Türk Biyokimya Dergisi [Turkish Journal of Biochemistry–Turk J Biochem] 2006; 31 (4) ; 161–163.

Conference [Konferans]

Yayın tarihi 21 Aralık, 2006 © TurkJBiochem.com

[Published online 21 December, 2006]

"The Manuscript below was presented by Dr. Sharon Ehrmeyer at a Conference organized by Turkish Biochemical Society, Clinical Chemistry and Laboratory Medicine Committee, at Pamukkale University, Denizli, on August 16, 2006. Dr. Ehrmeyer is a Professor at Pathology and Laboratory Medicine Department and Director of the Medical Technology and Clinical Laboratory Department, Faculty of Medicine, Wisconsin University, USA.

Aşağıdaki makale, 16 Ağustos 2006 tarihinde Pamukkale Üniversitesi, Denizli'de Türk Biyokimya Derneği, Klinik Kimya ve Laboratuvar Tıbbı Komitesi tarafından düzenlenen konferansta, Prof.Dr. Sharon Ehrmeyer tarafından sunulmuştur. Dr. Ehrmeyer, ABD'de, Wisconsin Üniversitesi, Madison Tıp Fakültesi, Patoloji ve Laboratuvar Tıbbı Bölümü Öğretim Üyesi ve Tıbbi Teknoloji ve Klinik Laboratuvar Bölümü Direktörüdür."

Regulations and Quality Assurance in Laboratory Medicine: USA Experience

[Tıbbi Laboratuvarcılıkta Tüzükler ve Kalite Garantisi: ABD Deneyimi]

Sharon S. Ehrmeyer

Pathology and Laboratory Medicine, University of Wisconsin Medical School, Madison, WI 53706 USA

ABSTRACT

In the U.S., all clinical laboratory testing is regulated by the Clinical Laboratory Improvement Amendments (CLIA). CLIA links test quality and adherence to a body of testing regulations intended to ensure accurate, reliable and timely patient test results.

CLIA regulations with specific minimum, performance requirements or safeguards are designed to prevent testing errors. The U.S. Institute of Medicine found that testing processes fail as a result of human error, lack of documentation and lack of test management. To ensure quality, we must focus on all three phases of the testing process – pre-analytical, analytical, post-analytical. We can no longer just hope that quality will happen as a result of following a series of prescribed protocols – rules, regulations, good laboratory practices, etc. Quality laboratory test results requires planning, leadership and oversight.

Key Words: Clinical Laboratory Improvement Amendments (CLIA), laboratory quality, regulations, medical errors, quality, quality control, quality assessment

ÖZET

ABD'de klinik laboratuvar testleri Klinik Laboratuvar Geliştirme Değişiklikleri (CLIA) ile denetlenir. CLIA test kalitesini yazılı bir grup kurallar aracılığı ile doğru, güvenilir ve zamanında hasta sonuçları vermek olarak ilintilendirir.

CLIA kuralları en basitinden performans nitelikleri ve önleyici tedbirler ile test hatalarını engellemeyi amaçlamaktadır. ABD Tıp Enstitüsü insan hatalarının, eksik dökümantasyon ve test idaresindeki eksikliklerin test süreçlerindeki başarısızlıklara sebebiyet veren ana faktörler olduğunu göstermiştir. Kalite güvencesi sağlayabilmek için analitik öncesi, analitik ve analitik sonrası, süreçlerinin hepsinin üzerinde yoğunlaşmak gereklidir. Artık sadece yazılı bir takım kurallara –kurallar, tüzükler, iyi laboratuvar uygulamaları vs.- bağlı kalarak kalitenin elde edilebileceğini umut etmek yeterli olmayacaktır. Laboratuvarcılıkta kaliteli test sonuçları verebilmek planlama, liderlik ve denetim gerektirecektir.

Anahtar Kelimeler: Klinik Laboratuvar Geliştirme Değişiklikleri (CLIA), laboratuvar kalite tüzükleri, tıbbi hata, kalite, kalite kontrolu, kalite değerlendirmesi.

Yazışma Adresi
[Correspondence Address]

Sharon S. Ehrmeyer

Pathology and Laboratory Medicine, University of Wisconsin Medical School, Madison, WI 53706 USA
Telephone: +1 608-262-0859;
Fax: +1 608-262-9520;
E-mail: Ehrmeyer@wisc.edu

Kayıt tarihi 16 Ağustos 2006
[Received 16 August 2006]

INTRODUCTION

In the U.S., all clinical laboratory testing is regulated by the Clinical Laboratory Improvement Amendments (CLIA) (1). CLIA links test quality and adherence to a body of testing regulations intended to ensure accurate, reliable and timely patient test results. These regulations actually specify minimum requirements for personnel, quality control, quality assurance, and proficiency testing (external quality assessment). Testing sites also are inspected every two years to assess and ensure, through threat of fines and penalties, compliance.

