Editorial

Laboratory Medicine - Current Perspective

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Laboratory medicine is an integral part of health care system that underwent major advancements in the last four decades. Clinical laboratories have recently been defined as 'the nerve center of diagnostic medicine' because they provide essential information for screening, prevention, early diagnoses, monitoring, and effective treatment of human diseases.[1] It is also true that laboratory services have a great influence on clinical decision making; about 60-70% of the most important decisions regarding patient management are based on laboratory test results and consequently, laboratory errors have a tremendous impact on patient safety including delayed or wrong diagnoses and unnecessary costs and care. The risk of adverse events and inappropriate care due to laboratory errors ranges from 2.7% to 12%, while in a larger percentage of cases (24.4% to 30%), the laboratory errors result in patient care problem.[2,3] Besides causing serious harm to patients, medical errors translate into huge costs for the national economy. In 1999, the estimated cost of medical errors in the United States was between $17 billion - $29 billion a year, and in 2006, it was much higher, approaching $282 billion.[4]

As clinical laboratories have such high degree of influence, the quality of laboratory testing and reporting is of utmost importance. Laboratory medicine has been a pioneer in the field of patient safety. Activities in laboratory medicine are precisely defined, closely monitored and are therefore more controllable than a procedure or treatment in any other medical settings. Laboratory medicine is also the pioneer in statistical quality control (QC) activities and the concepts and practices of quality assessment programs have long been routine in laboratory medicine. As a result error rates in laboratory activities are far lower than those seen in overall clinical health care.[4-6]

Laboratory testing is highly complex, consisting of a series of interrelated processes. Traditionally, laboratory practice can be divided into three phases pre-analytical, analytical, and post-analytical.[4,5] The analytical aspects of testing have long been under scrutiny and are being regulated by quality control methods and quality assessment programs. However, a number of surveys and reviews in recent decades demonstrate that quality in clinical laboratories cannot be assured by merely focusing on their analytical aspects. Many mistakes in the Total Testing Process (TTP) are called "laboratory errors", although these may be due to poor communication, action taken by others involved in the testing process (e.g., physicians, nurses and phlebotomists), or poorly designed processes, all of which are beyond the laboratory's control. The more recent surveys on errors in laboratory medicine conclude that in the delivery of laboratory testing, mistakes occur more frequently before (pre-analytical) and after (post-analytical) the test has been performed.[4,5,7] Most errors are due to pre-analytical factors (46-68.2% of total errors), while a high error rate (18.5-47%) has also been found in the post-analytical phase. Even the pre-pre-analytical phase is of much importance. Misuse of laboratory services through inappropriate laboratory test requesting is under scrutiny worldwide because of its impact on total costs and the inherent increased risk of medical errors and injury.[5]

Accurate patient identification is one of the first steps in ensuring correct laboratory results as misidentification of patients and specimens can have serious consequences. In particular, mistakes due to the use of incorrect containers or procedures (e.g., from infusion route or with excessive aspiration force) stress the importance of inter-departmental cooperation in improving

the quality of specimen collection and handling.[5,8] Appropriate and adequate specimen is also a critical factor in test result accuracy and usefulness which may otherwise contribute for over 60% of pre-analytical errors. There may be additional causes, such as lack of due signature, empty tube, wrong compilation of the requisition form, temperature not maintained, tube broken in the centrifuge, urine not acidified and so on. Less identifiable pre-analytical errors originate from variations in plasma volume and metabolites as a result of physical exercise, tourniquet placement and other patient-related physical variables (diet, stress, position).[5]

Pre-analytical errors can be prevented by a comprehensive plan involving five interrelated steps: developing clear written procedures, enhancing health care professional training, automating functions, monitoring quality indicators, improving communication among health care professionals and fostering interdepartmental cooperation.[4] Modern robotic technologies and information systems like computerized order entry, automated phlebotomy tray preparation, barcodes can also help to reduce pre-analytical errors.[9] There are now more reliable means for the automated detection of the serum indices, for example the hemolysis index. Visual detection of hemolysis must be abandoned as it is less sensitive and not reproducible. Laboratory personnel must ask for new samples when hemolysis is detected. If a new sample cannot be obtained, it is the responsibility of the laboratory specialist to communicate the problem to the clinician.[10] As stated by David Blumenthal in an editorial concerning two reports on laboratory errors and mistakes, the greatest quantitative reductions in laboratory errors are likely to be achieved through interdepartmental cooperation designed to improve the quality of specimen collection and data dissemination.[5]

A significant decrease in error rates has been documented over the last four decades, particularly for analytical errors. The laboratory has spent decades improving analytical quality by establishing internal quality controls (IQC) and external quality assessment (EQA).[4] In a survey carried out in 1947, analytical errors were 16.21% of total laboratory errors, whereas in 1996 these were 1.29% and in 1997 only 0.47%.[11-13] In recent decades, standardization, automation and technological advances have significantly improved the analytical reliability of laboratory results and decreased the error rates.[5] However, this is not the case in all areas of laboratory medicine. In particular, several recent studies demonstrate that a significant number of analytical interferences can occur with most of the present immunometric assays, are difficult to identify and that they can produce serious errors.[5,14]

The production and release of the laboratory report is the crucial step in post-analytical procedures. The most common mistakes in this phase are wrong validation, results that are delayed, not reported or reported to the wrong providers, and incorrect results reported because of post-analytical data entry errors and transcription errors.[5,15,16] Another well-recognized source of post-analytical problems is inter-laboratory variability and inaccuracy of reference intervals which may markedly affect the clinical interpretation of laboratory data, leading to errors in clinical decision-making.[5]

Significant improvements have been made to the post analytic phase in data transcription as a result of interfacing analyzers and laboratory information systems (LIS). Further important achievements concern policies and procedures used for reporting critical values as well as initiatives to improve the efficiency of test report delivery to requesting physicians. Automatic computerized communication systems can be very helpful.[3]

However, the first and foremost concern of the clinical laboratories is the safety and right of the patients to get accurate and appropriate laboratory services. So here lies the need to investigate any possible defect in the total testing process that may have any negative impact on the patient.[17] Although analytical methods and systems have been significantly improved in recent decades, we

should not become complacent. Team work and good communication within the laboratory and, more importantly, with clinicians and patients are crucial in improving our knowledge on laboratory errors and developing practical remedies. The cornerstone to identifying aberrant laboratory test results remains in clinical context and common sense. In a safety-oriented laboratory, personnel should have a healthy skepticism about everything they do that is they might be proud of their high standards, but should be constantly alert, and be aware that they can, and will, make mistakes from time to time.[5]

In fact any direct or indirect negative consequence related to a laboratory test must be addressed with a zero tolerance attitude, irrespective of which step is involved and whether the error is caused by a laboratory professional or by a non-laboratory operator and in this practice creation of a no-blame environment is of crucial importance.

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