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IFCC paper

Pre-analytical quality indicators in laboratory medicine: Performance of laboratories participating in the IFCC working group "Laboratory Errors and Patient Safety" project

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ABSTRACT

Quality indicators (QIs) are key tools for improving the quality of laboratory services, by reducing error rates and safeguarding patient safety. A body of accumulated evidence confirms the relevance of QIs and their impact on the overall quality of laboratory information. The consensus achieved on a list of "harmonized" QIs, along with the system used for data collection and reporting throughout an international benchmarking programme, has enabled achieving realistic performance targets, based on knowledge of the state-of-the-art. Data collected in 2017 and 2018 have been analyzed and performance measures obtained by laboratories participating in the project are summarized in the present article. The laboratory performance measures have been classified into three levels (optimum, desirable or minimum) in agreement with the widely accepted model of analytical quality specifications.

1. Introduction

Continuous monitoring of laboratory performances is a key activity for identifying errors and fostering further improvements in Laboratory Medicine. The laboratory professional community is increasingly aware of the inter-play existing across the different phases of the Total Testing Process (TTP), as well as of the importance of correctly carrying out all pre-analytical activities performed by laboratory and non-laboratory staff in safeguarding the quality and reliability of the final laboratory information. An error in any step of pre-analytical phase can adversely affect both the quality of analytical results and the interpretation of information provided [1].

The monitoring of critical pre-analytical activities is of utmost importance, especially if one considers that the percentage of errors occurring in this phase is higher than in all other TTP phases. Moreover, many pre-analytical activities are performed outside the direct laboratory control. Since the process of systematic and comprehensive performance verification seems rather challenging in many steps of the TTP, monitoring of critical activities by using quality indicators (QIs) shall be considered a highly suitable procedure for total process performance evaluation.

The quality improvement process needs continuous efforts by all members of an organization for meeting quality specifications (QSs) in performance assessment, and error measurement is hence the first

Abbreviations: EFLM, European Federation of clinical chemistry and Laboratory Medicine; IFCC, International Federation of Clinical Chemistry and laboratory medicine; LEPS, Laboratory Errors and Patient Safety; MQI, Model of Quality Indicators; QIs, Quality Indicators; QSs, Quality Specifications; TTP, Total Testing Process; WG, Working Group

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Table 1
Pre-analytical quality indicators: 25th, 50th and 75th percentiles of laboratory results and sigma values concerning the 2017 and 2018.

