Opinion Paper

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Quality indicators in laboratory medicine: state-of-the-art, quality specifications and future strategies

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Abstract: In the last few decades, quality in laboratory medicine has evolved in concert with the transformation and the changes (technological, scientific and organizational) in this sector. Laboratory professionals have faced great challenges, at times being overwhelmed, yet also involved in this progress. Worldwide, laboratory professionals and scientific societies involved in laboratory medicine have raised awareness concerning the need to identify new quality assurance tools that are effective in reducing the error rate and enhancing patient safety, in addition to Internal Quality Control (IQC) procedures and the participation in the External Quality Assessment Schemes (EQAS). The use of Quality Indicators (QIs), specifically designed for laboratory medicine are effective in assessing and monitoring all critical events occurring in the different phases of Total Testing Process (TTP), in particular, in the extra-analytical phases. The Model of Quality Indicators (MQI), proposed by the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and validated by experts in consensus conferences, is an important window of opportunity for the medical laboratory to demonstrate the use of an effective quality assurance tool fit for this purpose. Aim of this paper is to provide an update of the state-of-the-art concerning the most used QIs data collected in 2021 and the Quality Specifications (QSs) proposed for their evaluation. Moreover, a strategy for the future is proposed in order to improve the MQI and encourage its use in medical laboratories throughout the world.

Keywords: laboratory errors; quality improvement; quality indicators; quality specifications.

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Introduction

The term "quality" is mainly used by laboratories for referring to the reliability of their performance. Although all aspects of this topic appear to have been defined and known, the continuous progress made in laboratory medicine calls for the continuous review of both the characteristics of quality to be considered and the quality levels to be achieved, in order to provide performance that guarantees the best possible clinical outcomes and patient safety. The interest in quality in laboratory medicine has become increasingly relevant as scientific evidence highlights the crucial role it plays in the clinical decision-making process and patient management [1–4].

In the last few decades, as stated by Plebani [5], quality in laboratory medicine has evolved in concert with the transformation and the changes (technological, scientific and organizational) in this sector. Laboratory professionals have faced great challenges, at times being overwhelmed, yet also involved in this progress. They have, moreover, become key stakeholders in contributing to the definition of new approaches to diagnosis and therapy. In the fifties, quality assurance tools were focused on the control of analytical quality designed to obtain reliable results, determined manually or with the use of analytical systems, analytically accurate. The quality assurance tools in use enabled the assessment and monitoring of analytical performances, and their comparison with previous results within the same laboratory (via an Internal Quality Control procedure, IQC) and/or with the results obtained by other laboratories (via participation in the External Quality Assessment Program, EQAP) [6–10]. The use of IQC and participation in EQAP have considerably improved the

quality of the intra-analytical phase, thanks also to technological developments leading to the ever-increasing automation of diagnostic systems.

In 1981, Lundberg introduced the concept of the "brain to brain loop" according to which the phases of the total testing process (TTP) were extended and defined in detail. However, only after several years have laboratory professionals gained full awareness of the importance of the "brain to brain loop" and of the need to develop new quality assurance systems to control all phases of the TTP [11, 12]. Indeed, the study on the type and origin of errors associated with TTP activities, published in 1997 and 2007 by Plebani and Carraro [13, 14], highlighted the need to evaluate and monitor, not only the intra-analytical phases but, above all, the extra-analytical phases, which were found to be those at higher risk of error. Quality assurance systems in addition to IQC procedures and EQAPs have therefore been instated. Worldwide, laboratory professionals and scientific societies involved in laboratory medicine have raised awareness concerning the need to identify new tools that are effective in reducing the error rate and enhancing patient safety [15, 16].

In 2009, with a view to boosting activities designed to control and to measure the quality of laboratory performance, the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) implemented a Model of Quality indicators (MQI) for use in medical laboratories worldwide [17].

Aim of this paper is to provide an update of the state-of-the-art concerning the most used QIs data collected in 2021 and the QSs proposed for their evaluation. Moreover, a strategy for the future is proposed in order to improve the MQI and encourage its use in medical laboratories throughout the world.

