Chapter 8
The Clinical Laboratory and the Commitment to Quality: Update on Best Practices and Regulatory Requirements

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ABSTRACT

The main role that clinical laboratories play in the detection, diagnosis, and treatment of diseases is clearly evident. Clinical laboratories need to sustain a commitment to quality and demonstrate a certifiable level of compliance. Many strategies are used to reduce laboratory errors, including internal QC procedures, external quality assessment programs, implementation of QIs and six-sigma methodology. All strategies should be consistent with the requirements of the international standard for medical laboratory accreditation and suitable for promoting corrective/preventive actions. They must promote total quality and patient safety and be consistent with the definition of a laboratory error. Harmonization process is in progress; however, further efforts must be made. Total quality management must be evaluated periodically. For a patient-centered approach, there is the need to assure that each and every step of the total testing process is correctly performed, that weaknesses are recognized, and that corrective and preventive actions are designed and implemented.

DOI: 10.4018/978-1-7998-2390-2.ch008
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INTRODUCTION

Clinical laboratories play an important essential 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; Mourtzikou & Stamouli, 2017).

It is estimated that about 251,000 patients die every year in the U.S. due to medical errors, making medical errors the third most common cause of death in the U.S. Mistakes in medication and treatment, diagnostic errors and erroneous laboratory results are contributing mainly to these estimations (Makary & Daniel, 2016). In the United States between 7 and 10 billion laboratory tests are reported annually, while 15% of patients receive either incorrect or delayed reports (Noble, 2009). (Stamouli et al., 2019). Thus, the laboratory has an ethical obligation to produce reliable, unambiguous and reproducible analytic measurements and to provide clinicians with relevant information for the prevention, diagnosis, treatment and management of the disease (Plebani et al., 2019).

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 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 the latest 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.
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