Code	Quality indicator	Year	N.	Laboratory results			Sigma values		
				25th	50th	75th	25th	50th	75th
Misidentification errors									
Pre-MisR	Percentage of: Number of misidentified requests/Total number of requests.	2017	246	0.007 (0–0.010)	0.020 (0.020–0.030)	0.083 (0.067–0.100)	4.64 (4.59–4.70)	5.04 (4.93–5.04)	5.31 (5.22–6)
		2018	211	0.010 (0–0.010)	0.025 (0.020–0.030)	0.070 (0.054–0.100)	4.69 (4.59–4.77)	4.98 (4.93–5.04)	5.22 (5.22–6)
Pre-MisS	Percentage of: Number of misidentified samples/Total number of samples.	2017	214	0 (0–0.005)	0.020 (0.016–0.023)	0.041 (0.039–0.053)	4.84 (4.77–4.86)	5.04 (5.00–5.10)	6 (5.39–6)
		2018	163	0 (0–0)	0.020 (0.010–0.020)	0.040 (0.030–0.040)	4.85 (4.85–4.93)	5.04 (5.04–5.22)	6 (6–6)
Test transcription errors									
Pre-LabTDE	Percentage of: Number of requests with erroneous data entered by laboratory personnel/Total number of requests entered by laboratory personnel.	2017	78	0.002 (0–0.021)	0.166 (0.050–0.266)	0.680 (0.312–3.682)	3.97 (3.33–4.23)	4.44 (4.29–4.80)	5.61 (5.01–6)
		2018	48	0.030 (0–0.128)	0.207 (0.115–0.273)	0.766 (0.256–6.835)	4.03 (2.99–4.30)	4.37 (4.28–4.55)	5.14 (4.52–6)
Pre-OffTDE	Percentage of: Number of requests with erroneous data entered by offside personnel/Total number of requests entered by offside personnel.	2017	72	0.038 (0.020–0.079)	0.151 (0.088–0.227)	0.415 (0.236–0.499)	4.14 (4.08–4.32)	4.46 (4.34–4.63)	4.87 (4.65–5.04)
		2018	45	0.100 (0.100–0.170)	0.210 (0.170–0.250)	0.312 (0.247–0.433)	4.23 (4.12–4.31)	4.36 (4.31–4.43)	4.59 (4.43–4.59)
Incorrect sample type									
Pre-WroTy	Percentage of: Number of samples of wrong or inappropriate type (e.g. whole blood instead of plasma)/Total number of samples.	2017	154	0 (0–0)	0.003 (0.002–0.010)	0.022 (0.020–0.040)	5.01 (4.85–5.04)	5.48 (5.22–5.61)	6 (6–6)
		2018	135	0 (0–0)	0.002 (0–0.005)	0.021 (0.012–0.030)	5.02 (4.93–5.22)	5.61 (5.39–6)	6 (6–6)
Pre-WroCo	Percentage of: Number of samples collected in wrong container/Total number of samples.	2017	230	0 (0–0)	0.010 (0.010–0.020)	0.030 (0.030–0.040)	4.93 (4.85–4.93)	5.22 (5.04–5.22)	6 (6–6)
		2018	181	0 (0–0)	0.010 (0.004–0.010)	0.024 (0.020–0.030)	4.99 (4.93–5.04)	5.22 (5.22–5.44)	6 (6–6)
Incorrect fill level									
Pre-InsV	Percentage of: Number of samples with insufficient sample volume/Total number of samples.	2017	280	0.020 (0.010–0.020)	0.040 (0.030–0.058)	0.140 (0.104–0.160)	4.49 (4.45–4.58)	4.85 (4.74–4.93)	5.04 (5.04–5.22)
		2018	227	0.010 (0.006–0.011)	0.030 (0.022–0.040)	0.110 (0.079–0.130)	4.56 (4.51–4.66)	4.93 (4.85–5.01)	5.22 (5.19–5.35)
Pre-SaAnt	Percentage of: Number of samples with inappropriate sample-anticoagulant volume ratio/Total number of samples with anticoagulant.	2017	267	0.095 (0.062–0.139)	0.340 (0.223–0.450)	0.855 (0.690–0.980)	3.88 (3.83–3.96)	4.21 (4.11–4.34)	4.60 (4.49–4.73)
		2018	223	0.070 (0.040–0.114)	0.343 (0.220–0.420)	0.770 (0.690–0.980)	3.92 (3.83–4.00)	4.20 (4.13–4.35)	4.70 (4.55–4.85)
Unsuitable samples for transportation and storage problems									
Pre-NotRec	Percentage of: Number of samples not received/Total number of samples.	2017	252	0.090 (0.080–0.110)	0.340 (0.260–0.520)	1.110 (0.860–1.250)	3.79 (3.74–3.88)	4.21 (4.06–4.29)	4.62 (4.56–4.65)
		2018	216	0.090 (0.060–0.100)	0.190 (0.140–0.295)	0.889 (0.602–1.470)	3.87 (3.68–4.01)	4.39 (4.25–4.49)	4.62 (4.59–4.74)
Pre-NotSt	Percentage of: Number of samples not properly stored before analysis/Total number of samples.	2017	143	0 (0–0)	0 (0–0.002)	0.009 (0.004–0.010)	5.25 (5.22–5.44)	6 (5.61–6)	6 (6–6)
		2018	118	0 (0–0)	0 (0–0)	0.004 (0.001–0.007)	5.46 (5.29–6)	6 (6–6)	6 (6–6)
Pre-DamS	Percentage of: Number of samples damaged during transportation/Total number of transported samples.	2017	90	0 (0–0)	0 (0–0)	0.001 (0–0.002)	6 (5.61–6)	6 (6–6)	6 (6–6)
		2018	73	0 (0–0)	0 (0–0)	0 (0–0.001)	6 (6–6)	6 (6–6)	6 (6–6)
Pre-InTem	Percentage of: Number of samples transported at inappropriate temperature/Total number of samples.	2017	118	0 (0–0)	0.008 (0.001–0.285)	1.245 (0.780–1.557)	3.74 (3.66–3.92)	5.26 (4.30–5.80)	6 (6–6)
		2018	82	0 (0–0)	0.010 (0–0.790)	1.260 (0.947–1.457)	3.74 (3.68–3.84)	5.22 (3.91–6)	6 (6–6)
Pre-ExcTim	Percentage of: Number of samples with excessive transportation time/Total number of samples.	2017	87	0 (0–0)	0 (0–0.001)	0.035 (0.005–0.090)	4.89 (4.62–5.35)	6 (6–6)	6 (6–6)
		2018	68	0 (0–0)	0 (0–0)	0 (0–0.001)	6 (6–6)	6 (6–6)	6 (6–6)
Contaminated samples									

