Critical Systematic Errors in the Implementation and Follow-up of Performance in the Hematology Area: A Prospective Study

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Abstract

Due to the low use of the quality assessment of the hematological laboratories under the critical systematic error (ΔSE), and with the imperative to explore the implications of the use of the average of standard deviations and the control charts of each hematological parameter, we developed a prospective research at the University Clinic in Lima, Peru. We analyzed eight hematological parameters under the CLSI EP-15 A2 and CLSI H26-A2 guidelines for 19 days in the Landwind LW D3600 hematology autoanalyzer. In total, 1368 assays were performed (171 runs for each hematological parameter and 57 for each control level), which generated 19 averages in each level and for each parameter where we found 90 violations of the Westgard rules. Performance characteristics were optimal for leukocyte count (white blood cell) and platelets ($\Delta SE = \geq 5.8$) and were deficient for all erythrocyte parameters ($\Delta SE = 0.17-3.27$). We identify significant differences between the determined automatic mean (by the autoanalyzer) and the calculated mean, having in many cases marked the difference. The quality evaluation of the ΔSE analysis showed a heterogeneous performance and intra-parameter control levels, as well as violations of the Westgard rules and mismatches in the determination of means (calculated and automatic).

Key words: Quality control. Hematology. Critical systematic error. Average. Primary health care level.

Introduction

In recent years, new tools for the diagnosis of different diseases have been created (i.e., cancer and malaria and among others). In the pursuit of assuring quality results, reducing diagnostic costs, and improving their performance, while making them more accessible to different sanitary realities¹⁻⁵.

This development needs a quality guarantee which ensures trustworthy, efficient, and sustainable results, with a low error rate within the health-care systems. An inadequate quality in health-care endangers the patients' health. By 1999, estimations in the US suggested

that approximately 98,000 deaths were caused by medical errors⁶.

In clinical laboratories, quality is an ethical requirement and an imperative dynamic practice, which will allow us to issue results closer to the physiological reality of the patients. This assurance of quality is the initial component to ensure each stage of the diagnostic process⁷. From verification up to quality control, there are guidelines, parameters, and recommendations which assist clinical laboratories in improving processes and establishing optimal solutions^{8,9}.

In hematologic laboratories, performance Six sigma evaluations of performance and quality are rare. The

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most significant performance evaluation process of, for example, hematologic auto-analyzers is based on the fact that the standard deviations (SD) of hematologic parameters do not exceed the limits established by the maker, and that there are no errors shown in daily control graphics reflected in some infraction of the Westgard rules¹⁰⁻¹⁵. In 1963, Dorsey described the use of a daily mean of “mean corpuscular hemoglobin (MCH),” this fact almost went unnoticed up until the development of the Bull algorithm for erythrocyte indexes (red blood cell [RBC]) in 1974, representing the first quality control system for hematologic counters¹⁶. The benefits of quality management systems in different countries and health centers are unknown^{17,18}.

The objective of this investigation was to develop a quality evaluation of the critical systematic error (Δ SE) in the implementation and follow-up of hematologic performance in Lima, Peru, against the analysis comparative means of 8 hematologic parameters.

Materials and methods

To accomplish the established objectives, a prospective investigation was conducted at the Clinical Analysis Laboratory at the University Clinic in Lima, Peru. This study was approved by all institutions involved in its completion.

Automated analyzer

Conducive to performing determinations, an open-system Landwind Auto hematology analyzer LW D3600 was utilized (Landwind Medical Co., Shenzhen, China) for the analysis of 3 differentials, 20 parameters, and three histograms. This system processes 9.6 μ L of venous or arterial blood through an analytic run¹¹. For this study, the equipment was not switched off and was stabilized > 30 min before each daily use.

Reactives

Diagnostic reagents from COMING, Sozhou, China, were used (diluent reagents for hematology analyzer [Lot 2016121001], Lyser for hematology analyzer [Lot 20160707], and Cleaner for hematology analyzer [Lot 2016121601]). Hematologic controls were open-system reagents of three control levels (low, normal, and high) Myt-3D MYTHIC 18 (Lot B0816) from Orpée SA, Geneva, Switzerland. All analyses were conducted following the institution's operative necessities (Standardized

Operational Procedure or SOP), according to the maker's recommendations within the evaluation system.

