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Review

How can we make laboratory testing safer?

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Abstract

Background: Diagnostic errors occur in laboratory medicine resulting from an error or delay in diagnosis, a failure to employ indicated tests, and the use of outmoded tests. Since laboratory tests provide essential information used by physicians to make medical decisions, 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.
Methods: The US Quality Institute Conference in 2003 and the Institute for Quality in Laboratory Medicine in 2005 brought together providers of, users of, and payers for laboratory services to explore how working together they could help to reduce laboratory testing errors and enhance patient safety.
Results and conclusions: Users of and payers for laboratory services must become partners in the laboratory's efforts to reduce laboratory testing errors and enhance patient safety. They must be linked to a laboratory information system that provides assistance in decisions on test ordering, patient preparation, and test interpretation. Laboratory quality assessment efforts need to be expanded to encompass the detection of non-analytical mistakes. Healthcare institutions need to adopt a culture of safety that is implemented at all levels of the organization.
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Keywords: improving laboratory services; Institute for Quality in Laboratory Medicine; laboratory errors; patient safety; Quality Institute.

CDC studies on laboratory testing errors

In 1983 it was evident that laboratory testing errors were occurring despite the hard work of many dedicated individuals to try and prevent them. No one seemed to know how often errors occurred or whether there was a pattern to laboratory testing errors, and if so, whether targeted efforts to prevent them were effective.

Dr. John Ross, a pathologist in an Atlanta area hospital, had been tracking laboratory testing errors in his institution for several years. The Centers for Disease Control and Prevention (CDC) reviewed a full year of tabulated errors and tried to determine whether the mistakes that occurred actually resulted in any harm to patients. While this review found no evidence of patient harm, there were instances for which delays in receipt of appropriate care appeared to have occurred as a result of these mistakes (1). Whether the rate of errors found in this hospital or their impact on patient care was greater or less than that in similar hospitals across the nation was not known. This hospital had gone to great pains to try to identify patterns in their mistakes and to try to prevent them from occurring in the future. However, their approach relied almost exclusively on self-reported mistakes identified by laboratory or hospital staff and no one knew how often mistakes went undetected.

In 1989, the CDC in partnership with the Aspen Sentinel Practice Network (ASPN) investigated errors that occurred in laboratory testing associated with ambulatory care clinics. While the types of errors presented a somewhat different pattern than those found in the hospital study, mistakes were found that affected patient care (2).

Common to both the hospital and ambulatory studies was the finding that most errors that were detected occurred in the steps before or after the patient's sample was analyzed rather than during the analysis itself. Another common feature was that the person who made the mistake could be someone other than laboratory staff; therefore, mistakes appeared to only be preventable through a focus on all personnel and procedures involved in the laboratory testing process, including any steps requiring action on the part of the patient and care provider (Figure 1). It was also apparent that many of the errors could have been prevented if appropriate processes had been in place. This is consistent with the now accepted patient safety theme that considers that most errors result from a failure to design safe processes rather than personnel being error-prone.

Safety of the US healthcare system

Laboratory testing, like all medical and public health services, occurs within the context of the healthcare

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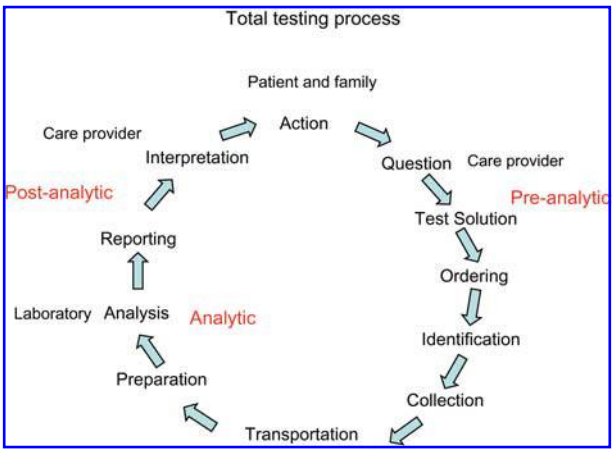

Figure 1 Total testing process showing 11 steps and areas of discrete and overlapping responsibility.

system. The 2000 US Institute of Medicine report *To err is human: building a safer health system* indicated that medical errors were the eighth leading cause of death in the US (3). Of added concern was a study that revealed that US citizens received appropriate care approximately 50% of the time and only 50% received the tests indicated for their condition (4). Therefore, in the context of patient care, it is important to include overuse, under-use, and misuse of laboratory tests and services as a measure of patient safety. In 2000, a US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) looking at 1000 occurrences of unexpected death or injury in 17,000 healthcare organizations found a 2.6% error rate in transfusions, an area to which much effort has been devoted to reduce mistakes. These types of studies have sparked a patient safety movement in the US and abroad. The efforts of Dr. Donald Berwick and the Institute for Healthcare Improvement (IHI) are finally beginning to have an effect through the 100,000 Lives Campaign and the recently announced 5 million Lives Campaign (http:/www.ihi.org). Such efforts focus on the root causes of mistakes in medicine that are often the result of poor system design leading to problems in communication, integration of services, and a lack of accountability for areas where one service ends and another begins, and fragmented information systems. In many cases these design failures include a lack of performance measures to appropriately monitor processes. These problems occur not only within institutions wherever transitions in service occur, but also between institutions and across state and country boundaries.