(*continued on next page*)

Table 1 (*continued*)

Code	Quality indicator	Year	N.	Laboratory results			Sigma values		
				25th	50th	75th	25th	50th	75th
Pre-MicCon	Percentage of: Number of microbiological contaminated samples rejected/Total number of microbiological samples.	2017	57	0.620 (0.460–0.750)	1.040 (0.750–1.230)	1.530 (1.230–2.040)	3.66 (3.54–3.75)	3.81 (3.75–3.93)	4 (3.93–4.10)
		2018	62	0.472 (0.027–0.720)	0.865 (0.720–1.280)	1.642 (1.325–2.100)	3.63 (3.53–3.72)	3.88 (3.73–3.94)	4.09 (3.95–5.64)
Pre-Cont	Percentage of: Number of contaminated samples rejected/Total number of not microbiological samples.	2017	65	0.003 (0.001–0.007)	0.014 (0.010–0.020)	0.030 (0.020–0.040)	4.93 (4.85–5.04)	5.13 (5.04–5.22)	5.51 (5.30–6)
		2018	66	0.010 (0.001–0.020)	0.020 (0.020–0.040)	0.070 (0.040–0.080)	4.69 (4.65–4.85)	4.93 (4.85–5.04)	5.22 (5.08–6)
Haemolysed samples									
Pre-HemV	Percentage of: Number of samples with free haemoglobin (Hb) > 0.5 g/L detected by visual inspection/Total number of checked samples for haemolysis	2017	147	0.111 (0.060–0.164)	0.300 (0.230–0.450)	1.435 (0.790–1.870)	3.69 (3.58–3.91)	4.25 (4.11–4.33)	4.56 (4.43–4.74)
		2018	130	0.110 (0.070–0.182)	0.288 (0.220–0.352)	1.105 (0.467–1.547)	3.79 (3.66–4.10)	4.26 (4.19–4.34)	4.56 (4.41–4.69)
Pre-HemI	Percentage of: Number of samples with free haemoglobin (Hb) > 0.5 g/L detected by automated haemolytic index/Total number of checked samples for haemolysis	2017	177	0.670 (0.504–1.090)	2.000 (1.480–2.217)	2.760 (2.580–2.970)	3.42 (3.38–3.45)	3.55 (3.51–3.67)	3.97 (3.79–4.07)
		2018	146	0.690 (0.460–0.970)	1.810 (1.490–2.230)	3.230 (2.595–3.800)	3.35 (3.27–3.44)	3.59 (3.51–3.67)	3.96 (3.84–4.10)
Pre-HemR	Percentage of: Number of samples rejected due to haemolysis/Total number of checked samples for haemolysis	2017	140	0.060 (0.040–0.142)	0.321 (0.265–0.390)	0.670 (0.484–0.822)	3.97 (3.90–4.09)	4.22 (4.16–4.28)	4.74 (4.48–4.85)
		2018	120	0.049 (0–0.165)	0.435 (0.300–0.500)	0.882 (0.587–1.410)	3.87 (3.69–4.02)	4.12 (4.07–4.25)	4.79 (4.44–6)
Clotted samples									
Pre-Clot	Percentage of: Number of samples clotted/Total number of samples with an anticoagulant checked for clots.	2017	290	0.117 (0.090–0.150)	0.280 (0.240–0.320)	0.517 (0.450–0.695)	4.06 (3.96–4.11)	4.27 (4.23–4.32)	4.54 (4.47–4.62)
		2018	252	0.080 (0.058–0.111)	0.237 (0.200–0.270)	0.402 (0.350–0.525)	4.15 (4.06–4.20)	4.32 (4.28–4.38)	4.65 (4.56–4.75)