Hematologic parameters

Analysis parameters were the leukocytes count (white blood cell [WBC]) $\times 10^3/\mu$ L, RBC $\times 10^3/\mu$ L, dosage of hemoglobin (HB) in g/dL, calculated automated hematocrit (HCT) in percentage. Furthermore, mean corpuscular volume (MCV) in fL, MCH in pL, mean corpuscular hemoglobin concentration (MCHC) in g/dL, and platelet count (PLT) $\times 10^3/\mu$ L.

Quality evaluation

The quality process was based on the evaluation of selected parameters during 19 days under the requirement guides CLSI EP-15 A2 and CLSI H26-A2^{19,20}. Before the beginning of the study, the system was calibrated under the maker's guidelines and an external quality control (data not shown). During the time of the study, control runs were conducted at the beginning of the work shift (12 h) 30 times before mixing the analysis tube²¹. Each control level (low, normal, and high) was run in triplicate, obtaining an average value calculated by the auto hematology analyzer's software, which was established as a daily control value. No repetitions of controls were performed.

To evaluate whether or not the Landwind LW D3600 data system reaches quality specifications, the Δ SE was calculated based on the Six sigma value (Δ SE = $\sigma - 1.65$) having previously obtained the quality bias, inaccuracy, and requirement values (TEa) for each hematologic parameter²⁰. The results of this evaluation were drawn on power function graphs indicating the quality control rules¹⁰.

Data analysis

Under the CLSI EP15-A2 guidelines, the mean SD or variation coefficient of each hematologic parameter was obtained, taking into consideration CLSI quality requirements on biologic variability for RBC, WBC, PLT, HB, MCV, HCT, and Rico's EQA values for MCH and MCHC^{20,22}. Based on the auto hematology analyzer's automatic average, they were compared with the calculations of the manual means (calculated average), which were compared through a simple linear regression. All runs were drawn on a chart based on SD for each parameter and were correlated with the sigma and Δ SE values using the Pearson correlation. The

data analysis was conducted using the IBM SPSS v21 statistical analyzer (Armonk, US) and MS-Excel 2010 (Redmond, US) for Windows.

Results

A total of 1368 runs were conducted (171 runs for each hematologic parameter and 57 at each control level), which generated 19 averages at each level and for each parameter. Ranges and values expected for the analysis of hematologic parameters are shown in Table 1.

In Figures 1-3, we can see the quality evaluations of all hematologic parameters. From this analysis, agreements between the analyzed values and those established as standards were obtained. For RBC at the low level, there was an agreement in 15 analyses; at the normal level, we obtained 14 agreements, and at the high level there were 12 agreements. In the case of WBC, we obtained 36, 18, and 7 agreements at the low, normal, and high levels, respectively. Moreover, for PLT, we obtained 19 coincidences at the low level, 38 at the normal level, and 47 at the high level. There were also agreements for hematologic parameters. For HB, we obtained 21 agreements at the high level, 11 at the medium level, and only 3 at the low level. For HCT, we obtained 10 agreements at the high level, 14 at the normal level, and 15 at the low level.

In the erythrocytes indexes, MCV presented 107 agreements with the mean, 13 at the low level, 53 at the medium level, and 41 at the high level, followed by MCH with 61 agreements, 41 at the high level, 19 at the medium level, and one at the low level. MCHC had 20 agreements, 11 at the high level, and 9 at the medium level ($p = 0.0001$).

