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Spanish Preanalytical Quality Monitoring Program (SEQC), an overview of 12 years' experience

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Abstract

Background: Preanalytical variables, such as sample collection, handling and transport, may affect patient results. Preanalytical phase quality monitoring should be established in order to minimize laboratory errors and improve patient safety.

Methods: A retrospective study (2001–2013) of the results obtained through the Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC) External quality assessment (preanalytical phase) was performed to summarize data regarding the main factors affecting preanalytical phase quality. Our aim was to compare data from 2006 to 2013 with a previously published manuscript assessing the 2001–2005 period.

Results: A significant decrease in rejection rates was observed both for blood and urine samples. For serum samples, the most frequent rejection causes in the first period were non-received samples (37.5%), hemolysis (29.3%) and clotted samples (14.4%). Conversely, in the second period, hemolysis was the main rejection cause (36.2%), followed by non-received samples (34.5%) and clotted samples (11.1%). For urine samples, the main rejection cause overall was a non-received sample (up to 86.1% of cases in the second period, and 81.6% in the first). For blood samples with anticoagulant, the number of rejections also decreased. While plasma-citrate-ESR still showed the highest percentages of rejections (0.980% vs. 1.473%, $p < 0.001$), the lowest corresponded to whole-blood EDTA (0.296% vs. 0.381%, $p < 0.001$).

Conclusions: For the majority of sample types, a decrease in preanalytical errors was confirmed. Improvements in organization, implementation of standardized procedures in the preanalytical phase, and participation in a Spanish external quality assessment scheme may have notably contributed to error reduction in this phase.

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Keywords: patient safety; preanalytical errors; quality monitoring; rejection samples.

Introduction

Scientific evidence supports the theory that most laboratory errors take place in the preanalytical phase, where processes are mostly manual and with little or no standardization [1–4]. Such processes involve different healthcare and non-healthcare professionals, as well as patients themselves. The fulfillment of these processes by organizations or individuals not directly dependent on the laboratory is considered to be a cause of increased error probability, and in turn hinders error detection, control and monitoring. Given that laboratory results have a significant impact in clinical decisions, the implication of such errors in patient safety may be highly relevant [5–9]. Accordingly, the improvement of preanalytical processes is currently one of the greatest challenges in laboratory medicine. The establishment of internal quality monitoring systems and participation in external peer comparison programs represent essential tools for the continuing improvement of these processes, as crucial as quality improvement of analytical processes used to be.

The American College of Pathologists was the first organization to perform external quality evaluation programs in the preanalytical phase (Q-probes, Q-tracks), and their results are periodically published. Every program includes several variables from both the preanalytical and the postanalytical phase [10–14]. The Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC) has extensive experience in the organization of external quality programs for the analytical phase and is aware of the relevance of preanalytical errors. Consequently, in 1998, it decided to start a pilot program for quality assurance of the preanalytical phase, which was consolidated later in 2001. The main objective of that program was to offer an easy tool for detecting the most frequent errors in the preanalytical phase to all Spanish clinical laboratories, so as to promote cross-comparison of results and thus stimulate continuous improvement. The implementation of these programs is increasingly becoming a priority worldwide given that the ISO 15189:2012 requires participation in "interlaboratory comparison programs". Subsequently, other programs assessing different aspects of the preanalytical phase have been developed [15–19], but are still scarce.

The program developed by the Commission on Quality Assurance in the Extraanalytical phase of the SEQC focused until 2013 on the analysis of the causes of sample rejection and included four cycles per year, collecting information on blood samples in two cycles and on urine samples in the other two. Participants were asked to register the number of and causes for rejections of routine or stat samples. The main objective of this program was to assess, for each laboratory, the frequency and type of sample errors (rejections) that occurred in the preanalytical phase, attributable to blood drawing, manipulation and collection. A rejection can be considered when one or several results cannot be delivered to a clinician due to causes related to preanalytical errors.