The goal of the CLIA legislation was to ensure a minimum, fundamental level of quality regardless of where clinical laboratory testing is performed (e.g., large reference laboratory, hospital, physician office). Despite the admirable intent of CLIA, fourteen years later testing problems abound. For example, a woman in Minnesota underwent a double mastectomy only to be told that her amputated breast tissue contained no malignant cells (2). Her "normal" breast biopsy was switched in pathology with specimens taken from another woman. The Pennsylvania Department of Health found that several patients in a skilled nursing facility died as a result of being overdosed with Coumadin (3). The test site used the wrong international sensitivity index (ISI) to calculate and report international normalized ratio (INR) values. Maryland General Hospital reported as many as 500 questionable HIV and hepatitis test results despite quality control values being outside of established tolerance limits (4). The analysts simply altered the quality control results so that they were within acceptable tolerance limits. The U.S. Institute of Medicine (IOM) estimated that 44,000 to 98,000 hospitalized Americans die each year due to "medical errors" and Newsweek, a popular weekly news magazine, reported that errors may actually result in as many as 195,000 deaths each year [5,6]. Although errors due to laboratory testing were not specifically enumerated in the IOM report, laboratory results certainly play a role. More than 7 billion laboratory tests are performed in the U.S. each year and the results generated provide approximately 70 % of information used in health care.

The CLIA Regulations And Error Prevention

CLIA regulations with specific minimum, performance requirements or safeguards are designed to prevent clinical laboratory testing errors. For example, CLIA mandates laboratories to follow written policies for specimen labeling and to have a system in place to ensure patient data are reliable and accurate from order entry to final report. Laboratories must have written policies addressing quality assurance or assessment practices for all phases of the testing process. At a minimum, testing sites are required to provide personnel with specific orientation to testing and ensure their competency. Testing sites also need to analyze and assess the results of quality control materials with reagent lot changes and major maintenance, review patient test results for inconsistencies with diagnosis or pertinent clinical data, and examine the overall distribution of patient test results. CLIA regulations flatly state that daily quality control results must be acceptable or within established tole rance limits before reporting patient test results. This requirement implies a three step process: (1) two levels of quality control materials are analyzed at least daily and concurrently with patient samples, (2) quality control tolerance limits are meaningfully set by the laboratory, and (3) quality control results are assessed, evaluated as being correct and documented before reporting patient test results. To further assess test result accuracy, test sites are mandated to participate three times each year in external quality assessment or proficiency testing. Each proficiency testing events includes five samples per analyte. To successfully pass proficiency testing, test sites must have, at a minimum, 4 of the 5 results per analyte correct. Finally, CLIA insists that the laboratory director is responsible for overall operation and administration of the laboratory which includes ensuring adequate laboratory staffing and adequate training of testing personnel and having testing systems that provide quality laboratory services for all aspects of test performance — pre-analytic, analytic, and post-analytic phases of testing.

What Has The USA Learned About Quality Under CLIA?

Agents of the government inspect laboratories every two years for compliance to the CLIA regulations. Inspection deficiencies can result in plans of corrections, fines, sanctions and even suspension of testing. Despite the serious and inexcusable testing errors sited above, all three laboratories passed inspections for CLIA compliance! As laboratory professionals, we want to believe, *a priori*, that following quality-based regulations such as CLIA improve laboratory test quality and positively impact patient outcomes. This view is demonstrated by the proliferation of national, international, and professional "laboratory" standards. However, regulations do not absolutely ensure quality! While adhering to minimum regulations MAY foster quality, regulations are not guarantees of quality. Moreover, inspections do not ensure quality. Testing sites clearly can have up-to-date, quality practices in place, routinely analyze quality control materials and dutifully record results. However, if the analysts consciously circumvent the intent of the requirements or not gather or ignore the quality assessment data, compliance still can be achieved while patients are poorly served.

What Really Impacts Test Quality?