Exceeding the quality limits (SD) of each parameter resulted in an infraction of the main Westgard control rules (in 90 analyses). Unfortunately, following the institution's SOP no corrective actions were taken (control actions for these errors), and the samples were analyzed despite this rule infraction. Therefore, RBC's low control level showed 4 infractions of the rules (1_{3s} , 1_{2s} , 6_x , and 31_s) at the normal and high levels (both with 2 infractions each); 2_{2s} , y 3_{1s} were observed. For WBC, 15 infractions of the Westgard rules were observed, 5 at the low level (1_{3s} , 1_{2s} , 9_x , and 3_{1s}), 5 at the normal level (1_{2s} , 1_{2x} , and 3_{1s}), and 4 at the high level (2_{2s} , 8_x y 7_T). In addition, the multilevel $2_{of}3_{2s}$ infraction was observed (yellow circles - Fig. 1B). Furthermore, global infractions were also observed with PLT 12 (low level 1_{2s} and 9_x], normal level 1_{3s} , 6_x , and 9_x], and high level 1_{2s} and 6_x]).

Likewise, for HB, we observed 12 infractions of the Westgard rules: 6 at the low level (3_{1s} , 6_x , 9_x , and 12_x), 2 at the normal level (2_{2s} and 12_x), and 2 at the high level (1_{2s} and 4_{1s}). Furthermore, 2 multilevel infractions were observed $2_{of}3_{2s}$ and 3_{1s} (light blue and yellow circles, respectively, - both in Fig. 2). For HCT, we observed a total of 10 infractions: 4 at the low level (1_{2s} , 6_x , and 9_x), 4 at the normal level (1_{2s} , 3_{1s} , 6_x , and 12_x), and 2 multilevel infractions 3_{1s} (both yellow circles - Fig. 2B).

For hematimetric values, infractions were 9, 14, and 17 for MCV, MCH, and MCHC, respectively. Two infractions were observed at the low level of MCV (2_{2s} and 9_x), 3 at the normal level (2_{2s} , 4_{1s} , and 9_x), and 4 at the high level (1_{2s} , 2_{2s} , 4_{1s} , and 9_x). In the MCH evaluation, we found 5 infractions at the low level (1_{2s} , 1_{3s} , and 6_x), 5 infractions at the normal level (1_{2s} , 8_x , 9_x , and 10_x), 3 at the high level (1_{2s} , 1_{3s} , and 8_x), and a multilevel 3_{1s} infraction (yellow circles - Fig. 3B). Finally, for MCHC, we found 6 infractions at the low level (1_{2s} , 4_{1s} , and 10_x), 6 infractions at the normal level (1_{2s} , 4_{1s} , 10_x , and 12_x), and 4 at the high level (1_{2s} , 4_{1s} , and 6_x), and a multilevel 3_{1s} infraction (Yellow circles - Fig. 3C).

The results of the analysis of the sigma metric and ΔSE are shown in Table 2. The hematological parameters that obtained a great performance were WBC and PLT, all the hematimetric indices (MCH, MCHC, and MCV) show a moderate/acceptable performance, and the values with low performance (poor quality) were RBC, HB, and HCT. A variability between control levels was observed within a parameter ($p = 0.001$) and between parameters ($p = 0.022$). Figure 4 shows example of the use of power charts for statistical control through ΔSE .

Finally, from our correlation analysis of averages, we observed that at the low level, only RBC and HCT presented agreement in all tests among all methods of media analysis (calculated and automatic - Fig. 5). At this level of control, HB did not present agreement between their means. WBC, PLT, MCH, MCV, and MCHC had 3, 11, 4, 9, and 1 agreement, respectively. In the normal level, we observed 25 agreements of means, with HCT showing agreement in 18 of its 19 media, and RBC showing 13 agreements ($p = 0.001$). At this level, all the parameters present agreement in at least one analysis.

Finally, the results of the high level show that HCT shows agreement in all its means, followed by RBC. *A contrario sensu*, the MCH did not observe agreement in any of their daily analyses. We also observed that other hematological parameters presented 1 (WBC), 2

Table 1. Standard ranges and values for the analysis of hematological parameters Myt-3D MYTHIC 18 (Orpée SA, Geneva, Switzerland) of lot B0816 for 18 hematological parameters