The information provided by laboratories (expressed as absolute number and type of rejection depending on sample type) was statistically analyzed, comparing individual laboratory results with the global results obtained from all participating laboratories. This information was later sent to every laboratory, for analysis of their own results, verification of objective achievement, and implementation of pertinent improvement actions.

The results for the first 5 years of the program (2001–2005) for blood and urine samples were published in 2006 and 2008, respectively [20, 21]. A retrospective analysis of the results (rejected specimens) obtained for blood and urine over the last 13 years (2001–2013) of the program is herein presented.

Materials and methods

The results (rejected specimens) have been divided into two periods: those obtained from 2001 to 2005 and those obtained from 2006 to 2013.

Design

Twice a year (March and October), the participants sent to the program the first 100 rejected blood samples, and twice a year (May and November) the first 50 rejected samples of urine produced each month, together with the total number of blood and urine samples processed during the period. If the first 100 rejected blood samples or the first 50 urine samples were obtained in a period of <1 month, only samples received in the period up to day of the threshold number for rejected samples were counted. In contrast, if in 1 month 100 blood samples or 50 urine sample rejections were not obtained, the total monthly data were counted. Table 1 shows the sample types and rejection causes for blood and urine (evaluated variables).

Program objective

The main objective was to evaluate the existing status of preanalytical phase quality and to obtain information allowing for identification and quantification of the most frequently found errors in this phase. The organization focused on the study of rejected specimens and reasons for their rejection.

Table 1: Sample types and rejection causes for blood and urine.

	Blood	Urine
Sample type	Serum	Urine
	ESR citrate	
	Coagulation citrate	
	Plasma heparin	
	Whole-blood EDTA	
	Whole-blood heparin	
Rejection causes	Clotted sample	Not received concurrent 24 h-urine sample
	Sample not received	Sample not received
	Insufficient sample	Insufficient sample
	Hemolyzed sample	Inadequate labeling
	Wrong container	Wrong container
	Transport defect	Transport defect
	Inappropriate sample-anticoagulant ratio	Interfering substances
	Other reasons	Other reasons

Definition of a rejection

A rejection can be considered when one result (or several results) cannot be delivered to a clinician due to causes attributable to preanalytical errors: test not performed or reported, as the specimen does not meet laboratory acceptability criteria. Rejections due to either lipidemia or icterus were not considered.

Statistics

All data were analyzed with the Statistical Package SPSS (SPSS Inc., Chicago, IL, USA). The following calculations were performed:

- Calculation of the percentage of rejected samples, by comparing them to the total number of samples according to (A) sample type, (B) reason for rejection, and (C) sample type and reason for rejection.
- Calculation of the percentage of rejected samples compared to all registered rejections for blood and for urine, respectively, according to rejection causes.
- Percentage of laboratories according to rejection rates.

To evaluate whether differences were statistically significant between periods, a χ^2-test was used to compare the rejection rates depending on sample type and rejection causes individually and together. Statistical significance was set at 0.05.

Results

In the first period (2001–2005) up to 105 laboratories were included [21], with a total of 433 participations, while in the second period (2006–2013), this increased to 121 laboratories with 585 participations.

For blood samples, a global rejection rate of 0.699% was detected (32,977 rejections in 4,715,132 samples) during the first period. When comparing the second period with the first, a significant reduction in the rejection rate was observed (0.488% vs. 0.699 $p < 0.001$). In the second period, 49,134 rejections were listed from among 10,060,666 samples (Table 2).

In both periods, the sample types with the lowest rejection rates were EDTA whole blood and serum (Table 2). For all blood sample types, the rejection rate decreased significantly when both periods were compared, except for plasma and whole-blood heparin where the rejection rate significantly increased. For urine samples, there was a similar decrease in the rejection rates in the second period (1.26% vs. 1.96%, $p < 0.001$) (Table 2).

In both periods, the most frequent sample overall is serum (45.7% and 49.3%, first and second period, respectively), followed by whole-blood EDTA (29.8% and 33.4%). The number of citrate erythrocyte sedimentation rate (ESR) samples substantially decreased, from 10.83% to 3.94%.

