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An Update On Best Practices and Regulatory Requirements for the Improvement of Clinical Laboratory Services through Quality

Antonia Mourtzikou, Department of Cytopathology, University General Hospital "Attikon," Athens, Greece
Marilena Stamouli, Department of Biochemistry, Naval and Veterans Hospital, Athens, Greece

ABSTRACT

The aim of this study is to emphasize the need for accurate, relevant and reliable results provided by the clinical laboratories, in order to achieve the best patient outcomes. The improvement of clinical laboratory services through quality is a continuous process, which includes constant changes and new regulatory requirements. Further efforts must be made to raise the awareness of all health personnel involved in the total testing process and highlight the importance of quality indicator implementation for improving the quality of laboratory services and patient safety. Laboratories and physicians must audit, update and continuously e their critical result management practices in order to provide safe and reliable care to patients. Moreover, implementation of six-sigma, a state-of–the-art quality management strategy, can further improve laboratory quality, by identifying biased or imprecise assays, so that appropriate quality monitoring strategies can be used. Harmonization of the total testing process, as a process of recognizing, understanding, and explaining differences and taking steps to achieve uniformity of results is of utmost importance for the use of data obtained from different laboratories interchangeably.

KEYWORDS

CQI (Continuous Quality Improvement), EQA (External Quality Assessment), FMEA (Failure Mode and Effect Analysis), LIS (Laboratory Information System), QI (Quality Indicator), Six-Sigma Approach, TAT (Turn Around Time), TQM (Total Quality Management)

INTRODUCTION

It is well known that the clinical laboratory plays an important role in the detection, diagnosis and treatment of diseases. Patient management, treatment, detection of complications, hospital admission and discharge are based on laboratory test results, (Mourtzikou et al., 2013). In the United States between 7 and 10 billion laboratory tests are reported annually, while a 15% of patients receive either incorrect or delayed reports (Noble, 2009). Thus, the laboratory has an ethical obligation to produce reliable, unambiguous and reproducible analytic measurements and observations and to provide clinicians with important information for the prevention, diagnosis, treatment and management of the disease. Clinical laboratory work is highly complex and with an absolute need for accuracy, confidentiality, time effectiveness and cost effectiveness. It includes both technical and management activities; coordination between them is essential for the production of high-quality and error-free test results. Concerns about the quality of the test results, have led to increased regulation and guideline

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establishment, and to the development of quality improvement programs. The guidelines for quality can be found in government regulations, accreditation standards, and national practice standards such as CLIA (Clinical Laboratory Improvement Amendments), JCAHO (Joint Commission on the Accreditation of Healthcare Organizations), NCCLS (National Committee for Clinical Laboratory Standards), ISO 15189:2012, ISO/IEC 17025 (International Organization for Standardization), as well as in the detailed guidelines from CAP (College of American Pathologists) and COLA (Commission of Office Laboratory Accreditation). Laboratories need to follow constantly the changes of these regulatory requirements and the addition of new ones. Moreover, since clinical laboratories must ensure the quality, integrity, and reliability of a wide range of patient results, they need to sustain a commitment to quality and demonstrate a certifiable level of compliance. The purpose of our study is to provide an update on best practices and regulatory requirements, for the improvement of clinical laboratory services through quality. The data and the examples presented in this study are based on our work and experience at biochemistry laboratories in NHS hospitals.

QUALITY IMPROVEMENT PROGRAMS

A laboratory quality improvement program is designed to detect, reduce, and correct deficiencies in a laboratory's work process. It is defined as the set of operations, processes, and procedures which ensure that the right test is carried out on the right specimen and that the right result and right interpretation are delivered to the right person at the right time (Berte, 2007). These programs include organization principles and personnel requirements, quality assurance, laboratory environment safety and facilities, equipment and measuring systems, reagents and materials, analytical procedures, result reporting, and archiving of patient medical data (Berte, 2007). The development of a quality improvement program takes into account the pre-analytical, analytical and post-analytical activities. Pre-analytical is the term that describes activities that occur before the time the sample arrives in the laboratory. Analytical is the term that describes activities that happen during the handling and analysis of the sample in the laboratory. Post-analytical is the term that describes activities that happen after a result is measured. All three phases are equally important, and each one includes factors that may directly influence the acceptability of a measurement result (Berte, 2007).

The Pre-Analytical Phase

The pre-analytical phase includes test request, patient preparation, patient and specimen identification, specimen collection, specimen transport, specimen centrifugation and handling. Although errors can arise at any of the three phases, many studies have shown that the pre-analytical phase accounts for 46% to 68.2% of errors observed during the total testing process (Barak & Jaschek, 2013; Hawkins, 2012). Evidence presented in the literature shows that pre-analytical error rates are lower when the laboratory staff performs the collection, identification, labeling, handling and transport of patient samples, and this, in turn, represents a key issue in defining strategies for reducing the risk of errors in the pre-analytical steps (Jegede et al., 2015; Kemp et al. 2012; Lippi et al., 2015; Plebani et al., 2015). Pre-analytical errors can be reduced with the right training, close coordination among all the members of staff involved (clinician, phlebotomist and laboratory staff) and implementation of good laboratory practices such as using appropriate technology for patient and sample identification (such as wristbands and barcodes), automated detection of serum indices (such as the haemolysis index), and link to the laboratory Information system. The use of appropriate blood collection systems, sample tubes and anticoagulants may contribute significantly to result quality (Hawkins, 2012; Söderberg et al., 2009). All laboratories must have written procedures about patient preparation, patient identification, specimen collection, specimen identification, specimen transport and preparation for analysis. They should also establish rejection criteria for specimens and should follow them closely, as well as corrective actions that should take place in such a case.