Controls (lot)	WBC ($\times 10^3/\mu\text{L}$)	RBC ($\times 10^6/\mu\text{L}$)	HB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	PLT ($\times 10^3/\mu\text{L}$)
Low LOTB0816L	2.0 ± 0.5	2.31 ± 0.18	62 ± 4	17.6 ± 1.5	76.0 ± 5.0	26.8 ± 2.5	353 ± 3	70 ± 20
Normal LOTB0816N	7.2 ± 1.0	4.50 ± 0.24	134 ± 6	18.0 ± 0.8	83.0 ± 5.0	29.8 ± 2.5	356 ± 3	250 ± 40
High LOTB0816H	19.7 ± 2.5	5.52 ± 0.30	180 ± 8	50.2 ± 2.4	91.0 ± 5.0	32.6 ± 2.5	358 ± 3	502 ± 60

WBC: white blood cell, RBC: red blood cell, HB: hemoglobin, HCT: hematocrit, MCV: mean corpuscular volume, MCH: mean corpuscular hemoglobin, MCHC: mean corpuscular hemoglobin concentration, PLT: platelet

Figure 1. Levey-Jennings control chart of the daily runs of blood controls. The main infractions of the Westgard rules have been noted (red circles and squares). (A) Red blood cell ($\times 10^6/\mu\text{L}$), (B) white blood cell ($\times 10^3/\mu\text{L}$), (C) platelet ($\times 10^3/\mu\text{L}$). Lot: LOTB0816.

(HB and MCV), and 4 (PLT) agreements during the quality evaluation ($p < 0.05$).

Discussion

Developing a quality evaluation system under the ΔSE analysis showed a heterogeneous performance between the hematological parameters and the intra-parameter control levels. Likewise, as a reflection of the high imprecision of each analysis, multiple infractions were observed at all levels of control, and significant differences were shown between the values of the

automatic mean and calculated for most hematological parameters.

Clinical laboratories carry out tests with commercial hematological controls to demonstrate, as a final indicator, if what is determined in the analyzer (daily) is real. In other words, if each process is under control and offers results that are closest to the physiological reality of each patient. Quality assessment provides a unique opportunity to know “what is going wrong” and recognize the multiple factors involved in these processes, and to modify them, adapt them to working conditions to avoid medically important wrong results, and work within the framework of continuous improvement.

Table 2. Summary of components of the quality evaluation under the analysis of critical systematic error (Δ SE) and sigma metric of eight hematological parameters

Analysis	Level*	Average	Bias%	CV%	Tea**	Sigma	Δ SE
WBC ($\times 10^3/\mu\text{L}$)	Low	2.26	0.25	10.97	7.5	7.5	5.83
	Medium	4.39	0.30	6.75		7.5	5.81
	High	5.35	0.43	8.10		7.4	5.80
RBC ($\times 10^6/\mu\text{L}$)	Low	1.93	0.16	8.41	3.0	3.0	1.33
	Medium	7.04	0.71	10.05		2.9	1.28
	High	17.00	1.24	7.27		2.8	1.18
HB (g/dL)	Low	53.46	5.52	10.32	3.5	3.0	1.32
	Medium	121.49	11.89	9.79		2.3	0.64
	High	168.28	16.21	9.63		1.8	0.17
PLT ($\times 10^3/\mu\text{L}$)	Low	114.43	35.54	31.06	12.5	11.4	9.71
	Medium	257.72	31.26	12.13		9.9	8.27
	High	515.26	31.50	6.11		7.3	5.70
HCT (%)	Low	17.33	1.95	11.22	3.0	2.8	1.18
	Medium	36.57	3.46	9.46		2.6	0.98
	High	49.67	4.76	9.58		2.5	0.85
MCV (fL) [†]	Low	71.8	1.60	2.2	4.0	3.3	1.62
	Medium	83	1.50	1.8		3.2	1.52
	High	92.7	2.08	2.2		3.1	1.40
MCH (pg) [‡]	Low	22.1	0.88	4.0	5.0	4.8	3.13
	Medium	27.6	0.99	3.6		4.7	3.08
	High	31.1	1.19	3.8		4.7	3.04
MCHC (g/dL) [‡]	Low	308.6	13.56	4.4	8.0	4.9	3.27
	Medium	333	12.02	3.6		4.7	3.01
	High	337.1	12.64	3.8		4.7	3.02

*Lots LOTB0816L (low level), LOTB0816N (normal level) y LOTB0816H (high level). **The quality requirements came from the CLSI H26-A3 guide. [†]Indicates the quality objectives according to CLIA 88²⁸. [‡]Ricos's Minimum analytical quality specifications²².