In Figure 1A and B, the distribution of participants is shown according to the rejection rate for both periods, for blood and urine samples, respectively. When both periods were compared, the percentage of laboratories with a blood sample rejection rate below 0.5% increased (34.7% vs. 27.4%). The same phenomenon was observed in urine samples: in the second period, the percentage of laboratories with a rejection rate below 1% is also higher than in the first period (28.9% vs. 17.9%).

For serum samples, the main rejection cause in the second period was hemolysis (36.2%), followed by non-received samples (34.5%) (Figure 2A). However, observations were reversed in the first period: the most frequent cause was non-received samples (37.5%), followed by hemolysis (29.3%). In both periods, the third cause was a clotted sample (11.14% vs. 14.46%). For urine samples, the main rejection cause overall was a non-received sample: up to 86.1% in the second period, from 81.6% in the first (Figure 2B).

In Table 3, the rejection causes are shown as a percentage of the total number of samples. The all-cause rejection rate in the second period was significantly lower ($p < 0.001$), except for defective transportation, with an increased rate, despite representing a low prevalence. The greatest decrease was seen in samples with insufficient blood volume compared to anticoagulant, followed by clotted and non-received samples. For hemolyzed samples, there was a smaller decrease.

When all rejection causes are assessed depending on sample type, hemolysis is the most prevalent for serum and plasma heparin (Table 4). While serum shows a

Table 2: Number and percentage of rejected samples according to sample type.

Type	2001–2005				2006–2013				p-Value
	Total, n	Total, %	Rejections, n	Rejections, %	Total, n	Total, %	Rejections, n	Rejections, %	
Serum	2,157,487	45.76	13,048	0.605	4,962,818	49.33	21,724	0.438	<0.001
ESR citrate	510,739	10.83	7522	1.473	396,824	3.94	3889	0.980	<0.001
Coagulation citrate	431,942	9.16	5030	1.165	777,643	7.73	7402	0.952	<0.001
Plasma heparin	122,118	2.59	1209	0.990	374,227	3.72	4062	1.085	<0.005
Whole-blood EDTA	1,404,941	29.80	5358	0.381	3,364,084	33.44	9943	0.296	<0.001
Whole-blood heparin	87,905	1.86	810	0.921	185,070	1.84	2114	1.142	<0.001
Total blood	4,715,132		32,977	0.699	10,060,666		49,134	0.488	<0.001
Total urine	395,408		7734	1.956	1,960,795		24,615	1.255	<0.001