necessary step of a continuous cycle of quality improvement.

Assurance of reliability in laboratory information requires an organized process, which shall then be systematically monitored by using accurate measures, which would ultimately enable achieving a high level of safety and quality. Laboratory information has a strong impact on safety and quality of patient care, as well as on clinical outcomes. However, an evaluation process can only be effective when the measures used are benchmarked with predefined and appropriate QSs. Additional necessary steps include regular and proactive identification and assessment of risk factors, and implementation of appropriate actions for attenuating the risks.

The adoption of well-defined and consensually approved QIs along with the establishement of an appropriate data collection strategy are effective tools for identifying and monitoring more critical activities and for achieving an effective evaluation of laboratory performance. Since the 2008, aiming to meet this challenge, the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has designed a Model of Quality Indicators (MQI) and implemented an informative platform for collecting QI data from many laboratories worldwide. All data collected are analyzed, and a report describing laboratory results benchmarked with those of other participating facilities is periodically issued.

2. Aim

This study is aiming to provide an update of the pre-analytical QIs data already described in previous papers published by the IFCC WG-LEPS [2,3].

The following information will be reported:

- statistical data (25th, 50th and 75th percentiles) of QIs laboratory results and sigma values collected in 2017 and 2018;
- QSs values defined according to criteria specified in the most recent Consensus Conference, to be used for 2018 laboratory results;
- percentage of laboratory performances achieved by participating laboratories for 2018 results, using defined QSs;
- benchmark analysis of laboratory performance measures for results collected between January and March 2018 and 2019.

3. Methodology

All pre-analytical QI data collected in 2017 and 2018 were analyzed on a yearly basis by an in house developed *R function* for estimation of 25th, 50th, and 75th percentiles and the corresponding 95% confidence intervals (95% CIs). Percentiles were estimated in R by the function "quantile" by assuming continuous sample distributions (type imposed to 7, the default method). Bootstrap statistics with R = 10000 interactions was used to calculate 95% CIs with non-parametric approach. A similar procedure was used to verify the distribution of *short-term sigma* [4], calculated from each laboratory result. When the estimation of sigma was > 6, the value was fixed at 6.

QSs were identified according to criteria defined in the most recent Consensus Conference, as reported elsewhere [2.3]. The thresholds for evaluation of laboratory performance were fixed at the 25th and 75th percentile according to the QIs State-of-the-Art 2017, and then applied to laboratory results collected in 2018.

The following levels of performance were identified:

- high, ≤ 25th percentile value, reflecting optimal performance;
- medium, between 25th and 50th percentiles values, representing the more common performance;
- low, ≥ 75th percentile, reflecting unsatisfactory performance.

Table 2
Pre-analytical quality indicators: Quality Specifications (QSs) and 2018 Laboratory performances.