State-of-the-art

As underlined in previous papers [18, 19], QIs must be adequately identified in order to control the most critical TTP procedures and activities, and to improve the processes designed to reduce risk of error. QIs should therefore be part of a coherent and integrated quality improvement strategy implemented according to the specifically-developed International Standard for Medical Laboratories Accreditation (ISO 15189:2012) [20].

Since 2008, three different MQI, proposed by IFCC WG-LEPS, have been followed in turn: their use in several laboratories throughout the world has highlighted the need for improvement in aspects such as wording, number of indicators and information included in periodical and confidential reports. In 2016, the Consensus Conference held in Padova (Italy) MQI was discussed and approved, and is now in use through an EQAP [21, 22]. Thanks to a dedicated website (www.ifcc-mqi.com), uniform data collection is managed, and data processing centralized, and a report for each participant provided.

Currently, the MQI includes 53 measurements for 26 quality indicators. In particular, the following numbers of measurements to be collected were identified: 43 for Key Processes (25 were defined for the pre-analytical phase, 6 for the intra-analytical phase, and 12 for the post-analytical phase); 5 for Support Processes and 5 for the Outcome Measures. An order of priority has been assigned on the basis of the importance of the specific indicator and difficulty in data collection. The priority 1 indicators are mandatory and must be the first to be used. About 500 laboratories are involved in the EQAP of QIs worldwide but, unfortunately, much less laboratories input data on the basis of deadlines requested.

In relation to each QI result provided by participants, a *short term sigma* is calculated and included in the periodical report provided by WG-LEPS in order to monitor variation in QIs data controlled, and to evaluate the goodness-capability of processes involved in order to produce a perfect work and to support the six sigma goals eliminating causes of errors [23–25].

Moreover QSs, have been identified and periodically updated for each QI in order to point out how the QI result is placed in comparison with those of others participants and if there are possibilities for improvement. This approach, based on benchmarking, allows performances to be assessed and compared, promotes continuous improvement, encourages information sharing and enhances the desire to implement best practices.

The criterion used to identify and update QSs is based on the results of participating laboratories: the 25th percentile represents the performance of high quality and the 75th, the performance of low quality. The use of the 75th percentile, as a lower limit, appears to be the most practical possible approach: no more than 25% of laboratories, in fact, are considered to have an unsatisfactory performance. According to the proposal by Fraser et al. [26], three different performance goals (optimal, desirable and minimum) identified allow laboratories to evaluate whether improvement actions are possible and encourage them to gradually improve their performance [27, 28].

Table 1 reports the 25th, 50th and 75th percentiles calculated on the QIs data collected in 2021, as a laboratory result and *short term sigma* value (STSV), concerning

Table 1: Quality indicators (with priority 1): 25th, 50th and 75th percentiles of laboratory results and sigma values (with confidence intervals) concerning the 2021.