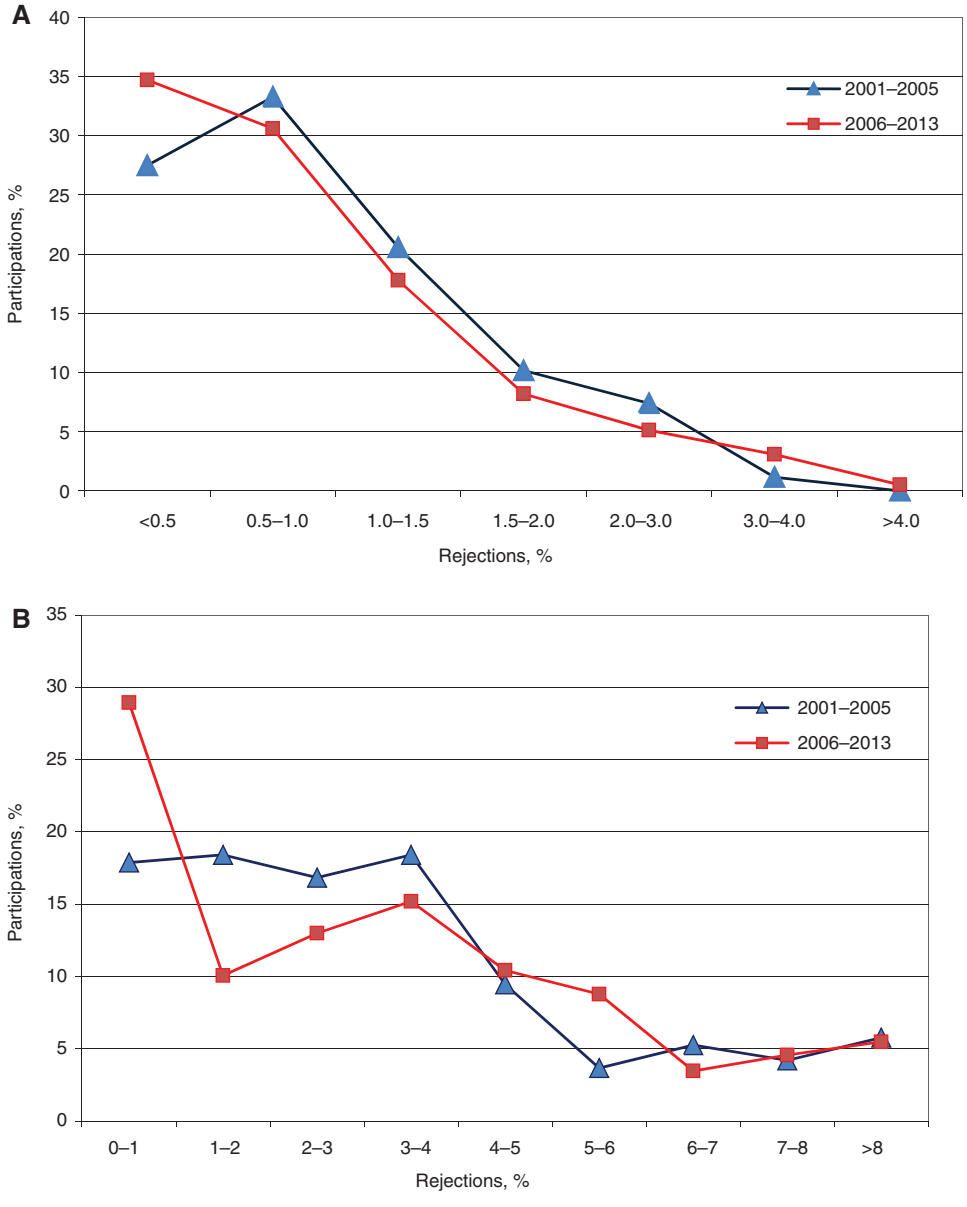

Figure 1: Distribution of participations.
(A) Distribution of participations according to rejection rate (blood). (B) Distribution of participations according to rejection rate (urine).

