Mini-Review

Quality Indicators to Detect Pre-Analytical Errors in Laboratory Testing

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Abstract
Pre-analytical steps, the major source of mistakes in laboratory diagnostics, arise during patient preparation, sample collection, sample transportation, sample preparation, and sample storage. However, while it has been reported that the pre-analytical phase is error-prone, only recently has it been demonstrated that most errors occur in the 'pre-pre-analytical phase'. This comprises the initial procedures of the testing process performed by healthcare personnel outside the laboratory walls and outside the direct control of the clinical laboratory. Quality indicators (QIs) should therefore cover all steps in the pre-analytical phase, from test requesting to sample storage. In the present paper, the state-of-the-art of QIs in laboratory testing is described. The focus is on the experience of a working group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) in developing a model of QIs, 16 of which concern the pre-analytical phase.

Introduction

Quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process (TTP) is correctly performed, thus assuring valuable medical decision making and effective patient care. As stated by Lundberg several years ago on introducing the concept of the 'brain-to-brain loop' for describing the TTP, the generation of any laboratory test result involves nine steps: ordering, collection, identification, transportation, separation or preparation, analysis, reporting, and action.[1] Interestingly, although the 'brain-to-brain' concept was defined as long as 40 years ago, it is still considered the working paradigm in assuring quality and safety for requesting physicians and patients. Indeed, consequent changes made to the medical landscape have greatly impacted on the quality and delivery of laboratory services.[2] In the past decades, a ten-fold reduction in the analytical error rate has been achieved[3] thanks to improvements in the reliability and standardisation of analytic techniques, reagents, and instrumentation, and advances in information technology, quality control and quality assurance methods.

However, whilst current QIs in laboratory medicine tend to focus on the performance and efficiency of analytical processes,[4] recent evidence suggests that most errors in the loop actually fall outside the analytical phase, and the pre- and post-analytical steps have been found to be more vulnerable to the risk of error.[5] The current lack of attention to extra-laboratory factors is thus in stark contrast with the body of evidence pointing to the multitude of errors that continue to occur in the pre-analytical phase.

The achievement of a consensus by a Technical Committee of the International Organization for Standardization (ISO/TC 212) on a comprehensive definition of errors in laboratory testing[6] was therefore a milestone, in that it encourages a patient-centred approach and emphasises the need to evaluate all steps of the testing process, whether or not they fall under the direct control of laboratory personnel.

Errors in the Pre-analytical Phase

Currently, pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation, and preparation for analysis and storage.[7] While patient preparation and sample collection (including patient and sample identification, and specimen handling) are widely recognised as frequent sources of errors, greater attention should be paid to sample transportation. This area needs improvement initiatives, as there is an increasing trend towards consolidation of laboratory facilities, with a consequent need for long-distance sample transportation.[8]

The most commonly reported types of pre-analytical error are: a) missing sample and/or test request, b) wrong or missing identification, c) contamination from infusion route, d) haemolysed, clotted, and insufficient samples, e) inappropriate containers, f) inappropriate blood to anticoagulant ratio, and g) inappropriate transport and storage conditions.[9]

However, while the pre-analytical phase is known to be error-prone, only recently have data been collected to demonstrate that the errors occurring are mainly related to procedures performed outside the laboratory walls, by healthcare personnel not under the direct control of the clinical laboratory.[10] Quality improvement initiatives must therefore take into account both the 'classical' pre-analytical steps and the initial procedures included in the so-called 'pre-pre-analytical phase', which are 'usually performed neither in the clinical laboratory, nor, at least in part, under the control of laboratory personnel'.[5] This is of prime importance since it has been proven that the automation of repetitive, error-prone and bio-hazardous pre-analytical processes performed within the laboratory walls, has effectively decreased errors in specimen preparation, centrifugation, aliquot preparation, pipetting and sorting.[11]

Moreover, the ISO 15189: 2007 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'.[12] This clearly recognises the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the brain-to-brain loop.