Pre-analytical quality indicator *Priority - measure*	Code	Quality specifications			Laboratory performances		
		High	Medium	Low	High	Medium	Low
		< or =	*between*	*> or =*	*Percentage*		
Misidentification Errors							
Percentage of: Number of misidentified requests/Total number of requests.	Pre-MisR	0.007	0.007–0.083	0.083	29.86	51.18	18.96
Percentage of: Number of misidentified samples/Total number of samples.	Pre-MisS	0	0–0.041	0.041	31.90	49.08	19.02
Test transcription Errors							
Percentage of: Number of requests with erroneous data entered by laboratory personnel/Total number of requests entered by laboratory personnel.	Pre-LabTDE	0.002	0.002–0.680	0.680	25.00	50.00	25.00
Percentage of: Number of requests with erroneous data entered by offside personnel/Total number of requests entered by offside personnel.	Pre-OffTDE	0.038	0.038–0.415	0.415		80.00	20.00
Incorrect sample type							
Percentage of: Number of samples of wrong or inappropriate type (e.g. whole blood instead of plasma)/Total number of samples.	Pre-WroTy	0	0–0.022	0.022	39.26	36.30	24.44
Percentage of: Number of samples collected in wrong container/Total number of samples.	Pre-WroCo	0	0–0.030	0.030	39.23	44.75	16.02
Incorrect fill level							
Percentage of: Number of samples with insufficient sample volume/Total number of samples.	Pre-InsV	0.020	0.020–0.140	0.140	40.08	41.35	18.57
Percentage of: Number of samples with inappropriate sample-anticoagulant volume ratio/ Total number of samples with anticoagulant.	Pre-SaAnt	0.095	0.095–0.855	0.855	29.15	49.33	21.52
Unsuitable samples for transportation and storage problems							
Percentage of: Number of samples not received/Total number of samples.	Pre-NotRec	0.090	0.090–1.110	1.110	27.78	49.54	22.68
Percentage of: Number of samples not properly stored before analysis/Total number of samples.	Pre-NotSt	0	0–0.009	0.009	63.56	27.12	9.32
Percentage of: Number of samples damaged during transportation/Total number of transported samples.	Pre-DamS	0	0–0.001	0.001	87.67	12.33	
Percentage of: Number of samples transported at inappropriate temperature/Total number of samples.	Pre-InTem	0	0–1.245	1.245	36.59	36.59	26.82
Percentage of: Number of samples with excessive transportation time/Total number of samples.	Pre-ExcTim	0	0–0.035	0.035	88.24	10.29	1.47
Contaminated samples							
Percentage of: Number of microbiological contaminated samples rejected/Total number of microbiological samples.	Pre-MicCon	0.620	0.620–1.530	1.530	32.26	37.10	30.64
Percentage of: Number of contaminated samples rejected /Total number of not microbiological samples.	Pre-Cont	0.003	0.003–0.030	0.030	21.21	34.85	43.94
Haemolysed samples							
Percentage of: Number of samples with free haemoglobin (Hb) > 0.5 g/L detected by visual inspection/Total number of checked samples for haemolysis.	Pre-HemV	0.111	0.111–1.435	1.435	26.15	53.85	20.00
Percentage of: Number of samples with free haemoglobin (Hb) > 0.5 g/L detected by automated haemolytic index/Total number of checked samples for haemolysis.	Pre-HemI	0.670	0.670–2.760	2.760	24.14	46.90	28.96
Percentage of: Number of samples rejected due to haemolysis/Total number of checked samples for haemolysis.	Pre-HemR	0.060	0.060–0.670	0.670	27.50	44.17	28.33
Clotted sample							
Percentage of: Number of samples clotted /Total number of samples with an anticoagulant checked for clots.	Pre-Clot	0.117	0.117–0.517	0.517	32.14	47.22	20.64

4. Results

The 25th, 50th and 75th percentiles of results and sigma values calculated from data provided by the different laboratories, are summarized in Table 1. Due to insufficient number of answers for QIs with priority 2, 3 and 4, only priority 1 QIs have been reported.

Table 2 shows the QSs identified on the basis of the State-of-the-Art 2017, along with the corresponding percentage of laboratory performance measures for 2018 data.

Fig. 1 shows a comparison between percentages of laboratory performance in the first three months of the years 2018 and 2019, respectively.