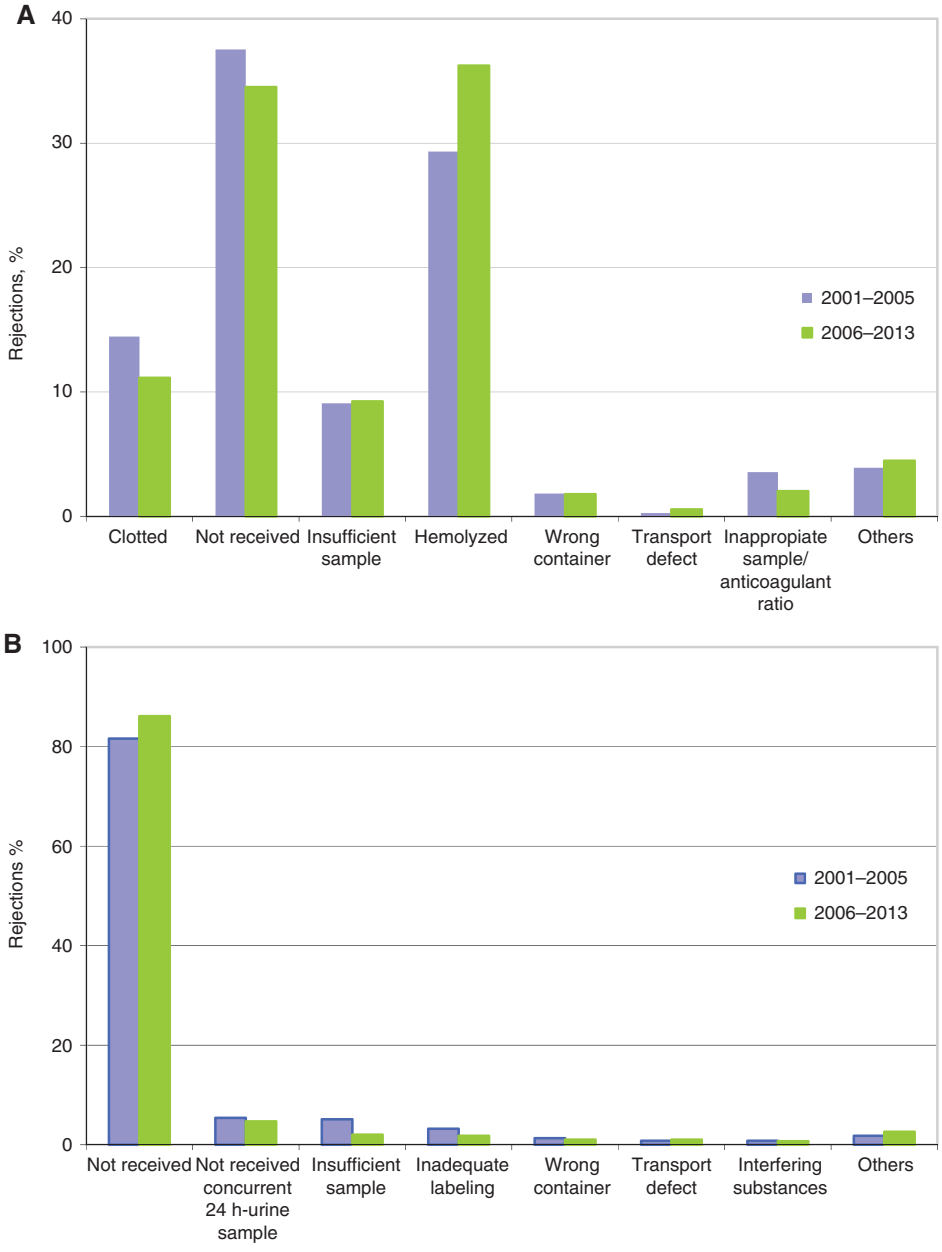

Figure 2: Rejection causes.
(A) Rejection causes expressed as percentages and compared to all registered rejections (blood). (B) Rejection causes expressed as percentages and compared to all registered rejections (urine).

statistically significant decrease (0.276% vs. 0.386%), conversely there is a significant increase in plasma heparin hemolysis (0.835% vs. 0.684%).

The main rejection cause in other samples was non-reception, with a significant reduction in the second period for the ESR-citrate (0.450% vs. 0.561%), coagulation-citrate (0.510% vs. 0.663%), and whole-blood EDTA (0.144% vs. 0.212%). For whole-blood heparin a statistically significant increase is observed in the second period (0.568% vs. 0.439%).

Discussion

These types of programs can help in identifying the existence of problems, and to stimulate corrective actions, but by themselves do not control anything and do not identify the causes of the non-conformities.

There are currently only a few external quality assessment schemes for the preanalytical phase worldwide, which, in addition, are poorly standardized. The program presented herein was developed by SEQC in 1998 and

Table 3: Sample rejection rates due to different causes for two time periods, expressed as percentage of received blood samples.

	2001–2005	2006–2013	Difference %	p-Value
Clotted	0.101	0.054	−46.2	<0.001
Not received	0.263	0.168	−35.8	<0.001
Insufficient	0.064	0.045	−29.1	<0.001
Hemolyzed	0.205	0.177	−13.8	<0.001
Wrong container	0.013	0.009	−32.1	<0.001
Transport defect	0.002	0.003	48.7	0.001
Inappropriate sample/anticoagulant ratio	0.025	0.010	−60.3	<0.001
Others	0.027	0.022	−18.9	<0.001
Total	0.699	0.488	−30.2	<0.001

offered to Spanish clinical laboratories starting in 2001. It was based on the comparison of preanalytical errors or the rejection causes attributable to blood drawing, handling, and sample collection.

