



## Is It Safe to Have a Laboratory Test?

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A recent U.S. Institute of Medicine report indicated that up to 98,000 deaths and more than 1 million injuries occur each year in the United States due to medical errors. These include diagnostic errors, such as an “error or delay in diagnosis, failure to employ indicated tests” and the “use of outmoded tests.”

Over 7 billion laboratory tests are performed annually in U.S. clinical laboratories. These tests provide up to 80 percent of the information used by physicians to make important medical decisions, according to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Therefore, it is important to determine how often laboratory testing mistakes occur, whether they cause patient harm, where they are most likely to occur in the testing process, and how to prevent them from occurring.

How often do laboratory testing mistakes occur and how do they affect patient care? In 1987, an investigation in a private hospital of medical records of patients that were involved in a laboratory testing mistake revealed that 70% of patients were not affected by these mistakes (Ross JW, Boone DJ, 1989. p. 173. Institute on Critical Issues in Health Laboratory Practice DuPont Press). However, 30% were either subjected to an unnecessary procedure (such as specimen redrawing) or were at risk of being harmed. Overall, 37.5/100,000 patients were placed at risk because of mistakes in the testing process. Another important finding was that 93% of mistakes occurred before or after the actual process of analysis. A study of primary care physicians revealed that laboratory testing mistakes occurred in 34/100,000 patient visits, 27% of these mistakes had an impact on patient care, and mistakes were most likely to occur before or after actual specimen analysis (Nutting et al, JAMA 1996;275:635-639).

A recent review of some 50 studies on errors in laboratory medicine found that most studies focused on analytical errors, since the incidence of inappropriate test ordering and interpretation are more difficult to detect (Bonini et al Clin Chem. 2002; 48:5, 691-698). All studies report a similar distribution of errors, with most occurring in the pre- and post-analytical steps in the total testing process. Another observation is that a complaint-based process for capturing mistakes is not nearly as effective as finding mistakes by reviewing each of the steps in the testing process.

The patient safety movement is gaining momentum as healthcare professionals begin to design processes that minimize the potential for human error and to implement non-punitive ways to deal with human error. For example, newly created JCAHO guidelines highlight the importance of having proper identification of patient samples since mistakes in labeling can lead to critical medical errors, such as administering blood products or medication to the wrong patient. Laboratory automation employing bar-code scanners to automate sample handling helps assure accurate patient identification and virtually

eliminate errors such as lost or improperly labeled samples. Other measures must be developed and employed to reduce the potential for mistakes in laboratory medicine including better indicators for the quality of laboratory service, such as having no lost specimen. Users of laboratory services need to be linked with the laboratory’s information system to assist them

with decisions about test ordering, patient preparation, and test interpretation. As laboratory scientists, we need to enhance our quality assessment efforts by expanding PT programs to encompass the detection of non-analytical mistakes and to improving our communication with the users of laboratory services.

What are the take home messages from these studies? First of all, the actual number of mistakes in laboratory testing is not fully recognized. We do not have a process in place to either determine how often mistakes occur or to systematically eliminate sources of error. We also tend to focus on mistakes that result in adverse events, not the near misses that cause no observable harm. Secondly, since most of the mistakes are occurring outside of actual testing of the sample, our quality assessment efforts must expand beyond QC and PT to encompass potential errors in the processes of patient testing from the time the test is ordered to the time it is applied to patient care. Finally, the users of laboratory services must become aware of where testing mistakes can occur and actively participate in designing processes to prevent mistakes. Most importantly, health care institutions need to adopt a culture of safety, which is implemented at all levels of the organization. This includes establishing closer links between laboratorians and everyone included in the healthcare delivery system. This was the theme of a Quality Institute Conference that was held in Atlanta on April 13-15, 2003 aimed at “*Making the laboratory a key partner on patient safety.*”

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