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ORIGINAL ARTICLE

Coefficient of variation selected as a quality specification for external evaluation systems in resource-limited environments

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ABSTRACT

Introduction: quality specifications for External Assessment Programs have proven useful in clinical laboratory management processes.
Objectives: to evaluate the Selected Coefficient of Variation for 13 analytes as a quality specification for an External Quality Assessment system for clinical chemistry in resource-limited environments.
Methods: an analytical, prospective, cross-sectional study was conducted in clinical laboratory services during the years 2023 and 2024. Using data from the External Evaluation Program, the Selected Coefficients of Variation were calculated through the aggregate variance and the weighted mean using an alternative and a commercial controller. They were compared using the Forkman Test, with a 95 % confidence interval. The lowest integer value was assumed. The performance of each participating laboratory was evaluated using the Average Variation Index and the Global Variation Index during the year 2024.
Results: no significant differences were found with the use of control materials. In all cases, the p value obtained was greater than 0,05. The coefficients ranged from 9 to 19. 6,6 % of the laboratories received an excellent rating, and the same percentage received an acceptable rating. 86,7 % showed good performance. No laboratory received a poor rating.

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Conclusions: obtaining the Selected Coefficients of Variation allows the program to evaluate the performance of clinical laboratories and analytical methods based on the limited resource conditions in which they operate.

Keywords: QUALITY CONTROL; QUALITY INDICATORS, HEALTH CARE; LABORATORIES, CLINICAL.

INTRODUCTION

Clinical laboratories are required to guarantee the reliability of their services through quality management systems. Each laboratory must adhere to the quality specifications established within internal and external quality assurance programs defined for its particular region.[1]

External evaluation schemes incorporate analytical quality specifications that, among other purposes, enable the assessment of laboratory performance, analytical methods, and working instruments. Since the Stockholm Consensus Conference in 1999 with its five-tier hierarchical model, followed by the 2014 Milan Strategic Conference with a simplified three-tier structure, these specifications have continued to evolve—offering both advantages and disadvantages—while always meeting client needs.[2]

In Cuba, the Selected Coefficient of Variation (SCV) as a quality specification was included in the PRONACEC Program until 2009.[3] However, since then, analytical methods, technology, reagent diversity, and other factors have changed considerably, requiring new approaches to adjust this variable to current working conditions—making performance evaluation more realistic within resource-limited environments.

In 2018, the PRICECLAB program (External Quality Evaluation Program for Clinical Laboratories in Pinar del Río) was launched. Its development required the use of an alternative control material, according to ISO 15189, to determine new SCV values adapted to the variability arising from economic constraints, equipment limitations, voltage fluctuations, transportation issues, and other contextual factors that differentiate local quality specifications from those in more developed regions.[4,5]

To validate these specifications, a commercially defined control material was required for comparison under identical conditions. Therefore, this study aims to evaluate the SCV for 13 clinical chemistry analytes as a quality specification that enables performance assessment of clinical laboratories in resource-limited environments.

METHODS

An analytical, longitudinal, and prospective study was conducted in the clinical laboratories of Pinar del Río province, Cuba, during 2023–2024.

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The universe consisted of 77 laboratories distributed across 11 municipalities. The sample included 30 laboratories that consented to participate and had chemical analyzers capable of testing the 13 selected analytes (uric acid, albumin, alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), calcium, cholesterol, creatinine, phosphorus, gamma-glutamyl transferase (GGT), glucose, total proteins, and triglycerides).

The PRICECLAB Program's Central Unit—Clinical Laboratory Service of "Dr. León Cuervo Rubio" Provincial Teaching Clinical-Surgical Hospital—was responsible for monthly distribution of both alternative and commercial control materials, each with normal and pathological levels, throughout 2023.[6]

- Alternative Control Material: Lyophilized material intended for internal quality evaluation, re-labeled and re-coded (month, lot, participant code, stability, reconstitution volume, and expiration date).
- Commercial Control Material: Lyophilized control from Spinreact® (Spain), designed for external quality assessment programs.

From PRICECLAB reports following analytical processing of both materials, robust means and standard deviations (according to ISO 13528)[7] were collected to calculate the required specification for each analyte.