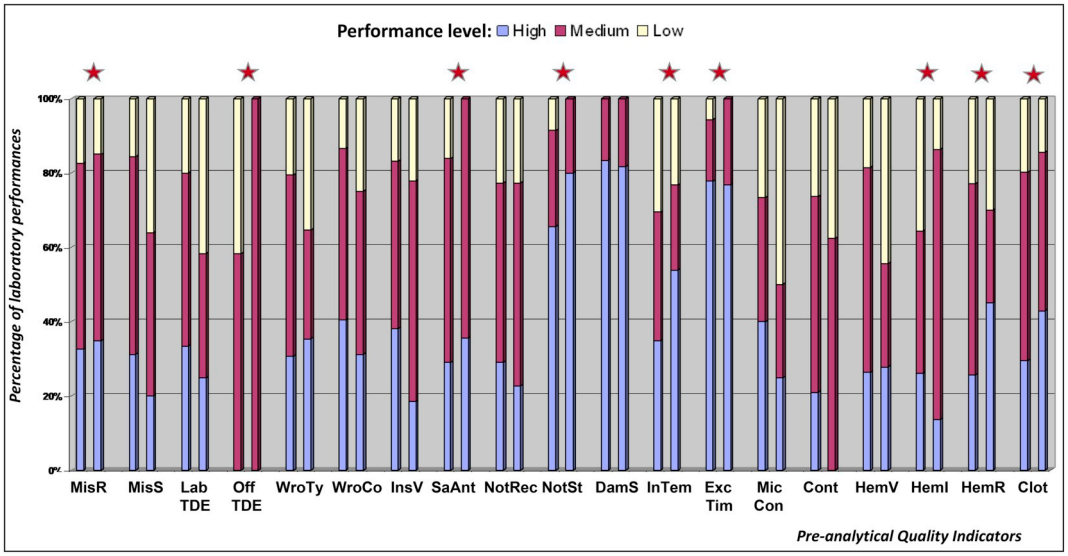

Fig. 1. Comparison of laboratory performances (%) obtained in 2018 (first column) and 2019 (second column) in the months of January, February and March (★ *improved performances*).

5. Discussion

A vast array of models has been proposed for identifying and reducing errors, and for categorizing them according to laboratory activities (errors due to laboratory problems or issues outside laboratory control or pertaining to the clinical-laboratory interface), nature (cognitive or non-cognitive) and consequences for the patient.

The priority 1 pre-analytical QIs have been more widely used by participating laboratories and measurement of unsuitable samples appeared the most commonly QI used in routine practice [5]. Concerning priority 2, 3 and 4 QIs, specific laboratory circumstances, challenges in collecting data and problems of staff constraint were found to be substantial barriers that contributed to limiting their usage.

Median values and data distribution varied depending on the specific QI, as shown in Table 1. For example, 0% values were obtained in both years for Pre-DamS. On the other hand, the QI for haemolysed samples detected using an automated haemolytic index (Pre-HemI), had median values of 2.00% and 1.81% in 2017 and 2018, respectively, whilst the corresponding 75th percentile values were 2.76% and 3.23%. Notably, these results shall be interpreted according to both type of error and simplicity of error collection. An automated procedure allows a more accurate and standardized data acquisition, whilst collection depends on personnel subjectivity and local environmental, as in the case of haemolysed samples detected using the serum index. The availability of devices for safeguarding blood samples during transportation, which is now widely used by many laboratories, is effective to prevent sample injury and is then associated with a low value of the Pre-DamS QI.

The calculated sigma level indicates that all processes involved were under control (> 3.9, typical quality of processes), with some of them achieving the highest value of 6 (i.e., world class).

Considering *misidentification errors* related to requests and samples, a stable level of performance (25th, 50th, 75th percentiles) can be seen during the last two years.This showed that the efforts made by the participating laboratories have been successful, especially of those with lower performance (75th percentile). The continuous monitoring of misidentification errors is crucial for identifying problems and encouraging laboratories to design appropriate corrective actions.

Concerning *test transcription errors*, the 2016 Consensus Conference has changed the data collection procedure compared to the previous MQI version, which is now more focalized on error origin. The analysis of our data highlights a lower percentage of transcription errors from laboratory staff compared to those attributable to offside personnel (personnel that are not under the laboratory control). This emphasizes the challenge of improving the actions of personnel not directly controlled by the laboratory. It is hence reasonable that activity performance is positively influenced by the level of laboratory supervision, by specific training and abilities, as well as by awareness of the importance of complying with quality specifications.