Quality indicator			Laboratory results			
Code	**Measurement**		**n**	**25th**	**50th**	**75th**
Pre-analytical phase						
Misidentification errors						
Pre-MisR	Number of misidentified requests/total number of requests	Percentage	255	0 (0–0.004)	0.013 (0.011–0.017)	0.035 (0.027–0.052)
		Sigma		4.89 (4.77–4.95)	5.15 (5.08–5.19)	6 (5.44–6)
Pre-MisS	Number of misidentified samples/total number of samples	Percentage	140	0 (0-0)	0.008 (0.002–0.016)	0.037 (0.027–0.043)
		Sigma		4.87 (4.83–4.96)	5.26 (5.09–5.61)	6 (6–6)
Test transcription errors						
Pre-LabTDE	Number of requests with erroneous data entered by laboratory personnel/total number of requests entered by laboratory personnel	Percentage	39	0.117 (0.078–1.105)	1.468 (0.437–1.957)	2.217 (1.705–2.518)
		Sigma		3.51 (3.46–3.62)	3.68 (3.56–4.12)	4.54 (3.79–4.66)
Pre-OffTDE	Number of requests with erroneous data entered by offside personnel/total number of requests entered by offside personnel	Percentage	33	0.004 (0.002–0.025)	0.056 (0.008–0.084)	0.112 (0.076–4.091)
		Sigma		4.56 (3.24–4.67)	4.76 (4.64–5.27)	5.44 (4.98–5.61)
Incorrect sample type						
Pre-WroTy	Number of samples of wrong or inappropriate type (e.g. whole blood instead of plasma)/total number of samples	Percentage	94	0.003 (0.001–0.006)	0.016 (0.011–0.021)	0.039 (0.026–0.090)
		Sigma		4.86 (4.62–4.97)	5.09 (5.03–5.19)	5.51 (5.35–6)
Pre-WroCo	Number of samples collected in wrong container/total number of samples	Percentage	147	0 (0-0)	0.006 (0.002–0.009)	0.019 (0.016–0.024)
		Sigma		5.05 (4.99–5.10)	5.35 (5.24–5.61)	6 (6–6)
Incorrect fill level						
Pre-InsV	Number of samples with insufficient sample volume/total number of samples	Percentage	261	0.012 (0.008–0.016)	0.033 (0.027–0.039)	0.070 (0.056–0.080)
		Sigma		4.69 (4.65–4.76)	4.90 (4.86–4.96)	5.17 (5.10–5.27)
Pre-SaAnt	Number of samples with inappropriate sample-anticoagulant volume ratio/total number of samples with anticoagulant	Percentage	235	0.199 (0.123–0.251)	0.560 (0.456–0.735)	1.227 (1.073–1.428)
		Sigma		3.75 (3.70–3.80)	4.04 (3.94–4.11)	4.38 (4.30–4.53)
Pre-NotRec	Number of samples not received/total number of samples	Percentage	211	0.034 (0.013–0.060)	0.113 (0.090–0.139)	0.300 (0.191–0.527)
		Sigma		4.25 (4.06–4.39)	4.55 (4.49–4.62)	4.90 (4.74–5.15)
Pre-NotSt	Number of samples not properly stored before analysis/total number of samples	Percentage	49	0 (0–0.003)	0.004 (0.001–0.006)	0.008 (0.006–0.012)
		Sigma		5.27 (5.17–5.35)	5.44 (5.35–6)	6 (5.51–6)
Pre-DamS	Number of samples damaged during transportation/total number of transported samples	Percentage	35	0 (0-0)	0 (0–0.001)	0.001 (0–0.002)
		Sigma		6 (5.61–6)	6 (6–6)	6 (6–6)
Pre-InTem	Number of samples transported at inappropriate temperature/total number of samples	Percentage	62	0 (0-0)	0.004 (0–0.022)	0.057 (0.023–0.068)
		Sigma		4.75 (4.70–5.01)	5.42 (5.06–6)	6 (6–6)
Pre-ExcTim	Number of samples with excessive transportation time/total number of samples	Percentage	35	0 (0-0)	0 (0–0.008)	0.010 (0.001–0.015)
		Sigma		5.22 (5.11–5.76)	6 (5.27–6)	6 (6–6)
Contaminated samples						
Pre-MicCon	Number of microbiological contaminated samples rejected/total number of microbiological samples	Percentage	26	0.730 (0.438–0.860)	0.933 (0.812–1.172)	1.256 (1.02–1.782)
		Sigma		3.74 (3.60–3.82)	3.85 (3.76–3.90)	3.94 (3.88–4.12)

Table 1: (continued)