The SCV (Equation A) was obtained through aggregate variance (Equation B) and weighted arithmetic mean (Equation C), where n_i = number of observations (participating labs per month i) and s_i^2 = analyte variance

Equation A: $$CV = \frac{S_p * 100}{\bar{X}_w}$$ Equation B: $$S_p^2 = \frac{\sum_{i=1}^{k}(n_i - 1)S_i^2}{\sum_{i=1}^{k}(n_i - 1)}$$ Equation C: $$\bar{X}_w = \frac{\sum_{i=1}^{k} n_i \bar{X}_i}{\sum_{i=1}^{k} n_i}$$

in month i. In Equation C, $\bar{X}_i$ = analyte mean in month i.

SCVs obtained from both materials were compared using the Forkman Test (95 % confidence). The lower integer value was selected as the official SCV for PRICECLAB. For calcium, amylase, phosphorus, and GGT, comparisons were not possible; thus, their unique values were adopted.

Performance indices were calculated for 2024 using:

- Variation Index $IV = \frac{\mathrm{V}}{\mathrm{CVS}} \times 100$
- % Variation $(\%\, V) = \frac{\mathrm{X} - \mathrm{X1}}{\mathrm{X1}} \times 100$

where X = value obtained by the laboratory, and X_1 = robust mean.

Performance categories were: Excellent (0–50), Good (51–150), Acceptable (151–250), and Deficient (>251).[4]

The Average Variation Index (AVI) for each laboratory represented annual performance, and the Global Average Variation Index (GAVI) summarized overall PRICECLAB performance in 2024.

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RESULTS

No significant differences were found between the alternative and commercial control materials for any analyte ($p > 0.05$). Coefficients ranged between 9 and 19. Minor differences were observed in creatinine and glucose values with the commercial control. PRICECLAB officially adopted the lowest integer SCV values for use as quality specifications in resource-limited settings.

Table 1. Selected Coefficients of Variation for PRICECLAB based on comparison between Alternative and Commercial Control Materials

Analyte	SCV (Alt. Control)	SCV (Comm. Control)	p-value (Forkman Test)	SCV (PRICECLAB)
Uric Acid	15,17	11,40	0,2877	11
Albumin	22,45	11,96	0,2858	12
ALT	21,17	16,16	0,2914	16
Amylase	18,90	0	0	19
AST	20,07	16,93	0,2943	17
Calcium	0	10,41	0	10
Cholesterol	17,81	12,15	0,2900	12
Creatinine	14,00	18,09	0,3154	14
Phosphorus	0	14,01	0	14
GGT	0	17,59	0	17
Glucose	14,16	14,87	0,3183	14
Total Proteins	13,42	9,06	0,2856	9
Triglycerides	21,92	12,26	0,2939	12

SCV: Selected Coefficient of Variation; Alt. Control: Alternative Control Material; Comm. Control: Commercial Control Material.
Source: PRICECLAB External Quality Evaluation Database.

In 2024, only two laboratories achieved an Excellent rating (VI < 50), none were Deficient, and two (codes 23 and 18) were Acceptable (VI: 151–250). The majority (86,7 %) achieved Good performance. The Global Average Variation Index (GAVI) was 108,4, corresponding to a Good rating.

