

Editorial

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The silk road to total quality in Laboratory Medicine

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Quality in Laboratory Medicine, a target that is constantly evolving, has been defined as an “unfinished journey” [1]. Following major developments in methods and programmes designed to achieve internal quality control (IQC), and external quality assurance/proficiency testing (EQA/PT) focussing on analytical quality, evidence of vulnerability in the pre- and post-analytical phases of laboratory testing led to the development and implementation of a model of quality indicators (MQI) covering both the intra- and extra-analytical phases of the testing cycle [2]. A body of evidence collected in the last five decades highlights the importance of defining analytical performance characteristics (analytical quality specifications) and using them in IQC and EQA/PT in order to decrease analytical error rates and improve analytical quality [3–7]. A more comprehensive, patient-oriented view of quality and safety, now needed in laboratory medicine, should be achieved through the assessment of risk and its prevention, and the measurement and monitoring of quality indicators (QIs) [8–11].

Regarding analytical quality, “irregular (individual) analytical errors”, as described by Vogeser and Seger [12], cannot be detected with conventional statistical quality control procedures, and this has paved the way for further efforts to identify possible sources of error. The limitations of available techniques for detecting analytical errors other than deviation from established performance specifications (imprecision and bias) are well known, and the need for more “personalised” approaches is widely recognised. Each and every individual sample can present a specific matrix, in some cases due to alterations in the ratios between different measurands (e.g. in end-stage renal disease patient samples) or, in others, the presence of cross-reactants, anti-reagents and anti-analyte antibodies. In addition, the overall performances of frequently requested tests still fail to meet the minimum performance specifications; commercially available and commonly performed immunoassays continue to be affected by analytical bias that sometimes exceeds desirable quality goals; when evaluated with stringent metrics

such as the sigma scale, analytical quality is as yet unsatisfactory [13]. There is therefore a pressing need to optimise reliability and accuracy in the analytical phase. However, the vast body of evidence collected in the last few decades on the greater vulnerability of the extra-analytical phases of the brain-to-brain loop of diagnostic testing prompted the search for QIs monitoring extra-analytical phases, as the frequency of errors and their magnitude in these phases are greater than in the analytical phase. The MQI proposed by the Working Group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC WG-LEPS), which has been consensually revised in the last few years, is now used by numerous clinical laboratories worldwide [8]. The current challenge is to understand whether the MQI should ensure that clinical laboratories are provided with the same valuable information on analytical performance characteristics in order to reduce errors and improve quality in the extra-analytical phases.

The paper by Duan et al. [14] appearing in the current issue of the *Clinical Chemistry and Laboratory Medicine*, describes the experience gained in a nationwide EQA programme in China involving 3450 clinical laboratories using 15 IFCC-MQI QIs that cover the most error-prone testing processes, and that were monitored from 2015 to 2018. Over this 3-year period of time, a gradual improvement was achieved in the performances of QIs, except in the case of pre-examination turnaround-time (i.e. time from sample collection to reception). This indicates that improvement in quality should be achieved through the continuous monitoring of indicators. In China, the EQA QIs programme has become “an important component of laboratory quality management”, and the data obtained confirm the previously reported experience of the College of American Pathologists (CAP) on seven QIs that documented significant decreases in defect rates in outpatient order entry, identification and critical value reporting errors and reduced order-to-report times for troponin and STAT tests [15]. The data also provide further evidence of the usefulness of QIs other than those adopted by the CAP.

In their analysis of QIs performances by disciplines (microbiology, haematology, chemistry and immunology),

Duan et al. demonstrate that the complexity of microbiology or immunology methodologies may generate poorer performances in relation to incorrect sample type/container and pre- and intra-examination TAT, respectively. These results suggest that, in addition to the existing and well-established measures, specific measures might be useful in improving the efficiency of tests in different sub-disciplines of laboratory medicine [14]. In this context, a valuable contribution has been made in the paper by Zhou et al. [16] in the current issue of the *Journal*. The aim of this pilot study, based on a survey conducted on 46 independent commercial laboratories, was to evaluate the effectiveness of specific QIs in assessing activities inherent to molecular diagnostics. According to peer consensus and results from a questionnaire survey, the specific QIs for improving quality in molecular diagnostics are: (a) unsuccessful DNA extraction rate; (b) unsuccessful library rate; (c) unsuccessful sequencing rate; (d) unsuccessful data analytical rate; (e) report error rate; and (f) report delay rate. The effectiveness of these specific QIs in molecular diagnostics has been evaluated by three volunteer diagnostic laboratories [16]. Although the data reported should be considered preliminary, the specific QIs proposed would appear to enable: the measurement of performances in molecular diagnostic laboratories, the provision of information for internal quality monitoring and improvement programmes, and the establishment of benchmarks between different molecular diagnostic structures. In the current era of precision medicine, where molecular diagnostics play an increasingly important role in optimising patient outcomes by accurately targeting disease, the identification of specific measures is of vital importance in keeping the process under control and minimising risk for the patient, particularly in view of the fact that these tests are often devoid of other quality assurance tools (IQC and EQA), and call for a high level of staff expertise. The guarantee of staff competency is crucial to the provision of quality-assured services and to continuous improvement in laboratory services. However, as reported by Epner [17], the value of laboratorians as critical members of the care delivery team, responsible for ensuring the proper application of the knowledge they bring, is rarely considered in system quality measurement strategies. In this context, MQI, among the 53 process measures of quality, includes a QI designed to measure the number of reports with interpretative comments impacting positively on patient outcome. However, because of difficulties inherent to data collection, a priority score of 4 (in a scale of 1–4) has been assigned to this particular QI [8].