Quality indicator		Laboratory results				
Code	**Measurement**		**n**	**25th**	**50th**	**75th**
Pre-cont	Number of contaminated samples rejected/total number of not microbiological samples	Percentage	25	0.001 (0.001–0.001)	0.004 (0.001–0.014)	0.016 (0.004–0.019)
		Sigma		5.10 (5.05–5.44)	5.44 (5.13–6)	6 (6–6)
Haemolysed samples						
Pre-HemV	Number of samples with free haemoglobin (Hb) >0.5 g/L detected by visual inspection/total number of checked samples for haemolysis	Percentage	49	0.456 (0–0.739)	1.344 (0.669–1.630)	1.650 (1.590–1.820)
		Sigma		3.63 (3.59–3.65)	3.71 (3.64–3.97)	4.11 (3.94–6)
Pre-HemI	Number of samples with free haemoglobin (Hb) >0.5 g/L detected by automated haemolytic index/total number of checked samples for haemolysis	Percentage	173	0.687 (0.437–0.888)	1.218 (1.095–1.400)	3.267 (2.360–3.532)
		Sigma		3.34 (3.31–3.48)	3.75 (3.70–3.79)	3.96 (3.87–4.12)
Pre-HemR	Number of samples rejected due to haemolysis/total number of checked samples for haemolysis	Percentage	131	0.076 (0.030–0.149)	0.281 (0.202–0.390)	0.637 (0.462–0.688)
		Sigma		3.99 (3.96–4.10)	4.27 (4.16–4.37)	4.67 (4.47–4.93)
Clotted samples						
Pre-clot	Number of samples clotted/total number of samples with an anticoagulant checked for clots	Percentage	289	0.126 (0.100–0.150)	0.240 (0.220–0.280)	0.527 (0.407–0.630)
		Sigma		4.06 (3.99–4.15)	4.32 (4.27–4.35)	4.52 (4.47–4.59)
Intra-analytical phase						
Unacceptable performances in IQC						
Intra-UnIQC	Number of IQC results outside defined limits/total number of IQC results	Percentage	98	0.704 (0.025–1.648)	2.429 (1.810–2.977)	5.519 (3.341–6.866)
		Sigma		3.10 (2.99–3.33)	3.47 (3.38–3.59)	3.95 (3.63–4.98)
Unacceptable performances in EQA-PT schemes						
Intra-unac	Number of unacceptable performances in EQAS-PT schemes, per year/total number of performances in EQA schemes, per year	Percentage	22	1.192 (0.420–1.793)	1.881 (1.290–2.722)	2.863 (2.116–3.800)
		Sigma		3.40 (3.27–3.53)	3.58 (3.42–3.73)	3.76 (3.60–4.13)
Data transcription errors						
Intra-ErrTran	Number of incorrect results for erroneous manual transcription/total number of results that need manual transcription	Percentage	25	0 (0-0)	0 (0–0.004)	0.004 (0–0.009)
		Sigma		5.44 (5.24–6)	6 (5.44–6)	6 (6–6)
Intra-FailLIS	Number of incorrect results for information system problems/total number of results	Percentage	12	0 (0-0)	0 (0-0)	0 (0-0)
		Sigma		6 (5.88–6)	6 (6–6)	6 (6–6)
Post-analytical phase						
Inappropriate turnaround times						
Post-OutTime	Number of reports delivered outside the specified time/total number of reports	Percentage	75	0.002 (0–0.096)	1.221 (0.162–5.300)	6.254 (5.457–9.746)
		Sigma		3.03 (2.80–3.10)	3.75 (3.12–4.44)	5.56 (4.60–6)
Post-PotTAT	Turnaround time, min, from sample reception in laboratory to release of result, of potassium (K) at 90th percentile (STAT)	Time	53	48 (45.5–52)	54 (52–57)	65 (56–79)
Post-INRTAT	Turnaround time, min, from sample reception in laboratory to release of result, of international normalized ratio (INR) value at 90th percentile (STAT)	Time	48	47 (42–53)	56 (51–60)	66 (59–77)
Post-WBCTAT	Turnaround time, min, from sample reception in laboratory to release of result, of white blood cells (WBC) value at 90th percentile (STAT)	Time	49	28 (22–31)	32 (31–37)	41 (37–43)
Post-TnTAT	Turnaround time, min, from sample reception in laboratory to release of result, of cardiac troponin (TnI or TnT) value at 90th percentile (STAT)	Time	49	47 (43–54)	57 (53–61)	65 (59–70)

Table 1: (continued)