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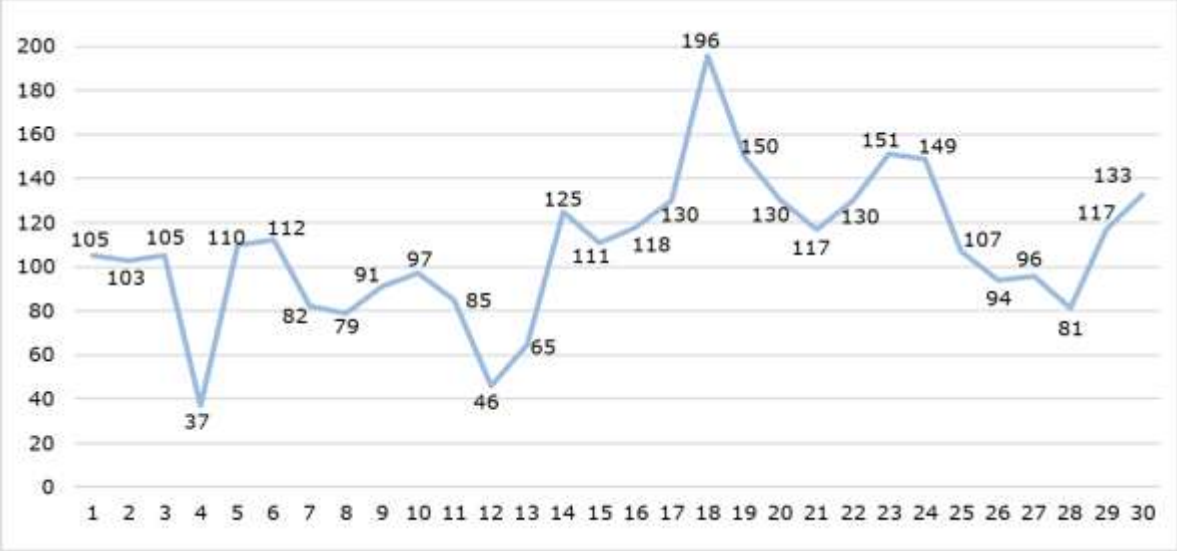

Source: PRICECLAB External Quality Evaluation Database.

Fig. 1 Laboratory performance assessment based on the Average Variation Index during the year 2024.

DISCUSSION

The primary goal of laboratory medicine is to produce analytical reports that support diagnostic decisions. Clinical laboratories must define measurable quality objectives through specifications to ensure reliable results.[2,8]

Analytical quality goals aim to produce accurate and reproducible results, based on imprecision, bias, and inaccuracy data—mainly derived from External Quality Assurance Programs.[2]

Such programs are essential for maintaining and improving analytical quality in laboratories and supporting evidence-based medical practice.[9]

The PRICECLAB program initially established local quality specifications using an alternative control material. This study, however, provides definitive SCVs for 13 clinical chemistry analytes after verification using a commercial control, confirming that either material may be valid if established standards are followed.[4,5,7]

Higher SCV values imply more permissive performance assessments. Historical data (Cruz Rodríguez, 1990s)[3] showed stricter CVs (≤10) under manual methods, yielding few Excellent ratings and many Acceptable or Deficient ones—information that led to abandoning several inaccurate methods.

Current expert analyses[9,10,11,12] stress the need for context-adapted specifications—not overly strict or lenient—to realistically reflect laboratory performance and encourage participation.

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The 2020 article *"Recommendations for the Use of Quality Specifications"*[13] states that EFLM's database is dynamic and specifications should be revised as new biological variation studies emerge. Analytical performance specifications should remain constant within a program's annual cycle for consistent evaluation but can evolve over time with methodological advances. PRICECLAB should therefore periodically review and adjust its analyte specifications accordingly.

As larger datasets enhance robustness,[14,15] the study's comparison limitations for calcium, amylase, phosphorus, and GGT—due to reagent scarcity—were mitigated by ISO 13528:2015-compliant robust processing, allowing valid single-value SCVs.[7]

Morancho et al.[16] propose that the ideal specification is that achieved by 20–25 % (P20–P25) or at least 50 % (P50) of participants. Here, only 10 % achieved Excellent ratings, suggesting potential category adjustments toward these benchmarks.

For laboratories in resource-limited settings, contextual adaptation is essential. Despite differing operational conditions, patient safety remains the ultimate goal. Yet, local realities—heterogeneous reagents, equipment brands, and inconsistent infrastructure—necessitate tailored specifications.[12]

An interesting finding was that the Central Unit itself (coded Lab 4) achieved Excellent performance, as did another semi-automated lab (Lab 12), demonstrating that advanced technology alone does not ensure superior outcomes—human expertise remains crucial.

CONCLUSIONS

Working under resource-limited conditions leads to differences between local and external quality specifications. Establishing context-appropriate specifications provides a more realistic reflection of analytical competence. This study defined clinical chemistry quality specifications for 13 analytes suited to resource-limited environments, enabling effective evaluation of laboratory and analytical method performance within the PRICECLAB External Quality Evaluation Program.

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Conflict of Interest
The authors declare no conflicts of interest.

Author Contributions
All authors contributed to the conception, design, data collection, statistical analysis, drafting, and approval of the final version.

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