Errors in laboratory medicine: The role of quality indicators

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Abstract

Errors in laboratory are heterogeneous in nature as it involves various complex procedures and a variety of persons preforming all the processes, starting from ordering of tests to reporting of result to its influence on ultimate patient care. The core job of a laboratory is to produce the correct test result. If we can't get the test results right, then we aren't doing our core job. It's our profession to know all the details of testing and instrumentation and quality control. It's our profession to assure that test results are correct. Improvements need not be only at "pre" or "post" or "analytical" - it should be at all three stages, as the consequence of error in any of the stage is the same: poor patient care. No error is worse than the other. We must make efforts on all fronts. Even if this means making small improvements in each area, a unified improvement effort will achieve better test results and better patient care than narrow efforts in either the pre-, post- or analytical area. To have a uniform consensus, the laboratories should have certain quality indicators to have control over the procedures that tend to generate errors.

Keywords: Pre analytical, Analytical, Post analytical phase, Quality Indicators.

Introduction

Laboratory services have a great influence on clinical decision-making: 60-70% of the most important decisions on admission, discharge and medication are based on laboratory test results.[1] The generation of any laboratory test result involves nine steps: ordering, collection, identification, transportation, separation or preparation, analysis, reporting and action.[2] Errors can occur in any of these crucial steps. Pre-analytical errors account for up to 70% (46- 68.2% of total errors) 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.[3,4] Analytical errors are reduced over time after implementation of IQC and EQPs. A high error rate (18.5–47% of total errors) has also been found in the post-analytical phase.[4]

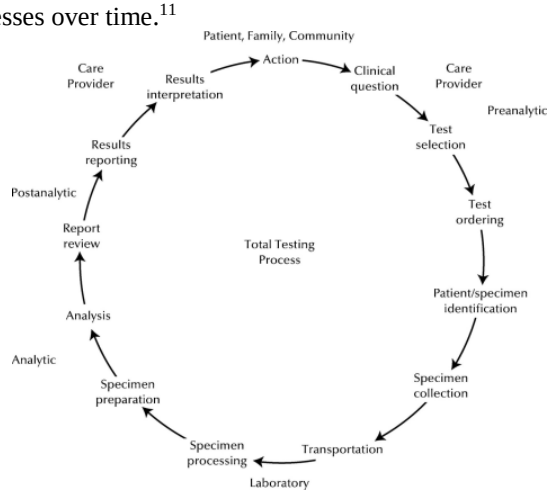
In order to reduce the errors, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) launched a working group named "Laboratory errors and patient safety" (WG-LEPS) with the primary goal of identifying and evaluating valuable QIs and related quality specifications in order to address all the stages of the total testing process (TTP). This project has been designed to define appropriate QIs for use in all laboratories worldwide, collect data from them, identify the current state-of-the art and define performance criteria to better address improvement actions, decrease the error rate and suggest steps to take in order to further improve performance.[5-7]

Successfully implementing total quality management (TQM) also requires commitment and full participation by all employees in continuous quality improvement activities, by continuously improving effectiveness and reducing the errors, defects and wastes.[8]

According to the latest version of the International Standard for clinical laboratory accreditation (ISO 15189:2012), "quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes". In addition, the document specifies that: "the laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes".[9]

The effectiveness of quality indicators is closely related to complete understanding of all the staff involved so as to the importance of using the specific indicator, the method of data collection and processing and result evaluation.[10]

The use of quality indicators (QIs), as performance measurements, is an effective tool for achieving an accurate estimate of the degree of quality, identifying problems that may need to be addressed, and monitoring processes over time.[11]



Total Testing Process[12]

The total testing process can be divided into pre-pre-analytical, pre-analytical, analytical, post-analytical and post-post-analytical. Some authors have introduced the "pre-pre-" and "post-post-" analytical phases to identify activities associated with the initial selection of tests and with the interpretation by clinicians respectively, to differentiate them for the pure collection/transport activities (pre-analytical phase) and reporting (post-analytical phase) [13,14]. There is some evidence that these

steps are more error-prone than other pre- and post-analytical activities [13-18].However, the definition and use of such terms is not universal. Indeed the definition of even basic terms such as pre-analytical, analytical and post-analytical can vary between authorities.

The commonest causes of errors in the total testing process as compiled by Plebani[19] are:

1. Pre-pre-analytical (46-68%): Inappropriate test request, order entry, patient/specimen misidentification, sample collected from infusion route, sample collection (hemolysis, clotting, insufficient volume, etc.), inappropriate container, handling, storage and transportation.
2. Pre-analytical (3-5%): Sorting and routing, pour-off, aliquoting, pipetting and labeling, centrifugation (time and/or speed).
3. Analytical (7-13%): Equipment malfunction, sample mix-ups, interference (endogenous or exogenous), undetected failure in quality control.
4. Post-analytical (13-20%): Erroneous validation of analytical data, failure in reporting/addressing the report, excessive turn-around-time, improper data entry and manual transcription error, failure/delay in reporting critical values.
5. Post-post-analytical (25-46%): Delayed/missed reaction to laboratory reporting, incorrect interpretation, inappropriate/inadequate follow-up plan, failure to order appropriate consultation.