Quality indicator		Laboratory results				
Code	**Measurement**		**n**	**25th**	**50th**	**75th**
Post-TATPotH	Number of potassium results (STAT) released after 1 h/Total number of potassium results (STAT)	Percentage	182	3.681 (3.180–4.267)	7.665 (6.018–9.958)	18.110 (15.814–21.393)
		Sigma		2.41 (2.30–2.50)	2.93 (2.78–3.05)	3.29 (3.22–3.35)
Incorrect laboratory reports						
Post-RectRep	Number of rectified by laboratory reports after the release/total number of released reports	Percentage	97	0.011 (0.009–0.016)	0.020 (0.017–0.025)	0.043 (0.031–0.061)
		Sigma		4.83 (4.73–4.92)	5.04 (4.98–5.08)	5.19 (5.10–5.24)

IQC, internal quality control; EQA, external quality assessment; PT, proficiency testing; STAT, immediately (from the Latin word “statim”).

the QIs with priority 1, except for Intra-IQC, Intra-EQA, Post-InsCR, Post-OffCr that highlight a very low number of results.

The STSVs, reported in Table 1, demonstrate a different control of processes in relation to QIs evaluated: 10 QIs (Pre-MisR, Pre-MisS, Pre-WroCo, PreNotSt, Pre-DamS, Pre-InTem, Pre-ExcTim, Pre-Con, Intra-ErrTran, Intra-FailLIS) demonstrate the highest control level of processes involved achieving a SSV equal to 6; 5 QIs (Pre-InTem, Pre-ExcTim, Pre-MicCon, Pre-HemV, Pre-HemI) a good control achieving a STSVs between 5.17 and 5.56; 6 QIs (Pre-WroCo, Pre-InsV, Pre-SaAnt, Pre-NotRec, Pre-NotSt, Pre-DamS) an acceptable control with a STSVs between 4.11 and 4.9. Actions are needed in order to improve the control of activities monitored by the 5 QIs with STSVs between 3.29 and 3.96 (Pre-MisR, Pre-MisS, Pre-LabTDE, Pre-OffTDE, Pre-WroTy).

Table 2 shows the QSs applied as from 2022.

The comparison with the data previously published could not be appropriate because of the particular context experienced by clinical laboratories in the last two years (2020 and 2021) due to the COVID-19 pandemic. In fact, laboratory professionals have been forced to cope with a number of absolutely new problems and to try out solutions to comply with clinical needs. In this situation, the systematic collection of QIs data and their entering on a dedicated website was often omitted impacting on the number and evaluation of results. It will be interesting to re-evaluate data collected in the last few years and analyse the trend when the pandemic will be definitively over and the operative flows in the laboratories stabilized. In fact, in order to correctly evaluate a possible improvement and/or worsening trends, the comparison among different months/years have to be made with results belonging to the same laboratories. The participation of new laboratories at a different time may affect the real trend of the data and the evaluation of the effectiveness of actions carried out by laboratories to improve their performances.

Future strategies

The awareness of the value of Laboratory Medicine is now well-established and proven by the evidence demonstrating the positive impact of laboratory results on patient outcome. The reliability of laboratory performance, in terms of analytical accuracy, appropriate choice of the right test at the right time, and the correct interpretation of laboratory results, are discriminating elements that determine this value. Therefore, the development of reliable quality assurance tools to evaluate laboratory performance is pivotal to guaranteeing patient safety. Moreover, the continuous scientific, technological and organizational progress, which improves knowledge and working procedures to define better diagnostic-therapeutic pathways, calls for the identification and use of further, new quality assurance tools to verify and monitor performance. In this context, laboratory professionals must be prepared to face, and manage, current and future challenges. This means that the project for QIs proposed by IFCC WG-LEPS needs to be consensually updated with the involvement of a group of experts. The following steps are of particular importance.

- Reviewing the MQI on the basis of analysis and evaluation of the:
  - new organizational contexts that involve laboratory medicine,
  - role of laboratory medicine in the complying with clinical needs,
  - role of Laboratory Medicine in interacting with the stakeholders involved in defining diagnostic therapeutic pathways,
  - needs highlighted by participating laboratories,
  - data collected in the last few years,
  - need to measure the impact of laboratory results on patient outcomes;
- Increasing the participation of laboratories worldwide, and promoting the leadership of national leaders

Table 2: Quality specifications of the quality indicators applied as from 2022.