The programs by the American College of Pathologists (Q-Track) and the Australian (KIMMS) are similar, since they are also based on the registration and peer-comparison of errors (rejections) [10, 11, 13, 14, 18]. The program developed by the Brazilian Society of Clinical Pathology is based on indicator comparison, including the concept of rejection, but not in an exclusive way [19]. In contrast, the IFCC project "Laboratory Errors and Patient Safety" [22] offers the participating laboratories the possibility of peer-comparison based on indicators for different processes.

In year 2008, an evaluation of our program was published, assessing the first 5 years of functioning, from 2001 to 2005 [21]. In the present manuscript, the study period is extended until 2013, with the aim of evaluating possible changes, and their impact on process improvement. A decrease in preanalytical errors (rejections) in participating Spanish laboratories was confirmed, for both urine and blood samples, with the decrease being greater for the latter.

The acknowledgment that the total laboratory process starts as soon as the physician makes a test request posed a shift in laboratory scientists' thinking. This included the assumption that responsibility for this process is shared among any healthcare professionals involved in the first part of the process, even when located far away from the central laboratory itself. The declaration of such responsibility, together with the verification of error production, led to a progressive implementation of measures aimed at improving quality control results in the preanalytical phase. Among other factors, continuous in-service training for phlebotomists, designation of preanalytical phase supervisors within the clinical laboratories, and registration of detected errors in the preanalytical phase are of the utmost importance for the establishment of useful indicators for the internal control of the preanalytical phase.

The automation of the preanalytical process, with the emergence of instrumentation for sample management and classification, as well as online communication with the laboratory information system, led to a gradual decrease in error probability [23, 24] and allowed for the possibility of automatic data collection and registration, without the need for manual registration.

The development of a feedback system between laboratories and blood-collection centers, with error communication and the adoption of consensus solutions is equally postulated as a contributing factor for improvement. Certification and accreditation impose quality criteria to be adopted by clinical laboratories that include the preanalytical phase. The implementation of such quality management systems is highlighted as a positive element in process improvement.

During the study period, an increasing interest in the preanalytical processes arose, as was demonstrated by the growing citations in PubMed ("preanalytic or pre-analytic or preanalytical"). In the first period, there were <200 citations, whereas there were more than 700 in the second period. Moreover, SEQC has promoted the organization of courses and conferences so as to increase the interest of laboratory professionals in such topics.

When the results were analyzed based on sample type and reason for rejection, several factors contributing to this improvement were identified. Worth mentioning is the implementation of the electronic laboratory request, which includes information regarding the number and type of samples needed to be drawn for the correct performance of the requested tests. This guidance for phlebotomists could have helped in lowering the rejections due to non-reception of samples.

For its part, the implementation of analyzers able to quantify ESR in EDTA tubes notably contributed to the decrease in the global rejection rate, since the formerly

Table 4: Rejection rates due to different causes and according to sample type for two periods, expressed as percentage of received blood samples.