Pre analytical errors and Quality Indicators: As per Carraro P et al, 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 condition.[20]

Table 1: Types and description of most common pre-analytical errors [21]

Pre-analytical errors	Description
Haemolysed sample	Presence of pink to red tinge in serum plasma
Insufficient sample	Serum obtained not enough for requested tests
Incorrect sample tube	Most samples received should not be in anticoagulated tubes
Sample not on ice	Samples for arterial blood gases analysis not transported on ice
Incorrect sample identification	Mismatch between name on sample and request form
Tube broken in centrifuge	The use of different tube sizes for sample collection
Delay in sample transportation	Samples were not sent to the laboratory on time
Expired Reagents	Some reagents expired before use
Sample mix-ups	Samples intended for other laboratories were sent to the biochemistry laboratory

Table 2: Quality Indicators in pre-analytical phase [22]

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 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 hemolysed (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 labeled samples (%)
QI-16 Samples	Number of improperly stored samples (%)

Errors in analytical phase

Because laboratory tests play an extremely important role in diagnosing, monitoring and evaluating patient out-

comes; evidence-based evaluation of laboratory performances is crucial to ensuring that patients receive safe efficient and effective care. A significant decrease in error rates in analytical phase has been achieved through laboratory automation, standardization and optimization of reagents; improved training of laboratory staff and implementation of IQC and EQAPS.[19]

The analytical phase commences when the sample arrives to the laboratory has been accessioned into lab computer system and analytical testing is initiated.[12] The importance of this phase is reflecting the clinical decision making process, the adequateness of treatment and interventions selected with respect to patient prognosis and continued disease prevention or treatment. This phase includes all actions performed within the laboratory and it begins with analytical quality design, which will determine the quality of the test.

Table 3: Quality indicators in the analytic phase

No.	Indicator	Flag review and quantify	Corrective actions
1	Lot to lot reagents	Reagents are out or not acceptable	Lab personnel contact manufacturer for information Request replacement of reagents Go to analytical test backup system Control standards and/or calibrators do not meet quality control rules for lab policy procedures
2	Instrumentation efficiency	Number of reports with delayed delivery for instrumentation failures/year/total number of reports	Establishing the use of diagnostic algorithms in laboratories Increases in turnaround time for tests that are really delayed Train lab personnel
3	Data entry	Number of incorrect results for erroneous transcription and/or manual entry data in computer system/total number of results (%)	Lab personnel must be retrained Efficiently perform data entry Double review is performed prior to release of final reports with emphasis on those which contain interpretation

Recent regulation and accreditation guidelines now require laboratories to focus their improvement efforts on, not only on the analytical step, but also the other steps of the TTP.[23]

Performance criteria and quality indicators for the post-analytical phase: Post-analytic communication entails laboratory professionals' communications with the clinician about timeliness of reporting, notification of significant abnormal test results, and presentation of relevant information through reports and interpretative comments. Breakdowns in communication lead to errors, events affecting patient safety, and inefficient and ineffective use of resources.

Prompt reporting of test results can improve efficiency in patient care and enhance clinician and patient satisfaction, even when it does not affect health outcomes.[24]

Errors leading to incorrect or delayed patient results can affect medical decisions and compromise the efficacy of patient treatment. Specific report content issues can include any of the following: un-interpretable information, incorrect data of reference intervals, inaccurate personal details of patient or incorrect reporting of measurand. Moreover, different types of error can occur during report formatting. Reports that lack units of measurement or use inappropriate units of measurement can lead to harmful misinterpretation of results and/or undervaluation of important information. The definition of QIs that includes the measurement of these aspects aims to obviate any misinterpretation and to promote accuracy and completeness.

Table 4: Quality indicators for the post-analytical phase

Turnaround-times Number of reports delivered outside the specified time/total number of reports
Laboratory reports Number of incorrect reports issued by the laboratory/total number of reports issued by the laboratory
Notification of critical values Number of critical values notified after a consensually agreed time (from result validation to result communication to the clinician)/total number of critical values to communicate
Time taken (from result validation to result communication to clinician) to communicate critical values of inpatients (min)
Time taken (from result validation to result communication to clinician) to communicate critical values of outpatient (min)

Turnaround time potentially encompasses all three phases of the total testing process and can be an excellent single measure of laboratory performance.

The mean and standard deviation are not an appropriate bases for defining TAT distribution, the most commonly used measurement being the time interval

during which 90% of results are completed (corresponding to 90th percentile). [25]

The interpretation of results is crucial to patient outcome yet, hoping to avoid giving inappropriate advice, many laboratories fail to provide interpretative comments in the absence of complete clinical information.

Critical values are defined as those, which represent potentially life-threatening situations and in which reporting delays can result in serious adverse patient outcomes.[26-30]

Conclusion

The use of QIs allows the identification of appropriate improving actions to be taken in order to reduce laboratory errors. Data collection and regular monitoring actions may therefore improve laboratory performance. Efforts must be made to encourage laboratories to collect QIs data and undertake the actions for improvement when results go beyond the defined quality specifications. Since laboratory tests play an extremely important role in monitoring and evaluating patient outcomes and assisting clinicians in their decision-making, the rigorous evaluation of laboratory performance is crucial to providing patients with safe, effective and efficient care.

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