Quality indicator		Quality specifications		
Measurement	**Code**	**High < or =**	**Medium Between**	**Low > or =**
Pre-analytical phase				
Misidentification errors				
Percentage of: number of misidentified requests/total number of requests	Pre-MisR	0	0–0.035	0.035
Percentage of: number of misidentified samples/total number of samples	Pre-MisS	0	0–0.037	0.037
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	0.117	0.117–2.217	2.217
Percentage of: number of requests with erroneous data entered by offside personnel/total number of requests entered by offside personnel	Pre-OffTDE	0.004	0.004–0.112	0.112
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	0.003	0.003–0.039	0.039
Percentage of: number of samples collected in wrong container/total number of samples	Pre-WroCo	0	0–0.019	0.019
Incorrect fill level				
Percentage of: number of samples with insufficient sample volume/total number of samples	Pre-InsV	0.012	0.012–0.070	0.070
Percentage of: number of samples with inappropriate sample-anticoagulant volume ratio/total number of samples with anticoagulant	Pre-SaAnt	0.199	0.199–1.227	1.227
Percentage of: number of samples not received/total number of samples	Pre-NotRec	0.034	0.034–0.300	0.300
Unsuitable samples for transportation and storage problems				
Percentage of: number of samples not properly stored before analysis/total number of samples	Pre-NotSt	0	0–0.008	0.008
Percentage of: number of samples damaged during transportation/total number of transported samples	Pre-DamS	0	0–0.001	0.001
Percentage of: number of samples transported at inappropriate temperature/total number of samples	Pre-InTem	0	0–0.057	0.057
Percentage of: number of samples with excessive transportation time/total number of samples	Pre-ExcTim	0	0–0.010	0.010
Contaminated samples				
Percentage of microbiological contaminated samples rejected/total number of microbiological samples	Pre-MicCon	0.73	0.73–1.256	1.256
Percentage of rejected contaminated samples/total number of non-microbiological samples	Pre-cont	0.001	0.001–0.016	0.016
Haemolysed samples				
Percentage of samples with free haemoglobin (Hb) >0.5 g/L detected visually/total number of checked samples for haemolysis	Pre-HemV	0.456	0.456–1.650	1.650
Percentage of samples with free haemoglobin (Hb) >0.5 g/L detected by automated haemolytic index/total number of samples checked for haemolysis	Pre-HemI	0.687	0.687–3.267	3.267
Percentage of: samples rejected due to haemolysis/total number of samples checked for haemolysis	Pre-HemR	0.076	0.076–0.637	0.637
Clotted sample				
Percentage of clotted samples/total number of samples with anticoagulant checked for clots	Pre-clot	0.126	0.126–0.527	0.527
Intra-analytical phase				
Unacceptable performances in IQC				
Percentage of: number of IQC results outside defined limits/total number of IQC results	Intra-UnIQC	0.704	0.704–5.519	5.519
Unacceptable performances in EQA-PT schemes				
Percentage of: number of unacceptable performances in EQAS-PT schemes, per year/total number of performances in EQA schemes, per year	Intra-unac	1.192	1.192–2.863	2.863
Data transcription errors				
Percentage of: number of incorrect results for erroneous manual transcription/total number of results that need manual transcription	Intra-ErrTran	0	0–0.004	0.004
Percentage of: number of incorrect results for information system problems/total number of results	Intra-FailLIS	0		
Post-analytical phase				
Inappropriate turnaround times				
Percentage of: number of reports delivered outside the specified time/total number of reports	Post-OutTime	0.002	0.002–6.254	6.254
Turnaround time, min, from sample reception in laboratory to release of result, of potassium (K) at 90th percentile (STAT)	Post-PotTAT	48	48–65	65

Table 2: (continued)

