The Journal Of The International Federation Of Clinical Chemistry And Laboratory Medicine
eJIFCC

# CALL FOR ENROLLING MORE PROFESSIONALS IN THE IFCC PROJECT ON LABORATORY ERRORS AND PATIENT SAFETY

**Mario Plebani, Laura Sciacovelli**

on behalf the WG_LEPS

Department of Laboratory Medicine, University-Hospital, Padova, Italy

***Corresponding author's address***

Mario Plebani
Department of Laboratory Medicine,
University-Hospital, Padova,
Cvia Giustiniani 21
35128 Padova, Italy
Phone and fax +39 049 663240
e-mail: mario.plebani@unipd.it

***Abstract***

Patient safety is the foundation of good care. In the last decades, a body of evidence has been accumulated to demonstrate that pre- and post-analytical phase are more vulnerable to errors in laboratory medicine than the analytical phase. Aims of the project of the IFCC Working Group on "Laboratory Errors and Patient Safety" (WG-LEPS) are: a) to develop a series of Quality Indicators (QIs), specifically designed for clinical laboratories, b) to create a common reporting system for clinical laboratories based on standardized data collection, and c) to define state-of the-art and Quality Specifications (QSs) for each QI Preliminary results demonstrate that a Model of Quality Indicators can serve as a tool to monitor and control the pre-, intra- and post-analytical activities. However, only after enrolling a more consistent number of clinical laboratories, it should be possible to assure consistency to the data collected and reliability to the QIs identified and to related QSs.

**Abbreviations**:

- QIs: Quality Indicators
- TTP: Total Testing Process
- WG-LEPS: Working Group "Laboratory Errors and Patient Safety"
- QSs: Quality Specifications
- QI: Quality Indicator.

## INTRODUCTION

*To Err is Human* (1), yet society demands that medical laboratories be faultless. In past decades, laboratory professionals have focused their attention on analytical errors and on mistakes resulting in adverse events; data reported in the literature well demonstrate the dramatic reduction of the analytical error rates (2). In more recent years clinical laboratories have attempted to develop methodologies and programs to minimise and prevent the occurrence of errors in the total testing process (TTP), including the pre- and post-analytical steps, and their subsequent impact on patient care. However, there are no consensually identified quality indicators (QIs) to promote the homogeneous collection of data among different clinical laboratories and related corrective and preventive actions.(3-10).

In order to reduce errors in laboratory testing, the IFCC Working Group on "Laboratory Errors and Patient Safety" (WG-LEPS) aimed to develop a series of Quality Indicators, specifically designed for clinical laboratories. The overall aim of the project is to create a common reporting system for clinical laboratories based on standardized data collection, and to define state-of the-art and Quality Specifications (QSs) for each QI independent of: a) the size of organization and type of activities; b) the complexity of processes and their interactions; and c) the different degree of knowledge and ability of the staff. Aim of this paper is to provide the "state-of-the-art" of the project and to ask for a wider collaboration and involvement by clinical laboratories at an international level.

## MATERIALS AND METHODS

In a preliminary stage of the project (11), the participating laboratories had identified, through consensus, 25 QIs that have been grouped according the main TTP phases as shown in Tables 1-3.

Table 1 - Quality indicators of the pre-analytical phase.

| | |
|---|---|
| **a) Tests ordering** | |
| QI-1 | Percentage of "Number of requests with clinical question from general practitioners/Total number of requests from general practitioners" |
| QI-2 | Percentage of "Number of appropriate requests, with respect of clinical question from general practitioners/Number of requests that reports clinical question from general practitioners" |
| **b) Formulation and input of request** | |
| QI-3 | Percentage of "Number of requests without physician identification/Total number of requests" |
| QI-4 | Percentage of " Number of unintelligible requests/Total number of requests" |
| QI-5 | Percentage of "Number of requests with errors concerning patient identification/Total number of requests" |
| QI-6 | Percentage of "Number of requests with errors concerning physician identification/Total number of requests" |
| QI-7a | Percentage of "Number of requests with errors concerning input of tests (missing)/Total number of requests" |
| QI-7b | Percentage of "Number of requests with errors concerning input of tests (added)/Total number of requests" |
| QI-7c | Percentage of "Number of requests with errors concerning input of tests (misinterpreted)/Total number of requests" |