To truly achieve clinical test quality, it is essential to focus not only on the analytical phase of testing, the pre and post-analytical phases of testing, and achieving the ultimate "value" from test results. Figures 1–3 show factors that influence each of these areas. The U.S. Institute

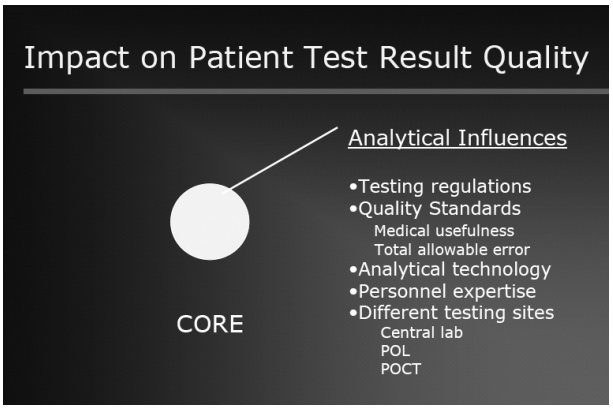

Figure 1: Analytical -- Impact on patient test result quality

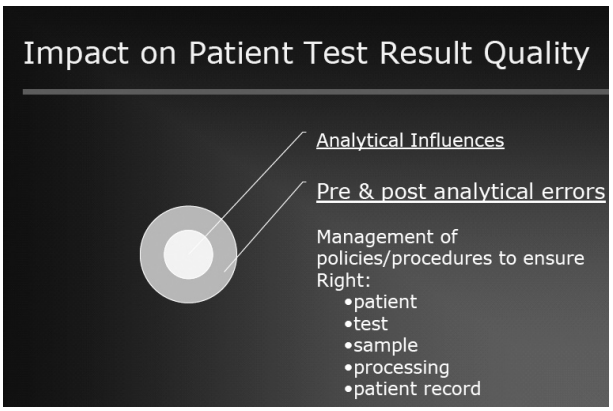

Figure 2: Pre and Post-Analytical -- Impact on patient test result quality

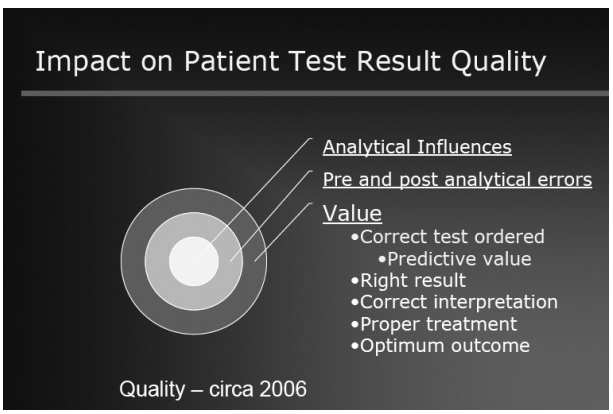

Figure 3: Value -- Impact on patient test result quality

of Medicine found that testing processes fail as a result of human error, lack of documentation and lack of test management [5]. As a start, the report recommends error reduction through technology — computerized physician order-entry, barcoded patient wristbands and samples, analytical automation, smart technology to ensure analytical quality, intra-hospital computer systems that "talk" to each other, and direct physician interface with patients' electronic records. A recent article in *Clinical Laboratory News*, recommends improving quality through "people power" — defined as skilled and dedicated laboratory professionals who undergo continuing education, training and competency assessment; work in a testing environment focused on patient safety; and adhere to quality management principles and on-going quality improvement plans (7). While the concept of people power is true, the reality today in the U.S. is that laboratory professionals are retiring, fewer students are entering the profession, more non-laboratorians are performing testing, and, in general, the laboratory staff has less knowledge of the "science" behind quality laboratory testing.

Conclusions

Achieving quality laboratory testing will not come solely from laboratory professionals. They will no longer be responsible for choosing the quality control protocol (algorithms, rules, criteria, etc.); performing the actual quality control testing and interpretations; or creating the documentation. These functions can be assigned to manufacturers and built into the test system to ensure an absolute level of defined quality in the test results. Professionals, however, will need to define the level of quality necessary and ensure the right test on the right patient at the right time with the right interpretation. Quality in 2006 and beyond is not about how to quality control. It is about how to ensure that full quality of the testing process – pre-analytical, analytical, post-analytical — is in fact achieved. Quality will not just happen! Planning, leadership and oversight are essential to achieve the goal of quality testing — right test, right patient, right result, right time, right record and ultimately the right treatment and outcome.

References

[1] Clinical Laboratory Improvement Amendments (current document including all revisions through October, 2004). http://www.phppo.cdc.gov/clia/chronol.aspx

[2] Associated press. http://www.cnn.com/2003/HEALTH/01/20/medical.mistake/

[3] Pennsylvania Department of Health. http://www.dsf.health.state.pa.us/health/cwp/view.asp? A = 190&Q = 229407

[4] Baltimore Sun. http://www.baltimoresun.com/news/local/balhospitaltests,0,7736886.storygallery? coll = bal-local-headlines

[5] Kohn LT, Corrigan JM, Donaldson MS (1999) To Error is Human: Building a Safer Health System. Washington DC: National Academy Press.

[6] Newsweek. http://msnbc.msn.com/id/5536730/

[7] McDowell J (June 2005) Clin Lab News.