WBC: white blood cell, RBC: red blood cell, HB: hemoglobin, HCT: hematocrit, MCV: mean corpuscular volume, MCH: mean corpuscular hemoglobin, MCHC: mean corpuscular hemoglobin concentration, PLT: platelet

CLIA 88 indicates (CV%) $\pm 6\%$ as a goal value of imprecision for the erythrocyte count (RBC) and HCT, $\pm 7\%$ as target for the determination of HB, $\pm 15\%$ for the leukocyte count (WBC), and $\pm 25\%$ as a goal for PLT count²³. Our heterogeneous results showed that only WBC and HCT were within these parameters. Furthermore, that PLT and RBC surpassed the values indicated by CLIA at all levels (Table 2). These values indicated by CLIA are considered the most permissible when setting limits that are not as demanding, just as for HB that only exceeded the high-level limits.

When we compare our results with what was reported by Fink *et al.*¹⁸, we observe that HCT and HB exceeded the established limit value up to 3 times. On the other hand, WBC and RBC were within them. Similarly, a recent review by Vis and Huisman²⁴ indicated different “state-of-the-art” acceptable limits of imprecision on reproducibility and inter-batches. All values of inaccuracy determined in this study disagree with these in large quantities at all levels of blood control, except MCHC, which could not be compared and were able to

Figure 2. Levey-Jennings control chart of the daily runs of blood controls. The main infractions of the Westgard rules have been noted (red circles and squares). **(A)** Hemoglobin (g/dL), **(B)** hematocrit (%). Lot: LOTB0816.

Figure 3. Levey-Jennings control chart of the daily runs of blood controls (hematimetric values). The main infractions of the Westgard rules have been noted (red circles and squares). **(A)** Mean corpuscular volume (fL), **(B)** mean corpuscular hemoglobin (pg), **(C)** mean corpuscular hemoglobin concentration (g/dL). Lot: LOTB0816.

affect the final result during the routine evaluation of patient samples.

The inaccurate results of the Auto hematology analyzer Landwind LW D3600 determined in this study when compared to the Samsung LABGEOHC10 hematology analyzer show that all parameters disagree between the imprecision values (WBC, HB, MCV, MCH, and MCHCup to 4 times, RBC up to 8 times, and PLT up to 10 times more) in all levels of control²⁵. When we

compare the results of the evaluation of the Sysmex XE-2100D analyzer (except HCT) and the Sysmex XE-2100 (except the erythrocyte indices), we observed that none of the hematological parameters showed agreement in the limits of imprecision determined in this study, evidencing a marked difference in performance between hematological analyzers^{26,27}.

Furthermore, we observed differences in the bias for each parameter. The values for biases designated as

Figure 4. Power functions graphs for the statistical control of hematological parameters. In both cases, there are referred values of ΔSE opposites that imply the possibility of using Westgard control rules based on the probability of error detection (Ped), and the probability of false rejection (Pfr) under a number (N) of normalized controls. **(A)** Mean corpuscular hemoglobin concentration in (g/dL) (low control). **(B)** Hemoglobin in (g/dL) (high control).

“desirable” by various authors^{28,29} show that only RBC and WBC are within range, that MCV, HCT, and MCH exceed the established range, and PLT alarmingly exceeded up to 6 times the desirable value of bias (desirable value: ± 5.9).

In the Sysmex analyzers, the same phenomenon of discordance in the biases was seen in the vast majority of parameters. In fact, only WBC presented

comparable values with the precision ranges of the Sysmex XE-2100D analyzer in the high and low control levels^{26,27}. When contrasted with our results, other than HB and HCT, the comparison of the desirable limits of bias recently reported for the Sysmex XN hematological analyzer showed that only WBC and MCH were within these ranges in the three control levels³⁰. Then as well, only our bias values for WBC

were within the range of optimal performance of other studies^{29,31}.