| c) Identification, collection, handling and transport of samples | |
|---|---|
| QI-8 | Percentage of "Number of sample lost-not received/Total number of samples" |
| QI-9 | Percentage of "Number of sample collected in inappropriate container/Total number of samples" |
| QI-10a | Percentage of "Number of sample haemolysed (haematology)/Total number of samples" |
| QI-10b | Percentage of "Number of sample haemolysed (chemistry)/Total number of samples" |
| QI-11a | Percentage of "Number of sample clotted (haematology)/Total number of samples with anticoagulant" |
| QI-11b | Percentage of "Number of sample clotted (chemistry)/Total number of samples with anticoagulant" |
| QI-12 | Percentage of "Number of sample with insufficient sample volume/Total number of samples" |
| QI-13 | Percentage of "Number of sample with inadequate sample-anticoagulant/Total number of samples with anticoagulant" |
| QI-14 | Percentage of "Number of sample damaged in transport/Total number of samples" |
| QI-15 | Percentage of "Number of sample improperly labelled/Total number of samples" |
| QI-16 | Percentage of "Number of sample improperly stored/Total number of samples" |

Table 2 - Quality indicators of the analytical phase: results performances.

| | |
|---|---|
| QI-17 | Percentage of "Number of unacceptable performances in EQAS/PT per year/Total number of performances in EQAS/PT" |
| QI-18 | Percentage of "Number of unacceptable performances in EQAS/PT occurred for a cause previously corrected, per year/Total number of unacceptable performance" |
| QI-19 | Percentage of "Number of tests with CV% higher than selected target, per year/Total number of tests" |
| QI-20 | Percentage of "Number of reports delivered outside the specified time for instrumentation failures, per year/Total number of reports" |

Table 3 - Quality indicators of the post-analytical phase.

| | |
|---|---|
| QI-21 | Percentage of "Number of reports delivered outside the specified time/Total number of reports" |
| QI-22 | Percentage of "Number of critical values communicated/Total number of critical values to communicate" |
| QI-23 | Average time to communicate critical values |
| QI-24 | Percentage of "Number of interpretative comments, provide in medical reports, that impacted positively on patient's outcome/Total number of interpretative comments, provided in medical reports" |
| QI-25 | Number of guidelines issued in co-operation with clinicians, per year |

Thereafter, QI data from the participating laboratories were collected using a specifically designed web site (www3.centroricercabiomedica.it). Participation in the project is based on two main characteristics: a) it is free of charge and, b) clinical laboratories are allocated individual usernames and passwords for data entry thus ensuring confidentiality. Data collected monthly for the period February 2008 to December 2009 have been analysed and the preliminary data published.

## RESULTS

Currently 39 clinical laboratories have been enrolled in the project from the different countries around the world, and eleven laboratories contributed the data described in this paper through the dedicated website.

We report the preliminary data of the laboratories who voluntarily joined the project. The following ranges of errors percentage were found.

Regarding the pre-analytical phase (pre pre-analytical phase), 9.5-87.4 (requests with clinical question); 16.5-97.3 (requests with appropriate tests); 0-55.7 (requests without identification of the physician), 0-21.4 (unintelligible requests).

Errors attributable to laboratory staff about the input of data reported in the request (pre-analytical phase): 0-10.5 (patient identification); 0-6.2 (physician identification); 0-14.6 (missing tests) 0-53.3 (added tests); 0-17 (misinterpreted tests). Moreover about the samples: 0.004-0.63 (not received); 0-8.8 (inappropriate container); 0.04-0.9 (hemolyzed in hematology); 0.3-3.4 (hemolyzed in clinical chemistry); 0.01-1.7 (clotted in hematology); 0.03-1.5 (clotted in clinical chemistry); 0.01-1.13 (insufficient volume); 0-52.5 (inadequate sample-anticoagulant volume ratio); 0-1.0 (damaged in transport); 0.0004-48.4 (improperly labelled); 0-0.1 (improperly stored).

Unsatisfactory analytical performances (analytical phase): 1.4-4.9 (unacceptable performance in EQA); 0-45.8 (persistence poor performance occurred despite an corrective action previously carried out); 5.6-11.1 (CV% higher than defined target); 0-0.01 (missing results due to instrumentation failures).

Concerning post-analytical phase: 0.02-8.9 (reports delivered outside the specified time); 15.4-100 (critical values communicated), 22-156 (average time to communicate critical values, in minutes); 1-11 (guidelines issued in co-operation with clinicians, in number).

