 5.34 to 5.35, Coagulated Samples σ 4.85 to 4.84, Hemolyzed Samples σ 4.88 to 4.90; p-values 1.00, 0.541, 0.774, 0.286, respectively). However, statistically significant differences (all p-values <0.05) were observed for three indicators: Sample Recollection (σ 3.99 to 3.92), Misidentified Requests (σ 5.31 to 4.95), both with decreased performance, and Incorrect Samples (σ 5.07 to 5.37), which improved (Table 1).

Table 1: Sigma metrics for the quality indicators

Quality Indicator	σ(2018)	σ(2023)	p value
Sample not received due to transport error	>7.0	>7.0	1.00
Incorrect container	5.34	5.35	0.541
Coagulated samples	4.85	4.84	0.774
Hemolyzed samples	4.88	4.90	0.286
Sample recollection	3.99	3.92	<0.05
Misidentified requests	5.31	4.95	<0.05
Incorrect samples	5.07	5.37	<0.05

CONCLUSIONS

Although some statistical variations were noted, the sigma performance metrics for most indicators remained consistent between 2018 and 2023, highlighting the stability of data from the benchmarking program. The results suggest that participating laboratories may not be actively implementing or may not be seeing significant improvements in pre-analytical processes. This study emphasizes the importance of sustained improvement efforts, particularly in sample recollection, to enhance laboratory performance.

DISCLOSURE

The authors confirm that they don't have any conflict of interest to declare.

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