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Review

Performance specifications for the extra-analytical phases of laboratory testing: Why and how

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ABSTRACT

An important priority in the current healthcare scenario should be to address errors in laboratory testing, which account for a significant proportion of diagnostic errors. Efforts made in laboratory medicine to enhance the diagnostic process have been directed toward improving technology, greater volumes and more accurate laboratory tests being achieved, but data collected in the last few years highlight the need to re-evaluate the total testing process (TTP) as the unique framework for improving quality and patient safety. Valuable quality indicators (QIs) and extra-analytical performance specifications are required for guidance in improving all TTP steps. Yet in literature no data are available on extra-analytical performance specifications based on outcomes, and nor is it possible to set any specification using calculations involving biological variability. The collection of data representing the state-of-the-art based on quality indicators is, therefore, underway. The adoption of a harmonized set of QIs, a common data collection and standardised reporting method is mandatory as it will not only allow the accreditation of clinical laboratories according to the International Standard, but also assure guidance for promoting improvement processes and guaranteeing quality care to patients.

Contents

1. Introduction

One of the more famous aphorisms is Osler's maxim "Medicine is a science of uncertainty and an art of probability" [1]. Laboratory information is increasingly recognised as crucial to reducing diagnostic uncertainty and enhancing quality care. Sound medical diagnoses and effective treatments are dependent on the accurate and timely reporting of laboratory test results, and the trend toward disease prevention and personalized care calls for more complex and effective tests and biomarkers. Today's clinical laboratory provides essential information for diagnosis, monitoring, screening, prevention, early diagnosis, tailored treatment and more effective monitoring of human diseases [2]. The better understanding gained concerning the molecular basis of human disease, the identification of risk factors for disease prevention and biomarkers for an early diagnosis as well as the advent of tailored treatment strategies has led to an upsurge in the demand for more numerous and more reliable laboratory tests. The increasingly important role of laboratory information in medical decision making has, however, led to the need for a greater focus on the quality and safety of laboratory services.

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2. Patient safety and laboratory - associated errors

The core of patient safety, an important aspect of quality across, and between, all settings of care, is prevention of errors associated with healthcare and, failing that, the mitigation of their effects [3]. Thanks to the landmark report from the Institute of Medicine, *To Err is Human* [4], it became clear that avoidable patient harm was far more common in health systems than previously realised. Yet the focus of most research was on falls, medication errors and related adverse drug events, wrong-site surgery, and nosocomial infections, diagnostic errors receiving little attention [5]. Although not all diagnostic errors, identified as an important patient safety issue, translate into harm, a substantial number are associated with preventable morbidity and mortality [6]. Diagnostic errors, which affect inpatients and out-patients, have an impact on each and every medical discipline, including laboratory medicine [7]. Historically, efforts to improve the diagnostic process in laboratory medicine have aimed to improve technology, achieving greater volumes and more accurate laboratory tests, but data collected relatively recently indicate the need to re-appraise the total testing process (TTP), the right framework for improving quality and patient safety [8]. After decades of focusing on improving indicators of analytical quality, such as analytical performance specifications (in particular, bias and imprecision), adopting valuable tools such as internal quality control (IQC) and external quality assurance/Proficiency tests (EQA/PT), clinical laboratories are now aware that the vulnerability of extra-analytical phases drives need for change in the paradigm. The focal point of the concept of quality in laboratory medicine is therefore shifting from internal processes (analytical quality) to the impact of laboratory information on patient care and/or assuring a healthy status to any individual and/or the entire population. As stated elsewhere "quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process is correctly performed, thus ensuring valuable decision making and effective patient care" [9]. This means that the current perspective on quality and errors in laboratory medicine focuses on a global view of the testing process, on the issue of laboratory-associated errors and a search for tools that minimize the risk of these errors in clinical practice. In addition to data available on errors in laboratory medicine, the evidence that errors related to laboratory testing are common, and account for a significant fraction of diagnostic errors in medicine, has heightened the awareness of the scientific community concerning the need for an innovative approach to quality and safety in laboratory testing [10]. There are thus two main drivers of the paradigmatic change of the landscape of laboratory medicine: one, the evidence of the vulnerability of the extra-analytical phases, and the other, the increased recognition of the need for a focus on the added value of laboratory information in improving the decision making process and clinical outcomes [8].

