Letter to the Editor

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The use of extra-analytical phase quality indicators by clinical laboratories: the results of an international survey

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To the Editor,

Quality in laboratory medicine is increasingly recognized as a fundamental issue to avoid diagnostic errors and ensure patient safety [1]. In recent decades a body of evidence has been collected to highlight the vulnerability of the extra-analytical phases of the testing process and to identify reliable quality indicators (QIs) to identify and reduce the risk of errors [2–6]. More recently, the chasm between the current interest in extra-analytical QIs and the limited number of clinical laboratories that collect regular and comprehensive data on QIs has been described as "the quality indicator paradox" [7]. To overcome the paradox, a series of initiatives has been promoted and in particular, the European Federation of Laboratory Medicine (EFLM) has established a Task Force on "Performance specifications for the extra-analytical phases" (TFG-PSEP) with the aim of identifying reliable performance specifications for the extra-analytical phases. The first initiative of the Task Force was to understand the state-of-the-art on QIs using a questionnaire administered to all National Societies of the Federation and other stakeholders (Table 1).

Here we discuss the main results obtained. Responses (152) were received from all European countries and from the US, Australia, India, China, Brazil, South Africa and Curaçao.

Almost all (98.7%) of responders believed that QIs and related performance criteria (PC) should be implemented in his/her clinical laboratory but a smaller percentage (90.1%) was actually measuring one or more extra-analytical QIs. The main difficulty in implementation related to the lack of an information system (LIS) to support data collection. For those laboratories implementing QIs, these were derived from the biomedical literature in 38% of cases, the use of QIs developed "in house" in 35%, with only 17.5% using QIs developed by the IFCC WG-LEPS project [8].

Virtually all (97.4%) responders were aware that QIs are included among the requirements of the International Standard for laboratory accreditation (ISO 15189) [9], while only 52% were aware of the model of quality indicators project (MQI) launched by the IFCC WG-LEPS and available at the website http://www.ifcc-com. Only a small number of laboratories (45) currently are collecting the data for the website.

The list of the "Top Ten" most adopted QIs and the percentage of laboratories is the following: 1) hemolyzed samples (82.4%); 2) sample misidentification errors (81.5%); 3) incorrect sample type (80.9%); 4) patient misidentification errors (78.3%); 5) incorrect fill level (75%); 6) clotted samples (73.6%); 7) turnaround times outside target (70%); 8) unsuitable samples due to transportation and storage problems (67%); 9) incorrect laboratory reports (61%); test transcription errors (53%).

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Table 1: The questionnaire on QIs and PC.

1: Do you believe that Quality Indicators (QIs) and related performance criteria (PC) for extra-analytical phases should be implemented in your practice?
1b: If yes, are you already measuring some QIs or not?
1c: If not, why?
1d: If yes, what is the source of the QIs you use (e.g. literature, developed in house, etc.)?
2: Are you aware that QIs are included among the requirements of the International Standard for Laboratories Accreditation (ISO 15189:2012)?
3: Are you aware of the Model of Quality Indicators initiative promoted by a Working Group of the IFCC (available at the website http://www.ifcc-mqi.com/)?
– If you are aware, are you already collecting and introducing the data on the IFCC QIs in the website?
– If not, why?
4: Do you currently measure this indicator? **5:** If you measure this QI: what definitions do you use for this QI? **6:** Do you collect data for this QI manually or through your LIS? **7:** How often would you be able to report these data?
– Patient misidentification errors
– Sample misidentification errors
– Test transcription errors
– Incorrect sample type
– Incorrect fill level
– Unsuitable samples due to transportation and storage problems
– Contaminated samples (e.g. IV fluid, microbiological issues)
– Hemolyzed samples
– Clotted samples
– Data transcription errors
– Turnaround times outside target
– Incorrect laboratory reports (e.g. erroneous results, incorrect interpretative comments, incorrect date/time, etc.)
– Notification of critical values outside target time
8: What initiative(s) should be done for achieving higher awareness of the importance of QIs and performance criteria (PC) in the extra-analytical phases?
9: Are there some alternatives to establish performance criteria for extra-analytical phases other than Quality Indicators?
10: Do you have suggestions/recommendations for defining performance criteria (PC) in the pre- and post-analytical phases?

Less than 50% of respondent laboratories collected data on the following QIs: contaminated samples; notification of critical values outside target time, and data transcription errors.

Automated collection of data using the LIS was found to be available for the following QIs (and related number of clinical laboratories): 1) test transcription errors (61.4%); 2) data transcription errors (60%); unsuitable samples due to transportation and storage problems (53%); patient misidentification errors (52%), and sample misidentification errors (51.4%). For all other QIs the percentage of clinical laboratories collecting automated data is lower than 45%.

Most laboratories (>50%) are collecting QI data monthly, but some collecting data annually (17%), and quarterly (11%).

A majority of responders (57%) believe that performance criteria for the extra-analytical phases should be derived from the QIs, although 35% of responders did not answer the question and did not indicate alternatives for setting the performance criteria. Some suggestions to improve the awareness on the issue of QIs and related PC were received: a) to organize a consensus and scientific meeting on this topic; b) to provide papers and release guidelines; c) to publicize the work of the IFCC WG-LEPS; d) to stimulate the national accreditation bodies to better understand the relevance of QIs when assessing and accrediting clinical laboratories; e) to stimulate national scientific societies to organize working groups and meetings on this issue.

There are several main "take-home messages" from the questionnaire. First, the data confirm the existence of the quality indicators paradox as all responders were aware of the need to implement QIs and related PC in their laboratories but the number and type of QIs monitored varied significantly. Given that 35% of responders are using "in house" QIs and many others are not collecting data in a harmonized way, makes it impossible to benchmark and compare performances between laboratories.

Second, most laboratories are using only a set of "conventional" QIs such as hemolyzed samples incorrect sample type, and sample misidentification errors but essential QIs such as data transcription errors, delayed

turnaround time and contaminated samples are used by fewer than 50% of clinical laboratories.

Third, the true bottleneck in implementation of QIs is the lack of automated data collection functionality in the LIS thus requiring manual data collection and uploading onto the specifically developed website which is both time consuming and wasteful of human resources.

Fourth, although the adoption and monitoring of QIs is included as a specific requirement in the International Standard for laboratory accreditation, there is poor awareness by both regulatory bodies and individual laboratories of the need to use a harmonized set of QIs and related PC. The ISO 15189:2012 only requires the laboratory to establish QIs for analytical and extra-analytical phases without further specification and list three examples. In fact, QI data should be reviewed and appropriate corrective and preventive actions taken. This, is turn, requires that clinical laboratories should compare their performances on a harmonized set of QIs and using a standardized reporting system.

Finally, there is an important role for national societies and international federations to increase awareness in clinical laboratories and to encourage participation in initiatives to develop consensus on the QIs to be employed and the related PC.

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