In the overall evaluation, we made with the Levey-Jennings control chart, we pointed out the ≥ 90 infractions of the main Westgard rules in each control level, in addition to 7 violated multi-rules (Figs. 1-3). In general, the lower control presented more infractions to the rules (41 infractions) followed by the normal control (34 infractions) and the high (22). There were almost twice as many reports of systematic errors (64 infractions) than random reports (33 infractions).

The main erythrocytic components showed much inter-daily variability, usually by random (1_{2s} y 1_{3s}) and systematic errors (3_{1s} , 6_x , 9_x , and 2_{2s}). Although in previous studies the stability of the erythrocyte indices (MCV, MCH, and MCHC) have been described in hematological analyses of patients^{32,33}, in our study we observed 40 infractions of the Westgard rules, mainly of a random error type (1_{2s}). Similarly, for leukocytes and PLT, > 27 infractions were reported at all levels, mainly of the random error type (1_{2s} , y 1_{3s}). In addition, trends were observed in different hematological parameters (more than five data gradually increased or decreased) (Figs. 1-3).

Corrective activities must have been implemented for all these infractions, providing solutions for the laboratory to carry on the daily activities of clinical analysis^{7,11,14,15,20,34}. Unfortunately, the real scene of the vast majority of laboratories in Peru, and surely in other countries, is different. Although new quality development objectives and sanitary provisions have been established for clinical laboratories, these are for various reasons (economic, technical, lucrative, etc.) not being adopted, or are being inappropriately implemented.

In this sense, clinical work is often disconnected with quality. Many laboratories do not use hematological controls, others use them monthly or annually, or wait until equipment is "calibrated" by the specialist technicians provided by the manufacturer. This problem can be explained by the lack of education about quality management, the costs involved in initiating quality circuits/processes, work overload, and the poor efficiency of health systems to meet the demand of personnel, along with the pursuit of profit.

These problems are reflected in the work flowchart of the laboratories. For example, according to different hematology laboratory guidelines, only in cases of suspected hematological alteration should a direct review of peripheral blood smears and manual differential leukocyte counts be performed. However, this is carried out in each evaluation (whether the hematological

alteration is present or not), leading to unnecessary expenses, delays in the emission of results, and inefficiency of man-hour costs due to the low quality of results of these health-care centers. This happens not only in the laboratories of low strata but also in those of great prestige and high specialization³⁵.

For more than three decades now, the evaluation of organizational performance has been improved with the sigma metric, eliminating defects, and errors³⁶. At present, its use in clinical analysis laboratories and in health care not only ensures reliable and efficient results but also allows the fulfillment of competencies and continuous improvement, in addition to international certification and accreditation.

These should be a priority for health systems of all countries, systems that allow education and training of staff to develop these processes in their work and with the tools they have. However, the National Institute of Health of Peru, as an example of these cases, does not refer to any recommendation on the processes of quality management in hematology, neither for manual processes nor for automated ones^{37,38}.

In this study, we determined sigmas and ΔSE to be heterogeneous between hematological parameters and control levels (Table 2); the performance characteristics were optimal for WBC and PLT ($\Delta SE = \geq 5.8$). They were also deficient for all erythrocyte parameters ($\Delta SE = 0.17-3.27$).

The power functions graphs describe the acceptable errors and inaccuracies and the quality control that is necessary to monitor the performance of the method (just like the OPSpecs or sigma charts). These control charts also evaluate the performance of the test under stable conditions and warn of changes that may affect the report. Their objective is to obtain $\leq 5\%$ probability of false rejection and $\geq 90\%$ Ped in a single analytical run^{10,17,34}.

The main erythrocyte components showed low ΔSE and significative daily variability. Although WBC obtained a high performance (sigma and ΔSE), it presented 31 infractions of the Westgard rule at all levels, as well as 37 infractions in PLT. If the institution had done quality planning, it would have established the rules and/or multi-rules necessary for the control of the analyses. Some of these infractions would have been omitted because they were considered part of the analytical run, and others that indicate systematic or random errors, which affect the results, would be corrected^{10,17,20}.