Efforts to assure safer laboratory services

Considering the total testing process (Figure 1) as the framework in which laboratory services are delivered, it is evident that, like the Doppler effect, an individual's perspective on the cause of an error in laboratory testing sometimes depends on where the individual sits in this cycle. For the patient and family, it really does not matter where in the testing process the error occurs or who is responsible. What matters is whether the error is detected before it causes any delay in care or outright harm. A recent report on specimen identification errors indicates that significant decreases can result from systematic attempts to reduce such mistakes (5). However, these decreases required performance improvement strategies that took 4–14 months to implement. This study conducted by the University of California at Los Angeles illustrates how changes in both managerial and technical processes may be necessary to address the complex nature of some laboratory service errors. It is also likely to require the engagement of many groups within and among institutions in these efforts to achieve success.

Laboratory professionals, like other healthcare workers, face ever-increasing workloads, new technologies, financial constraints, changes in standards of practice, and more demanding groups of users, payers, and overseers of services. Recognizing these constraints, as well as the major role that laboratory services play in healthcare, in 2003 the CDC, along with 41 partner organizations, convened a Quality Institute aimed at making the laboratory a key partner in patient safety. The goals of the institute were to develop: 1) a framework for a national report on the quality of laboratory services; 2) criteria for indicators of quality in laboratory services; and 3) a process for ongoing data collection and analysis of laboratory testing and services. Conference participants agreed that there is a great need to improve the non-analytical areas of the testing process, where most of the errors in laboratory testing occur. They also felt that a core set of indicators is needed for the quality of processes involved in all testing steps. However, any efforts to improve service quality and enhance patient safety will hinge on the ability to enhance communications between the laboratory and clinical practitioners, to have adequate surveillance of the quality of laboratory testing practices and services, and to find ways to identify and disseminate best practices.

In 2005 an Institute for Quality in Laboratory Medicine (IQLM) was convened to follow-up on the recommendations of the Quality Institute. The IQLM was seen as an organization that could harness the power of both the public and private sectors to assure that the providers of, users of, and payers for laboratory services worked together to improve laboratory services and patient safety. The aim of the IQLM was not to compete with or duplicate the already outstanding efforts of other clinical specialty or laboratory organizations or those organizations involved in healthcare delivery. Strategically, it could serve the following purposes: 1) serve as a clearing house for laboratory practices by helping to define what works and what does not; 2) serve as a driving force to promote continuous improvement and excellence in laboratory services; and 3) promote the important role that laboratory services play in patient care.

The IQLM was seen as promoting a set of interrelated activities (Figure 2), developing laboratory networks to help to identify emerging issues, developing

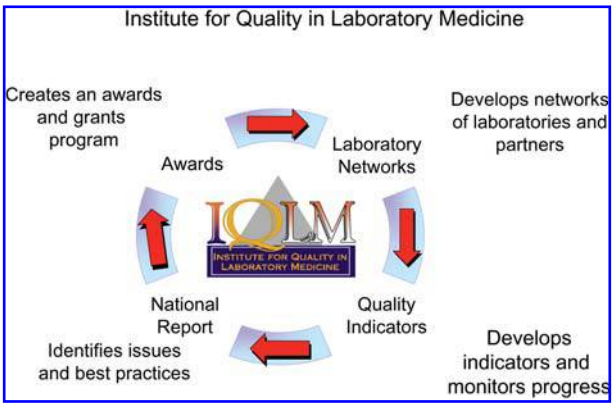

Figure 2 Institute for Quality in Laboratory Medicine: interrelated program activities.

measures to monitor changes in practices and their impact on the field, identifying issues needing focused efforts on the part of providers of, users of, and payers for laboratory services, and recognizing significant contributions by individuals or groups to the field of laboratory medicine.

The IQLM represents a new approach to bringing together all the parties with an interest in assuring that health laboratory services work together to improve communications and collaborations between healthcare sectors. Participants in the April 2005 IQLM conference were enthusiastic about the possibilities that this offered to them at a national level, while recognizing what it could also do for them at the local level. However, for the IQLM to be successful, several additional steps had to take place.

The first step was the creation of an actual organization. The IQLM was incorporated as a 501c3 organization in the State of Virginia in 2005 and an initial Board of Directors was appointed. It has its own website at http://www.iqlm.org. A monthly newsletter has been launched and IQLM-sponsored articles have appeared in Medscape (http://medscape.org). The success of this new organization in fulfilling the role it was envisioned to play will depend on the development of a plan of action consistent with the intended objectives and on securing adequate funding to carry out the objectives.

