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Quality indicators to detect pre-analytical errors in laboratory testing

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ABSTRACT

The identification of reliable quality indicators (QIs) is a crucial step in enabling users to quantify the quality of laboratory services. The current lack of attention to extra-laboratory factors is in stark contrast to the body of evidence pointing to the multitude of errors that continue to occur, particularly in the pre-analytical phase. The ISO 15189: 2012 standard for laboratory accreditation defines the pre-analytical phase, and recognizes the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the testing cycle, including those performed in the phase of requesting tests and collecting samples, the so-called "pre-pre-analytical phase". Therefore, QIs should allow the identification of errors and non-conformities that can occur in all steps of the pre-analytical phase. Traditionally, pre-analytical errors are grouped into identification and sample problems. However, appropriate test requesting and complete request forms are now recognized as fundamental components in providing valuable laboratory services.
The model of QIs developed by the Working Group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) includes indicators related to both identification and sample problems as well as all other pre-analytical defects, including those in test requesting and request forms. It, moreover, provides the framework (with objective criteria) necessary for promoting the harmonization of available QIs in the pre-analytical phase.

1. Introduction

The journey towards quality and patient safety in laboratory medicine is complicated by myths, imperfect knowledge and human fallibility. One myth is that a "zero error rate" can be achieved, while "imperfect knowledge" reflects the poor understanding of the total testing process (TTP) and its complexity. In addition, human frailty makes processes incapable of high reliability. Further barriers to a safer system are the changing face of the discipline accompanied by the need for interventions that are multifactorial, complex and involve numerous individuals, including laboratory professionals, those in care teams and patients. The approach to errors in laboratory medicine has varied greatly in the last two decades, shifting from a "laboratory-centered" scenario that might recognize only analytical errors, to a "patient-centered" scenario that focuses on errors in the total testing process. In fact, the new millennium has hailed a formidable improvement in the analytical phase with a ten-fold reduction in error rates, thanks to an improved standardization of analytic techniques and reagents, advances in instrumentation and information technologies, as well as to the availability of more qualified and better trained staff [1]. In addition, this achievement is due, at least in part, to the evidence that in the last few years, reliable quality indicators and quality specifications have been developed and introduced for the effective management of analytical procedures [2]. Internal quality control rules, as well as objective analytical quality specifications, and the availability of Proficiency Testing (PT)/External Quality Assessment (EQA) programs have allowed clinical laboratories to measure, monitor and improve their analytic performance over time. According to recent evidence, most errors fall outside the analytical phase, while pre- and post-analytical steps have been found to be more vulnerable to the risk of error [3,4]. Achieving consensus on a comprehensive definition of errors in laboratory testing [5] was a milestone in reducing errors and improving upon patient safety since this definition emphasizes the need to evaluate all the steps in the TTP whether or not they fall under the direct control of laboratory personnel, the ultimate goal being to improve, first and foremost, quality and safety for patients. However, the current lack of attention to extra-laboratory factors and related quality indicators is in stark contrast to the body of evidence pointing to the multitude of errors that continue to occur, particularly in the pre-analytical phase. The present paper therefore aims to suggest a possible road map for the harmonization of quality indicators in the pre-analytical phase.

2. Quality indicators

Quality indicators (QIs) are fundamental tools enabling users to quantify the quality of laboratory services: they are objective measures

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that can evaluate all critical domains of the testing cycle, including pre-analytical procedures and processes [6]. Data should be collected continuously over time to identify, correct defects improving on performance and patient safety by identifying and implementing effective interventions.

As previously underlined [6], QIs should 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) [7] which, in addition to requirements for personnel, environmental and laboratory equipment conditions, recognizes the need to subdivide the TTP into pre-examination, examination and post-examination procedures, commonly defined as pre-, intra-, and post-analytical phases. For each phase, the International Standard identifies several components in clauses and sub-clauses without specifying quality indicators and quality specifications [8]. However, QIs and related quality specifications are essential both for the institution (the laboratory in this case) and the inspectors as objective criteria of documentation and translation in practice of the standards; they are the most valuable available evidence of compliance with all, but particularly the most relevant, requirements for the accreditation of a clinical laboratory. Although there is a "considerable challenge in identifying, defining, and ultimately implementing indicators that cover the various stages of the total testing process" [9], we propose QIs that meet three inclusion criteria: 1) the use of a quantitative measure associated with laboratory testing; 2) the coverage of all stages of the TTP, as required by the current definition of "laboratory error" (ISO/TS 22367: 2008); and 3) the potential to be related to at least one IOM (Institute of Medicine) health care domain [9,10].