3. Vulnerability of extra-analytical phases

Evidence collected in the last few decades demonstrates that pre-analytical and post-analytical phases of the TTP are more prone to error than the analytical phase [11–13]. Moreover, the pre-pre-analytical (initial procedures performed for test request, sample collection, handling and transportation) and the post-post-analytical (final procedures performed after the notification of laboratory results) phases are even more error prone, and vulnerable to errors compromising patient safety [14]. The diagnostic testing process has therefore been divided into five phases: pre-pre-analytic, pre-analytic, intra-analytic, post-analytic and post-post-analytic [15]. Yet although the paradigm of quality in laboratory medicine is widely accepted, there is little clarity concerning the inter-relationship between the different phases of the cycle and the inter-dependence between quality in the pre-analytical phase and analytical quality, and the role of post-analytical steps in affecting ultimate laboratory information [16]. In pre-pre-analytical steps the procedures for test requesting, sample collection, handling and transportation are still neglected even though they greatly affect the quality of biological specimens and, in turn, the accuracy of analytical results. Evidence collected on the final steps of the loop, reveals poor/delayed acknowledgment of laboratory reports, errors in interpretation and utilization of laboratory information, and a direct correlation between missed, wrong and delayed diagnoses and patient harm [17]. In the first Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine, it was unanimously agreed that "for patient care, optimizing the quality of the total (pre-analytical/analytical/post-analytical) examination process is the ultimate goal and therefore it would be desirable to go beyond setting analytical performance specifications and to establish examination performance specifications. In principle, the performance specifications for the pre- and post-analytical laboratory processes should follow the same models as for analytical performance specifications. When components of these additional phases can be expressed in numerical terms, they should be added in defining examination performance specifications. In other situations, pre- and post-analytical performance specifications will be best represented by separate quality indicators...." [18]. There are no data in the literature on extra-analytical performance specifications based on outcomes, neither on clinicians' opinion, and collection of data on the state-of-the-art based on quality indicators is ongoing.

While analytical quality indicators (QIs) based on a widely accepted hierarchy of performance criteria and well-known tools (Internal quality control and external quality assurance/Proficiency testing schemes) have been available for the last fifty years, the development and utilization of reliable QIs for the extra-analytical phase is still in its infancy. There is not only a need to achieve consensus on a harmonized list of QIs, but also to collect data and establish performance specifications for each and every QI. According to the ISO 15189:2012, clinical laboratories should identify critical activities and implement Quality Indicators (QIs) in order to highlight and monitor errors when they occur [19]. QIs, managed as a part of laboratory improvement strategy, are a suitable tool for monitoring and achieving improvement [20], their end purpose being to keep the error risk to a minimal level, thus curbing the likelihood of patient harm, given that no activity is completely risk-free. However, data in the literature demonstrate that this tool's effectiveness is closely linked to the list of QIs chosen, and to: a) data collection method, b) data processing procedure in use, c) appropriate analysis of results, and d) an understanding of the priorities for corrective actions according to performance of the various QIs [21–22]. If individual laboratories were to implement and monitor their own QIs for establishing "internal" improvement actions, only a consensually harmonized list of QIs could assure reliable comparison between individual performances, thus serving as a valuable benchmark and a realistic evaluation of quality [23]. If the final goal is "zero defect", this level of performance should be selected only for high-risk errors linked to some QIs (e.g., patient and sample identification errors), while for many other extra-analytical quality indicators a better definition of "acceptable" performances is needed since "zero defect" is a "mission impossible". The project launched by the "Laboratory Errors and Patient Safety" (LEPS) Working Group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) aimed to develop a Model of Quality Indicators (MQI) based on a list of consensually defined QIs, a common reporting system and a preliminary proposal for performance specifications representing the state-of-the-art [24–26]. Most QIs included in the MQI are process measures; papers on this project have already appeared in literature, and an update on it is available in this current special issue of the Journal. Another initiative, promoted by the European Federation of Laboratory Medicine (EFLM), involves a Task Force on