Quality Indicators

According to the approach of the Institute of Medicine (IOM) to quality in healthcare, the identification of reliable quality indicators (QIs) is a crucial step in enabling users to quantify the quality of a selected aspect of care by comparing it against a defined criterion.[13] A quality indicator is thus 'an objective measure that potentially evaluates all critical care domains as defined by the IOM (patient safety, effectiveness, equity, patient-centredness, timeliness and efficiency), that is based on evidence associated with those domains, and can be implemented in a consistent and comparable manner across settings and over time'.[14]

Therefore, when assessing the quality of laboratory services using QIs, it is important to ensure systematic and consistent data collection and analysis by using a comprehensive set of indicators that addresses all stages of the TTP and focuses on the areas with an important impact on patient care and health outcomes. The need to harmonise proposed QIs has also been underlined.[15] Yet, as pointed out by Shahangian and Snyder, there is a 'considerable challenge in identifying, defining, and ultimately implementing indicators that cover the various stages of the TTP …. that address the IOM domains, various testing environments, and multiple relevant stakeholders'.[16]

In 2008, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) launched a working group named 'Laboratory errors and patient safety'(WG-LEPS), its primary goal being to identify and evaluate valuable QIs and related quality specifications in order to address all the stages of the TTP.[17] This model complies with the requirements of the Standard UNI 11097, according to which a quality indicator is, 'the information, qualitative or quantitative, that is able to evaluate its change during the time and to verify the defined quality goals, in order to take the correct decisions and choices'.[18] The prerequisites for selected QIs were: a) relevance and applicability to a wide range of clinical laboratories at an international level; b) scientific soundness, with a focus on areas of great importance for quality in laboratory medicine; c) feasibility, both regarding the data availability and the definition of thresholds for acceptable performance; d) timeliness and possible utilisation as a measure of laboratory improvement. The aims of, and steps taken in, the IFCC WG-LEPS project have been described and communicated to the laboratory community.[17] A fundamental source of information regarding the continuous measurement and monitoring of key incident indicators in the TTP is represented by the KIMMS (Key Incident Monitoring and Management Systems) project provided by the Quality Assurance Scientific and Education Committee of the Royal College of Pathologists of Australasia (www.rcpaqap.com.au/kimms).

Quality Indicators in the Pre-analytic Phase

As stated above, the pre-analytical phase should be subdivided into a 'pre-pre-analytical phase' and a 'true' pre-analytical phase, which is undertaken within the laboratory walls after specimen reception. The former phase, which comprises initial procedures usually performed neither in the clinical laboratory nor undertaken, at least in part, under the control of laboratory personnel, includes test requesting, patient and sample identification and sample collection. The latter involves the steps required to prepare samples for analysis (centrifugation, aliquotting, and sorting). In a patient-centred scenario, QIs should be designed to cover all steps of the pre-analytical phase, including the appropriateness of test selection, which is a key issue in projects aiming to ensure clinical effectiveness.

Table 1. Quality indicators in the pre-analytic phase. [17]

QI-1: Appropriateness of test request	Number of requests with clinical question (%)
QI-2: Appropriateness of test request	Number of appropriate tests with respect to the clinical question (%)
QI-3: Examination requisition	Number of requests without physician's identification (%)
QI-4: Examination requisition	Number of unintelligible requests (%)
QI-5: Identification	Number of requests with erroneous patient identification (%)
QI-6: Identification	Number of requests with erroneous identification of physician (%)
QI-7: Test request	Number of requests with errors concerning test input (%)
QI-8: Samples	Number of samples lost/not received (%)
QI-9: Samples	Number of samples collected in inappropriate containers (%)
QI-10: Samples	Number of samples haemolysed (haematology, chemistry) (%)
QI-11: Samples	Number of samples clotted (haematology, chemistry) (%)
QI-12: Samples	Number of samples with insufficient volumes (%)
QI-13: Samples	Number of samples with inadequate sample-anticoagulant ratio (%)
QI-14: Samples	Number of samples damaged in transport (%)
QI-15: Samples	Number of improperly labelled samples (%)
QI-16: Samples	Number of improperly stored samples (%)

The 16 QIs developed by the IFCC WG-LEPS for the pre-analytic phase are shown in Table 1. A preliminary evaluation of data collected by several laboratories worldwide, underlined the need for an improved specification of some QIs.[19] For example, the QI 'Number of requests with errors concerning patient identification/Total Number of requests' should be split into two categories: a) 'true' patient misidentification and/or mismatch, and b) minor errors in patient identification (e.g. age, gender or requesting physician recorded erroneously) that do not 'significantly' compromise patient safety.

Conclusions

The development of QIs in accreditation programs for laboratory medicine is a fundamental step in providing sound evidence of quality in all procedures and processes of the TTP. QIs also play a key role in ensuring that targeted continuous improvement activities aiming to reduce the risk of errors in clinical practice are undertaken. However, particularly in the pre-analytical phase (which investigates procedures that are usually performed by healthcare operators outside the laboratory walls), collecting and monitoring data on QIs, does not automatically result in quality improvement.[21] Effective improvements in the initial (and final) steps of the TTP can be achieved only if further efforts are made to achieve consensus on the preparation, adoption and monitoring of effective standard operating procedures in the initial steps of laboratory testing.[10]

Competing Interests: None declared.

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