Patient Safety Concerns Grow in Congress

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Anyone who reads newspapers and watches television news probably realizes that the media and the public are very interested in the safety of healthcare. Interest was first heightened by the Institute of Medicine (IOM) report "To Err is Human: Building a Safer Health System" issued in December 1999. It contained a controversial estimate of the number of patient deaths caused by errors in the healthcare system, giving a range of 47,000 to 98,000 deaths annually. The first IOM report was followed in 2001 by a second entitled "Crossing the Quality Chasm: A New Health System for the 21st Century". The second report recommended specific safety measures, such as electronic ordering of all medications and other information technologies, to avoid legibility problems.

Much of the publicity in the aftermath of the first IOM report dealt with medication errors and wrong-site surgery. Many healthcare institutions have implemented new initiatives to improve processes and systems related to medication administration, and safeguards to prevent errors in surgery. Many of the same concerns that are raised about medication administration also apply to administration of blood products provided by the laboratory.

Are current accreditation systems for hospitals and other healthcare entities effective in ensuring patient safety? An article headlined "Patients suffer as agency shields troubled hospitals" appeared in the Chicago Tribune on November 10, 2002. The article referred to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The writers "…found that the Joint Commission often fails in its role as public guardian". They criticized the fact that fewer than 1% of hospitals fail to become accredited, that inspections are scheduled in advance rather than being unannounced, and that JCAHO does not have accurate data on the number of avoidable patient deaths.

Some hospitals that are JCAHO accredited have been investigated by the Centers for Medicare and Medicaid Services (CMS) in conjunction with specific patient incidents. In some cases these hospitals have been threatened with removal of their ability to participate in the Medicare program, that is, to be paid for care of Medicare patients. However, since reporting of 'sentinel events' to JCAHO is voluntary, it is limited by the willingness of accredited hospitals to share this information. That willingness is limited by liability concerns on the part of the hospitals. If voluntary reports to the JCAHO are discoverable in a suit against the hospital, as is currently believed, then legal advisors are likely to advise against sharing the information. While the press may think that JCAHO should have this data, the reality is that very little voluntary reporting occurs.

The dilemma for healthcare providers is the dichotomy between a culture of blame versus fixing systems in such a way as to prevent errors. Management often says that it wants to know about errors, and encourages that all errors should be reported, so that systems can be improved in order to avoid repeated errors. Sometimes one of the systems factors may be short staffing due to personnel shortages and/or budget constraints. Many times it is difficult for the individual employee to gauge whether their management is only paying lip service to the systems approach. If the employee reports an error he/she made, will there be consequences such as discipline or loss of job? Or will the information be used in some type of quality improvement initiative to prevent future errors of the same type?

Our colleagues in pharmacy are very aware of this in their attempts to address medication error issues. We think of quality improvement or process improvement as defining a problem and identifying an improvement, then monitoring data to show that the improvement is indeed occurring. I recently saw a preliminary report of a process improvement effort in prevention of medication errors, in which the presenters pointed with pride to an increase in the number of errors

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reported. This was obviously not because they thought more errors were being made, but because more of the errors that do occur were being reported. Their belief was that this would then provide better data on how to improve systems in order to eliminate sources of error.

In the laboratory much of our concern about errors centers on the preanalytical phase of our work. Is the sample drawn from the correct patient? Is it labeled correctly? Are the correct tests performed? In the case of blood products, are they given to the correct patient? Various companies now offer bar-coded patient wristbands that can be scanned at the bedside to ensure they match the label placed on the tube drawn. Medication doses and blood products can also be bar-code labeled and scanned before administration to the patient.

In addition to preanalytical concerns, a series of articles in the November 2002 issue of Clinical Chemistry addresses the incidence of false results in various immunoassay measurements due to antibodies the individual patient may have. Estimates of false results range from 0.5% to 6%, figures that may be surprising to laboratory practitioners.

In addition to internal reporting of errors within an institution, there is a growing discussion in response to a new JCAHO standard that requires that patients and their families be "informed about outcomes of care, including unanticipated outcomes". This is prompting institutions to evaluate how much they tell the patient, who tells them, and in what setting. Organizations that have implemented an open policy about discussing errors with patients believe that it decreases the number of suits and the amounts of monetary settlements. Honest and timely disclosure may defuse anger when people feel that information is not being withheld.

The National Coalition on Health Care is a non-partisan health reform alliance comprising 80 large employers, consumer, labor and religious groups. It and other employer groups such as the Leapfrog Group, are pushing for improved quality of healthcare as a cost saving measure. They quote a statement made earlier this year to a Senate hearing by then Treasury Secretary Paul O'Neill warning that because of our lack of attention to quality, the nation wastes 30%-50% of the 1.3 trillion dollars spent annually on healthcare. If that statement is at all accurate, it will get the attention of employers, whose cost to provide health insurance to their employees has seen double digit increases in each of the past two years.

In June 2002, the Patient Safety and Quality Improvement Act was introduced in the House of Representatives by Representative Nancy Johnson (R-CT). The bill would create a medical errors reporting system in which independent patient safety organizations would analyze reports of adverse events and give feedback on how to fix problems (share "best practices"). Information reported voluntarily for quality improvement and patient safety purposes would be held privileged and confidential for legal purposes.

The ASCLS Government Affairs Committee will monitor the progress of Representative Johnson's bill and other bills on this subject to try to ensure that laboratory concerns are addressed appropriately.