3. The pre-analytical phase

The ISO 15189:2012 standard for laboratory accreditation defines the pre-analytical phase as "steps starting in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins" [7]. This definition clearly recognizes the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the TTP, including the procedures performed in the so-called "pre-pre-analytical phase". According to a previously proposed definition, the pre-pre-analytical phase includes all initial procedures of the testing process including test request, patient identification, sample collection, handling and transportation. These procedures – usually performed neither in the clinical laboratory nor, at least in part, under the control of laboratory personnel – are evaluated and monitored unsatisfactorily, often because the process owner is unidentified and the responsibility falls in the boundaries between laboratory and clinical departments. As evidence, currently recommended quality indicators in the pre-analytical phases should be grouped into two categories. The first should focus on pre-analytical error related to identification problems, while the second should deal with sample problems. Both error types are taken into consideration in several proposals and projects on quality indicators. However, some further issues affect quality and safety in the pre-analytical steps. In particular, the appropriateness of the test request and the completeness of the request forms are now recognized as fundamental components in providing valuable laboratory services. Moreover, in recent decades, due to increasing pressure to cut costs in healthcare organizations, we have experienced the increasing consolidation and centralization of laboratory diagnostics within large facilities, with a consequent need to transport a large number of specimens from peripheral collection sites to the core laboratories; this has led to a dramatic increase in the risk of errors in this step, and the urgent need for appropriate sample transportation conditions and adequate quality indicators.

4. "Traditional" quality indicators for the pre-analytical phase

As previously mentioned, there are two main categories of pre-analytical errors that are related to identification and sample problems, respectively. Table 1 summarizes the main identification problems.

Although the correct identification of patient samples should be easily perceived by all care operators as an essential issue for safety in laboratory testing, a large body of evidence demonstrates that the level of quality in this fundamental step is unsatisfactory. In some longitudinal studies on laboratory specimen misidentification, a rate of 1 in 1000 opportunities was found, the most common categories of misidentification events being mislabeled (1%), mismatched (6.3%), and unlabeled specimens (4.6%), respectively [11]. In another study, the misidentification rate in transfusion medicine was found to occur in 1 in 2000 of specimens, while it occurred at a much higher rate (approximately 1 in 100) in clinical laboratory specimens. Sample misidentification can have significant consequences for patients as it may result in unnecessary diagnostic procedures, delays in diagnosis or treatment, and physical harm [12]. This is why the Joint Commission and the WHO Alliance for patient safety have established that the first goal for clinical laboratories should be to "improve patient and sample identification" [13]. In transfusion medicine, technological improvements, better education and training, and changes in policy and procedures have led to a significant reduction in, but not the elimination of, misidentification errors [14]. In clinical laboratories, problems persist, and the current misidentification rates will be reduced only if a cultural change takes place: technological tools can play a major role but this is not enough.

The second category of pre-analytical errors includes sample problems, as shown in Table 2 which reports findings made using data collected in our department from 2009 to 2011.

Hemolysis and samples in inadequate quantity are the primary cause of errors, while the error rates for inpatients are significantly higher than that for out-patients These observations are confirmed in a study reporting an error rate of 74.6% for inpatients and 25.4% for outpatients [15]. Although this difference may be related to the clinical complexity of blood drawing procedures in patients admitted to hospitals, a body of evidence demonstrates that the compliance with standard operating procedures and guidelines in the wards is unsatisfactory, as underlined elsewhere [16,17].

In the last few decades, data have been accumulated to identify the rates of sample errors [18–20], to document the different rates between inpatients and outpatients and to establish whether error rates are related to inadequate collection techniques and non-compliance with existing operational procedure guidelines [21]. Differences in complying with operational procedures may explain why the sample error rate is lower for outpatients with care operators in this situation being under the direct control of the laboratory Director. The introduction of pre-analytical workstations and tools such as serum indices has been proven effective in decreasing most errors due to specimen preparation, centrifugation, aliquoting, pipetting and sorting [20,22], while no significant decrease in pre-pre-analytical mistakes (e.g. patient/sample identification, unsuitable samples due to wrong collection procedures) has been achieved. With intra-laboratory procedures deemed safer, greater attention should be paid to extra-laboratory procedures, guidelines for blood collection, the training and education of health care operators,

Table 1
Main identification problems.

a) Unlabeled samples
b) Mislabeled samples
c) Insufficiently labeled samples
d) Samples suspected of being from the wrong patient, sometimes referred to as "wrong blood in tube"
e) Irregularities in transfusion labeling requirements (e.g. signature of phlebotomist)