In addition to these important evaluations of performance and quality in the hematology laboratory, the American College of Pathologists indicates that the use

Figure 7. Comparative chart of means between the automatic average (black line) and the calculated average (solid red line) in the high level of blood control. **(A)** White blood cell ($\times 10^3/\mu\text{L}$), **(B)** red blood cell ($\times 10^6/\mu\text{L}$), **(C)** hemoglobin (g/dL), **(D)** platelet ($\times 10^3/\mu\text{L}$), **(E)** mean corpuscular volume (fL), **(F)** mean corpuscular hemoglobin (pg), **(G)** mean corpuscular hemoglobin concentration (g/dL).

of controls with stabilizers, specimens of retained patients, or a mixture of these should be included, to act as monitors of any changes in the means of the hematological parameters³⁹. All these variables depend on the sample and control storage hours, the type of storage, their rational use, and the established guidelines, as well as the time and type of mixture before use and the number of determinations, as well as their calculation, etc.^{29,40}.

Regarding the latter, we reported inconsistencies in the establishment of means for each hematological parameter, finding differences between daily results and among levels of control. We identified significant differences between the determined automatic mean (by the autoanalyzer) and the calculated mean, having in many cases marked differences (Figures 5-7). RBC showed greater robustness and agreement in the estimation of means, in general, in the three levels of controls.

The HCT and RBC (56 and 46 results, respectively) were those with the highest agreement of means, followed by PLT (17 results), MCV (13 results), and MCH (9 results). The very rigorous evaluation character (decimal evaluation in g/dL), could explain why MCHC (5 agreements) obtained low agreements, but worryingly, does not explain those obtained for HB (6 agreements). These 142 agreements of means (calculated and automatic) allowed us to establish these as the daily values (after 3 analyses of the same serial control), in addition to those used to evaluate the quality of the autoanalyzer and the daily results¹¹. Regardless of the deviation values of the manufacturer that situate the majority of averages within these parameters, in this analysis, we demonstrate the variability between the determination of means by the equipment (in the measurement of three runs of each control for the estimation of the average mean) compared to that determined by the user (such as by checking daily averages).

Our results should be interpreted considering the following two limitations. First, that the evaluation was not performed with the new CLSI EP15-A3 guide for the conditions and access of the laboratory to this information (a study that should be carried out given that this new guide presents substantial modifications of the quality assessment processes). Second, the elimination of extreme values was not performed with the Dixon or Grubbs test⁴¹.

Finally, it has been recommended that each laboratory should estimate their quality control ranges for each type of analyzer based on the recommendations of several guidelines^{20,42-44}. However, these regulations

are still not very accessible or well-known by the workers at the hematological laboratory (technicians, phlebotomists, medical technologists, medical service managers, and manufacturers), or failing that; their use is dispensed with because it implies, among other things, investment in quality.

In Peru, both the Peruvian Institute of Quality of Peru (INACAL) and the National Institute of Health and the Peruvian Association of Quality Management of Peru (ASPEGC) must issue regulations and guidelines that allow clinical laboratories to manage the quality processes, as has been established in other countries¹⁴. We hope that this will happen in the coming years in Peru, and throughout the region.

Conclusions

The quality evaluation under the Δ SE analysis showed a heterogeneous performance of eight hematological parameters and between the intra-parameter control levels in the Landwind LW D3600 analyzer. We also determined > 90 infractions of the Westgard rules and mismatches in the determination of means (calculated and automatic) in 1368 trials in Lima, Peru.

Although the controls were outside the limits of one or more parameters, patient samples were analyzed, threatening health security and generating uncertain results. These could have medically important errors that affect the patient's health.

Ethical disclosures

Protection of humans and animals. The authors declare that the followed procedures conform with the ethical guidelines of the human committee of responsible human experimentation and in accordance with the World Medical Association and the Helsinki Declaration.

Data confidentiality. The authors declare that they have followed the protocols of their center about publishing patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients and/or of all the subjects referred in this articles. This document is in the hands of the corresponding author.

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Conflict of interest

The authors declare that they have no financial or labor conflicts of interest.

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