Chapter 69
An Update on Best Practices and Regulatory Requirements for the Improvement of Clinical Laboratory Services Through Quality

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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.

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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 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).