Conclusions and recommendations

Laboratory-related mistakes are often difficult to detect. For example, if incorrect or inappropriate laboratory tests are ordered, the likelihood of detecting this mistake by anyone other than the care provider is low. In addition, direct linkage to an adverse patient outcome is often difficult to determine, even when a laboratory testing error has been documented to have occurred. A good framework to consider where mistakes can occur in laboratory testing services is the total testing process (Figure 1). A mistake can potentially occur in each of the 11 steps in this process, or at any of the places where a handoff can occur (represented by the arrows). Variability in error rates among the studies on errors in laboratory medicine can be attributed in part to a lack of a common framework and several other factors, including differences in the definition of what constitutes an error, the lack of linkage of most errors with patient outcome, and the absence of a standard study methodology (6).

For laboratory medicine to be a real contributor to improvements in healthcare and patient safety, it must first be recognized that because of the central role of laboratory services in healthcare, the laboratory can substantially enhance both the coordination and continuity of care. By helping to integrate the information used by healthcare providers, the laboratory could help to address the current fragmented healthcare delivery system. This in itself could help to reduce errors in patient management and therefore improve services and enhance patient safety. Although medical and public health practice is increasingly dependent on laboratory services, these services are often taken for granted as being of high quality and low cost. While tens of thousands of dedicated laboratory professionals work diligently to assure accurate and reliable laboratory services, they cannot and should not be taken for granted. If laboratory services were better integrated into healthcare, they could greatly enhance the delivery of timely, appropriate, and effective healthcare. For this vision to become a reality, the laboratory must be viewed as an essential core asset, not an afterthought or something that is taken for granted.

Making this transition will become increasing difficult under the combined pressure of increasing workload, financial constraints, and incorporation of new information and testing technologies over the next few years and beyond. If a cultural change in healthcare, whereby all of those involved are viewed as partners in contributing to the wellbeing of patients and the community, does not occur, those in laboratory medicine will do their part, but it will not be as effective as if their efforts were truly integrated.

A cultural change must occur for laboratory services to be as safe and effective as they can be. This change requires the direct participation of nurses, physicians, hospital administrators, communities and patients in helping to eliminate the features in the healthcare system that prevent laboratory testing mistakes from being dealt with in an atmosphere not linked to blame and malpractice litigation. While some healthcare institutions are making progress in this realm, the lack of connectivity across healthcare providers, insurers, and others responsible for assuring access and appropriate use of effective care, makes these isolated rather than universal occurrences.

With better communication, collaboration, and connectivity between those who provide, use, or pay for laboratory services, a new era in healthcare is possible. This is the vision of a September 2007 CDC-sponsored Institute on Critical Issues for Health Laboratories ''*Laboratory services that are integrated with the healthcare system play a larger role in the coordination and continuity of care by ensuring that*

the right test analyzed by the best method is performed on the right person at the right time and that the right information is reported at the right time to the right people''. Together we can make this vision a reality for all communities and patients.

A broad-based and widely supported agenda could help to create interest at a national level that would help to assure the success of patient safety initiatives at the local level. The agenda could support projects such as:

- Evidence-based laboratory practices directed toward improved patient outcome;
- Research in the design and implementation of effective laboratory services;
- Dialog on mechanisms to improve the quality of laboratory services;
- Promotion of the best measures for the quality of laboratory services;
- Sentinel networks of laboratories that can provide timely factual information on the state of laboratory practice;
- Fellowship programs to conduct much-needed research.

Although almost 70% of physicians believe that the reduction of medical errors should be a national priority, physicians are much less likely than the public to believe that quality of care is a problem (7). This conclusion is somewhat surprising, since 35% of physicians and 42% of the public report that either they or a family member has experienced an error in care (8). Thus, while there seems to be concern among physicians about medical errors, most do not believe that they are significant. A barrier to changing this view is access to data on the true incidence of mistakes, which is difficult within the culture of blame that exists and the fear of malpractice litigation.

How can we make laboratory testing safer? While most laboratory testing and services are inherently safe, they are not as safe as they should or could be with better integration of laboratory medicine into healthcare, such as has occurred for pharmaceutical services. For the quality of laboratory services to reach the level of that expected by the public, several changes in the healthcare system and in laboratory services must occur. A cultural change must occur to deal with quality and error prevention as issues of systems design rather than as evidence of malpractice or the fault of individuals. The non-system of healthcare that exists must be patched together using information technology and interdisciplinary teams oriented toward problem identification and solution within and across institutions and any other boundaries. In addition to being viewed as a reliable source of data, laboratories must take on the role and responsibility of assuring that laboratory testing is relevant and effective in patient care and as error-free as possible. In addition, with greater knowledge about where errors are likely to occur, laboratory managers, hospital administrators, and others should be using this knowledge to carefully consider redesigning processes to prevent errors before they occur (9, 10). This amounts to what Carren Bersch, the editor of Medical Laboratory Observer, described in March 2006 as ''The war on error''. Finally, we must create an integrated system of healthcare in which everyone takes both their own role and that of others in the system as collectively responsible for the quality and safety of services. Otherwise, the misuse and underuse of laboratory tests and services will remain a serious problem for the US healthcare system. With better communication, collaboration, and connectivity, the use of both laboratory tests and laboratory services will be improved. The CDC hopes to continue to forge links between all of the partners involved in laboratory services to help to create this vision and to improve patient care and safety.

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