## DISCUSSION

Medical laboratories are the first, and up to now unique, medical discipline for which a specific International Standard (ISO 15189: 2007) has been elaborated and delivered, linking the needs of quality management systems, according to the ISO 9001:2000, with specific technical requirements that determine competence in clinical laboratories (12). The value of this International Standard is irrefutable both for promoting the harmonization of existing accreditation programs worldwide and for further detailing quality indicators. In fact, the International Standard identifies not only general requirements for personnel, accommodations, environmental conditions and laboratory equipments as well as for pre-, intra-, and post-analytical phases but also several clauses and subclauses. However, it does not, and cannot, specify quality indicators and related quality specifications. An indicator is the measure for assessing a particular process or outcome, and it is a tool for the quantitative measurement of quality. therefore a consensus has to be achieved among professionals to identify and use appropriate quality indicators. Unfortunately, despite some proposals (13-14), no valuable and consensually accepted quality indicators exist in laboratory medicine.

The IFCC-LEPS project aims to involve from the beginning clinical laboratories around the world, with different size and complexity, in order to identify appropriate quality indicators and to collect data to define related quality specifications for all and each quality indicator. As for any other quality specifications, however, there is the need to collect a significant number of data from different clinical laboratories to achieve a statistical power. Therefore, this paper aims to press clinical laboratories and laboratory professionals to join currently involved laboratories to collect data on identified quality specifications and to introduce them into the website thus allowing an effective benchmark and inter-laboratory comparison. It is also possible and realistic, due to differences among countries, that some

indicators are not appropriate for some laboratories. Therefore, some laboratories are requested to identify and collect data only for the quality indicators that are appropriate and workable in the specific organizational and clinical setting. The IFCC-LEPS project described here will help laboratories to standardize approaches to the measurement of laboratory quality which satisfies the accreditation requirements for continuous monitoring and benchmarking in laboratory medicine. Nevertheless, its success will depend on the participation and collaboration of laboratories enrolled in the project in offering their professional expertise and performance data to help define best practice and so improve performance. Developing and implementing a strategy for improving patient safety is challenging but exciting and therefore efforts should be done to increase the number of participating laboratories and to accumulate a statistically significant number of data for each and all indicators. As the participation is free of charge and it guarantees confidentiality, we implore clinical laboratories around the world to go to the website, achieve full information on the project and to request a specific password to introduce the data collected on appropriate quality indicators.

***References***


1. Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academy Press, 1999.
2. Plebani M. Exploring the iceberg of errors in laboratory medicine. Clin Chim Acta 2009;404:16-23.
3. Frankel A, Gandhi TK, Bates DW. Improving patient safety across a large integrated health care delivery system. Int J Qual Health Care 2003;15:i31-40.
4. Carraro P, Plebani M. Errors in a Stat Laboratory: types and frequencies 10 years later. Clin Chem 2007;53:1338-42.
5. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101-10.
6. Lippi G, Plebani M. The importance of incident reporting in laboratory diagnostics. Scand J Clin Lab Invest 2009;69:811-3.
7. Peña A, Virk SS, Shewchuk RM, Allison JJ, Williams OD, Kiefe CI. Validity versus feasibility for quality of care indicators: expert panel results from the MI-Plus study. Int J Qual Health Care 2010;22:201-9.
8. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM. Accountability measures-using measurement to promote quality improvement. N Engl J Med 2010;363:683-8.
9. Shahangian S, Snyder SR. Laboratory medicine quality indicators: a review of the literature. Am J Clin Pathol 2009:131;418-31.
10. Plebani M. Towards quality specifications in extra-analytical phases of laboratory activity. Clin Chem Lab Med. 2004; 42: 576-7.
11. Sciacovelli L, Plebani M. The IFCC Working Group on laboratory errors and patient safety. Clin Chim Acta 2009;404:79-85.
12. ISO 15189:2007. Medical laboratories — Particular requirements for quality and competence specifies the quality management system requirements particular to medical laboratories.
13. Ente Nazionale Italiano di Unificazione (UNI). Gestione per la qualità. Indicatori e quadri di gestione della qualità. Linee guida generali. UNI 11097:2003.
14. Clinical and Laboratory Standards Institute (CLSI). Development and use of quality indicators for process improvement and monitoring of laboratory quality. Proposed guideline. GP35-P. Wayne, PA, USA:CLSI, 2009.