Quality indicator		Quality specifications		
Measurement	**Code**	**High < or =**	**Medium Between**	**Low > or =**
Turnaround time, min, from sample reception in laboratory to release of result, of international normalized ratio (INR) value at 90th percentile (STAT)	Post-INRTAT	47	47–66	66
Turnaround time, min, from sample reception in laboratory to release of result, of white blood cells (WBC) value at 90th percentile (STAT)	Post-WBCTAT	28	28–41	41
Turnaround time, min, from sample reception in laboratory to release of result, of cardiac troponin (TnI or TnT) value at 90th percentile (STAT)	Post-TnTAT	47	47–65	65
Percentage of: number of potassium results (STAT) released after 1 h/total number of potassium results (STAT)	Post-TATPotH	3.681	3.681–18.110	18.110
Incorrect laboratory reports				
Percentage of: number of rectified by laboratory reports after the release/total number of released reports	Post-RectRep	0.011	0.011–0.043	0.043

IQC, internal quality control; EQA, external quality assessment; PT, proficiency testing; STAT, immediately (from the Latin word “statim”).

appointed in each Country to coordinate the local participating laboratories;
- Cooperating with the Accreditation Bodies of each Country and with the European co-operation for Accreditation (EA), in order to achieve recognition of participation in the EQAP on QIs proposed by the WG-LEPS, mandatory in order to comply with the requirement of ISO 15189 for Laboratory Accreditation;
- Publishing consensus documents to facilitate the harmonized use of QIs and the best practice;
- Organizing training courses to guarantee the correct understanding of the rationale of each of the QIs proposed by the WG-LEPS and the procedures employed in order to guarantee the correct management of QIs and promote the culture of Patient Safety;
- Validating dedicated software that can be connected with the different Laboratory Information System (LIS) on the market in order to facilitate and harmonize the collection of QI data;
- Proposing a consensus procedure that describes how the QIs data can be used in the process of risk management in order to guarantee harmonized identification, evaluation, and prioritization of risks in order to minimize, monitor, and control the impact of undesirable events and to maximize the realization of improvement opportunities.

The WG-LEPS is committed to achieving the above goals.

Conclusions

In the last few years, the acknowledgment that laboratory medicine is vital to healthcare has considerably increased, although its complete potential has not yet been fully recognised. There remains a need to continuously reinforce the power of laboratory medicine, through the use of the best possible practices that can demonstrate how the leadership and/or involvement of laboratory medicine enables the provision of measurable benefits for patients, clinicians, and the entire healthcare system [29]. It is up to each laboratory professional to guarantee processes and procedures at the lowest possible risk of error and to support and increase the value of laboratory testing.

The quality of laboratory performances is critically important for the future of laboratory medicine because only accurate, reliable error-free results can be considered valuable for diagnosis, monitoring, and risk assessment. The implementation of procedures and practices providing a systematic feedback on performance to laboratory professionals are of crucial importance in evaluating the risk of error and guaranteeing a high-quality level of performance [30, 31].

The use of QIs, specifically designed for laboratory medicine are effective in assessing and monitoring all critical events occurring in the different phases of TTP, in particular, in the extra-analytical phases. The availability of MQI as proposed by the WG-LEPS, and validated by experts in consensus conferences, is an important window of opportunity for the medical laboratory to demonstrate the use of an effective quality assurance tool fit for this purpose. Moreover, the availability of a straightforward, secure and speedy web-based software application to collect data on a common set of QIs enables the standardization of data collection and stimulates the measurement of events that need to be controlled. Moreover, the capacity to generate reports and export data, in an anonymous and confidential way, it provides important information for

laboratory professionals and encourages benchmarking and best practice. Another advantage of this international project is that it allows the autonomous management of the QIs data processing of participating laboratories in specific countries through the appointment of national leaders thus making it possible to satisfy any needs inherent to specific contexts.

In conclusion, the continuous use of QIs in a defined and structured system has important advantages: the promotion of the culture of patient safety; improvement in performance adopting policies and practices promoting a non-punitive culture that values open discussion and feedback on performance; and the implementation of a mechanism for voluntary reporting and learning from unsatisfactory events.

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