ABSTRACT

Health care providers need test results that are relevant, accurate, and reliable for patient care. The term “quality control” is used to describe the set of procedures used to check that the results of laboratory tests are reliable for the intended clinical use. A laboratory might produce results that are considered unsatisfactory. While the cause for this might be immediately apparent, the identification of the underlying problem is neither always straightforward, nor easy because many factors can affect result quality. Internal quality control (IQC) and external quality assessment (EQA) are two distinct but complementary components of a laboratory quality improvement program. IQC ensures day-to-day laboratory consistency. EQA permits the identification of poor individual laboratory performance, as well as the detection of reagents, instruments and methods that produce unreliable or misleading results, by means of a retrospective analysis of data obtained by participating laboratories. Continuous participation in EQA schemes has been linked to improved laboratory performance.

Keywords: Clinical Laboratory, External Quality Assessment, Internal Quality Control, Laboratory Information System (LIS), Quality Indicators, Test Results

INTRODUCTION

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. 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. 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 and 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), International Organization for Standardization (ISO) 15189:2012, ISO/IEC 17025, as well as in the detailed guidelines from CAP (College of American Pathologists) and COLA (Commission of Office Laboratory Accreditation) (Greenberg et al., 2008; Huisman et al., 2007; ISO 17025:2005, ISO 15189:2007; Tholen et al., 2008). 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 highlight the effort which usually takes place in the clinical laboratories of the NHS hospitals in Greece, in order to achieve high quality and error free test results.

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 Lucia, 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 Lucia, 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 Lucia, 2007; Kirchner et al., 2007; Elston, 2008).

The Pre-Analytical Phase

Up to 68.2% of laboratory errors occur in the pre-analytical phase, which includes procedures performed neither in the clinical laboratory nor under the control of the laboratory personnel (Bonini et al., 2002; Huisman, 2011; Kouri et al., 2005; Lippi et al., 2006). The pre-analytical phase includes the test ordering process, proper patient identification and preparation for the test (food and drug consumption, body posture, exercise history, stress, fasting), specimen collection (type of vial, specimen volume, use of anticoagulants or preservatives), specimen transportation to the laboratory (temperature, timing, careful handling, agitation, light exposure). Biological variation is also an important factor of this phase. Many blood constituents fluctuate significantly in a circadian rhythm during the course of the day while others fluctuate according to patient age, pregnancy or clinical conditions. All these variables are important
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