Before evaluating the impact of interpretative comments on patient outcome, the quality of interpretative

comments themselves must be assured. Although several recommendations on interpretative comments are available in the literature [18, 19], no standards have been set to assess their quality. EQA programmes, which can play a part in assessing and demonstrating the competence of laboratory staff, play an important role in education and continuous professional development. Huang et al. [20], in a paper appearing in the current issue of the *Journal*, evaluated the quality of interpretative comments and their potential in improving upon the interpretation of laboratory results. A total of 772 clinical laboratories, including 1472 participants from different Chinese provinces, submitted interpretative comments through an EQA reporting system. The final scores and ranking of participants from tertiary hospitals was higher than secondary hospitals, or other institutes. When grouped according to their professional title, the median final score of physicians was higher than that of technicians, while no statistically significant differences were found between the two categories on analysing the length of services (senior, intermediate and junior staff). These results suggest that high specialisation on the one hand, and training courses in addition to the knowledge of the total testing process, on the other hand, are key elements in ensuring the best possible patient outcome.

In the last few decades, the automation of processes and the development of new technologies have led to an ever-increasing demand for tests, and the consequent utilisation of both known laboratory tests and new and increasingly sophisticated tests. Consequently, every day clinical laboratories generate billions of interpretative reports by means of a multistep process. It is of the utmost importance for clinical laboratories to maintain quality along the entire testing process, including not only analytical processes but also testing-relating elements, such as equipment, reagents techniques and, above all, personnel, thus ensuring a failure-resistant system that can “catch” mistakes before they become a problem. Well-established quality assurance tools, including IQC and EQA/PT schemes, have ensured a significant reduction in intra-laboratory errors that negatively impact on the quality of laboratory information. However, the following points should be borne in mind: 1) third party internal quality controls materials and external quality assessment schemes are not available for all laboratory tests; 2) results are often associated with interpretative commenting, the quality of which is difficult to guarantee; 3) quality should be guaranteed in all phases of the results generating process, thus safeguarding quality assurance at each level – this

often entails a multidisciplinary approach. The adoption of QIs as a tool for improving laboratory performances and assuring quality has been demonstrated by several authors in the last few years. Several QIs programmes are now available, and studies on this topic are available in the literature [21–25]. The efforts made by the IFCC WG-LEPS to identify a list of consensually harmonised QIs and define a system reporting and quality specifications have played a key role in the field of development of quality assurance tools applied not only to analytical but mainly to extra-analytical phases.

The experiences reported by the cited authors, which have involved a large number of Chinese laboratories, are testimony to the fact that monitoring laboratory performances over time by adopting MQI-QI has led to an overall improvement in processes, indicating that QIs are a valuable tool in guaranteeing quality of extra-analytical phases equally as IQC and EQ/PT in ensuring quality in the analytical phase. These papers also demonstrate: (1) the awareness of healthcare professionals worldwide of the importance of reporting and managing undesirable events as they represent the driving force of quality assurance; (2) the strength of QIs in defining the state-of-the-art and guaranteeing an appropriate benchmark when numerous laboratories are involved.

However, as quality is an “unfinished journey”, laboratory professionals must face ever newer challenges. Further efforts are required to improve harmonisation across laboratory practices and all laboratories should be encouraged to adhere to the MQI programme, as this is the key to assuring appropriate benchmarking and to achieving state-of-the-art quality in the TTP. Furthermore, as demonstrated by the pilot study on QIs applied to molecular diagnostics, a search should be made for new and more specific QIs to monitor activities of specific disciplines or techniques (i.e. mass spectrometry). In addition, the identification and definition of QIs for monitoring “irregular analytical errors” might be conducive to further improving analytical performances.

Finally, the involvement of clinicians in defining and monitoring outcome measures is required in order to facilitate the collection of data and to empower this quality assurance tool in the path toward patient safety.

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