	Serum		ESR citrate		Coagulation citrate		Plasma heparin		Whole-blood EDTA		Whole-blood heparin	
	2001–2005	2006–2013	2001–2005	2006–2013	2001–2005	2006–2013	2001–2005	2006–2013	2001–2005	2006–2013	2001–2005	2006–2013
Clotted			0.482	0.191	0.12	0.075	0.029	0.008	0.11[a]	0.102[a]	0.235	0.365
Not received	0.142	0.093	**0.561**	**0.450**	**0.663**	**0.510**	0.182[a]	0.177[a]	**0.212**	**0.144**	**0.439**	**0.568**
Insufficient	0.036	0.031	0.271	0.285[a]	0.108[a]	0.097[a]	0.015[a]	0.021[a]	0.021[a]	0.026[a]	0.069[a]	0.089[a]
Hemolyzed	**0.386**	**0.276**	0.006	0.001	0.085	0.107	**0.684**	**0.835**	0.005	0.002	0.046[a]	0.032[a]
Wrong container	0.012	0.008	0.008[a]	0.009[a]	0.015[a]	0.015[a]	0.034[a]	0.023[a]	0.01	0.005	0.065	0.040
Transport defect	0.002	0.003	0.001[b]	0.000[b]	0.001[a]	0.002[a]	0.005[a]	0.008[a]	0.001[a]	0.001[a]	0.018[a]	0.011[a]
Sample/anticoagulant ratio			0.093	0.012	0.147	0.122	0.002[b]	0.001[b]	0.004	0.000	0.01[b]	0.001[b]
Other	0.021[a]	0.026[a]	0.051	0.030	0.019[a]	0.024[a]	0.026	0.013	0.016	0.015	0.019[a]	0.036[a]
Total	0.605	0.438	1.473	0.980	1.165	0.952	0.99	1.085	0.381	0.296	0.921	1.142

The bold font refers to the most frequent cause of rejection. [a]$p \geq 0.05$. [b]No criteria.

used sample (citrate ESR) presented the highest rejection rate.

There is a smaller reduction of rejections due to hemolysis compared to other causes due to the fact that a high number of participant laboratories detected hemolysis by means of the hemolysis index reported by biochemistry analyzers (79.1%, according to our survey; data not published) instead of visual inspection, which was the most used method in the first period. This automatic inspection allows for the detection of hemolysis below 0.3 g hemoglobin/L, which goes visually undetected. Nevertheless, the lack of harmonization of this indicator is important, both in the visual and the automatic methods, together with the rejection criteria of each laboratory for every hemolysis-affected magnitude. This phenomenon has recently been described elsewhere [25, 26], thus showing the need for a consensus regarding rejection criteria which would include serum indices (hemolysis, icterus, lipidemia), as currently used by WEQAS [18]. A recent multicenter study in several Spanish laboratories was performed to evaluate whether a control material could be used to verify the value of the serum indices in different analyzers [27].

The lack of standardization in data collection by the participating laboratories is one of the limitations of this study. In most laboratories, data registration is not automated, hence requiring manual registration and making it personnel dependent. Neither is the required activity for data calculation standardized, since there is no consensus as to the number to which the errors will be compared (number of patients, number of samples, number of tubes, number of laboratory requests, number of blood collections, etc.). In a recent study by Cornes et al. [28] including the results of a survey of 157 laboratories in the UK, the same disparity is evidenced in the indicator calculation: up to 51% of the laboratories compared the number of errors to the samples requested, whereas the other 49% did so to the number of requests. Information systems often allow little access to these data, or none at all. This lack of standardization makes it practically impossible to compare our results with other publications.

Another limiting factor in result interpretation is the low participation in the program (similar in both periods). This might be due to the difficulty in obtaining the requested data (lack of automatic registration), thus making data collection tedious. In addition, the importance of inter-laboratory comparison is already known for the analytical phase, and should be equally understood for any preanalytical process. Moreover, as most preanalytical steps take place outside the laboratory, where the culture of monitoring is poorly developed, the participation in programs is also negatively affected.

The difficulty in data collection and the need for standardization, not only in the preanalytical processes but also in any laboratory step, has been brought to light by different groups [16, 29] working in the harmonization of quality indicators and their establishment as a tool for improvement and benchmarking among different laboratories, with the aim of reducing errors and enhancing patient safety.

In view of the different evaluations of the program, and considering the suggestions of participants in the satisfaction surveys at the end of each period, the program was redesigned in 2014. The main objectives of the new design were, on the one hand, better accessibility to the program for users, enabling easier data collection and submission, and, on the other hand, an enhancement of the program's robustness by increasing the length of time for each laboratory to register rejections.

Participation in peer-comparison programs like the one described is a powerful tool, but only for promoting error registration and for raising awareness of their relevance, or of the need for intervention if the frequency is much different from the median, not for error detection itself (the program itself does not detect errors, just registers those detected).

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