The QI data for the set of *unsuitable samples* (*incorrect type sample, samples with incorrect fill level, unsuitable samples for transportation, and storage problems)* display stable values over time. Similar trend can be seen for *clotted samples*.

Concerning *contaminated samples,* the percentage of errors for microbiological samples (e.g. blood culture, urine, sputum, pharyngeal secretion, etc.) was found to be higher than for all other samples (contaminated by infusion, drugs, anticoagulants - EDTA, citrate-, parenteral nutrition, X-ray contrast material, etc.).

As predictable, *haemolysed samples* is the most common type of errors reported in literature. The analysis of the different approaches used for identifying sample haemolysis, i.e., *visual inspection* or *automated serum indices*, allows an improved understanding on how haemolysis detection is strongly influenced by subjectivity. Although automated assessment appears the only suitable approach for verifying sample quality in high-volume clinical laboratories [6], an ongoing investigation is now aiming to establish whether the participating laboratories which use this QI have uniformed their decisional threshold at 0.5 g/L of cell-free haemoglobin. Notably, the various commercially available automated analytical systems use different approaches (sample size, diluents, wavelengths, algorithms, data expression, measuring unit, etc.) to assess and report cell-free haemoglobin in serum or plasma [6,7]. The information garnered with this study will hopefully promote a better approach for collecting data and, consequently, for a more straightforward and harmonized interpretation [8–10]

Poor results characterize *request without clinical question* for not hospitalized patients (priority 2). This is probably due to the many national regulations for description clinical questions in the test request. Since participating laboratories did not consider the process associated with this QI as critical, monitoring was deemed unnecessary and hence ignored. Poor results were also found for *unintelligible requests* (priority 3), related to not hospitalized and hospitalized patients. The scarce use of these indicators may have been due to the low number of handwritten test requests, which have been widely replaced by computerized order entry.

No data could be collected for *inappropriate requests, with respect to clinical question* (priority 4), for both not hospitalized and hospitalized patients. This is possibly due to the complexity of the data collection procedure. Close collaboration with clinicians would hence be needed for accurate measurement and analysis of these QIs.

Some challenges have been identified in interpretation of the QI *samples not collected at a defined time* (priority 2). Missed or delayed phlebotomy bookings were actually measured and reported erroneously.

Only samples for which the hour of collection directly impacts on interpretation of test results shall be measured. This is the case, for example, of tests needing multiple samplings (e.g. prolactin, oral glucose tolerance test).

Table 2 summarizes the QSs defined from the 2017 QI analysis, along with the values of different levels of performance achieved by the different laboratories in 2018. Most laboratory results were classified as 'medium performance'. This demonstrates that improvement could be achieved, and continuous monitoring can help laboratories to verify the effectiveness of their corrective actions. Exchange of experiences between laboratories is also a valuable tool for disseminating the best available practice.

Fig. 1 summarizes the performance comparison (in percentages) calculated on laboratory data collected between January-March 2018 and 2019, defined by applying QSs shown in Table 2. The improvement of some indicators confirms the importance of using QIs, as well as the effectiveness of participating in a benchmark programme for improving quality.

Major collaboration among working groups of international federations of laboratory medicine, such as the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and the IFCC, is a necessary step for identifying the needs of laboratories using QIs, but would also be effective for providing useful procedures and tools for controlling critical laboratory activities and further limiting the error risk.

6. Conclusion

All laboratory professionals recognize that efforts must be made in daily practice for improving quality and safeguarding patient safety. The implementation of widely agreed and approved QIs (whose regular use is also needed for fulfilling the accreditation standard ISO 15189) is an effective tool for fostering further performance improvements.

The correct identification of any undesirable event which has occurred, or which may occur, plays a key role in maximizing quality in clinical laboratories. The measurement process of QIs is highly challenging, in fact the data collection includes voluntary and systematic approach to error reporting, and a strong awareness of their importance. In this perspective, an active support from scientific societies and organizations, with dissemination of official documents and practices, is of strategic importance for improving the pathway towards quality and safeguarding patient safety.

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