

Colloquium report: responding to medical device incidents.

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Yadin David, EdD, William A. Hyman, ScD, and Vicky D. Woodruff, MA, BS.

The Healthcare Technology Foundation, Texas Children's Hospital, and Texas A&M University sponsored a colloquium on March 7, 2007, at The University of Texas MD Anderson Cancer Center in Houston, Texas, on responding to medical device incidents. About 70 professionals attended the meeting representing engineering, clinical, administrative and regulatory personnel. The presentations are posted at www.utccrs.org/ccrs/home.jsp?pagename=publications.

Executive Summary

When adverse events involving medical devices occur, a number of important responses must be initiated. The internal risk management team usually responds primarily to prevent recurrence and secondarily to determine and manage liability exposure. External reporting requirements may also be triggered and include the US Food and Drug Administration's (FDA's) Medical Device Reporting, the Joint Commission Sentinel Event program, and individual state-level departments of health. Each of these programs has the goal, although to varying degrees, of sharing information on current hazards. Equally important is their ultimate impact on future medical device design and use. This colloquium was designed to investigate these issues.

Background Information

Medical device technology is growing at an astounding pace, but effective safety standards and systems of checks and balances have not always kept pace. An initiative led by Drs Yadin David and William Hyman is helping to bridge this gap by encouraging greater communication and collaboration among all of the stakeholders, especially in the area of medical device incident investigation and information sharing.

Achieving a higher safety level will require a concerted effort to bring together manufacturers, regulators, care providers, other end users, maintainers, and patients. Every segment of the healthcare delivery system--from manufacturers to users--will have to find a way to collect and share information in such a way that problems can be more clearly identified and reduced and, ultimately, patient safety improved.

In a 2006 editorial in the industry magazine MX ("Failing to Succeed," MX July/August 2006), Dr David set the wheels in motion for the colloquium by calling on leaders from the various segments of the technology-related and healthcare delivery system to come together and communicate about ways to improve patient safety. When communication

among the engineers who design devices, the clinicians who deploy them, the clinical engineers who support them, the administrators who purchase them, the regulators who monitor them, and the patients on whom they are used is limited or nonexistent, the outcome is, too often, far less than optimal.

During the past 20 years, the average number of medical devices at the point of care (the patient's bedside) has increased from about 7 to 26. Owing in part to high-profile recalls of both drugs and medical devices, the public is becoming increasingly concerned about device safety. At a recent seminar on risk management, FDA representatives reported a 20% increase in the number of device-related recalls in the 2 years from 2003 to 2005. They also reported that the most frequent noncompliant issue observed during FDA inspections of medical device manufacturing facilities was inadequate complaint-handling procedures. In response, the FDA is moving rapidly to ramp up mechanisms for additional postmarket device performance monitoring. However, this suggests another Band-Aid approach that misses the opportunity to evaluate the resiliency of systems and processes rather than devices one at a time. Furthermore, it is not clear whether the FDA's collecting ever greater amounts of information will be particularly effective, unless the FDA develops a vastly improved ability to process and respond to this information. Consequently, the need for an integrated platform for event information sharing became apparent because clinicians seldom benefit from information collected until a critical level of safety variance is reached in the form of an adverse event or a recall. To improve system surveillance and assessment, global information about the environment and conditions that lead to adverse events, near misses, or even near-near misses must be collected and shared. If such data can be collected and shared, we will reach a higher level of risk reduction not obtainable otherwise.

This was the theme for the Houston Colloquium on Responding to Medical Device Incidents, during which diverse stakeholders came together to increase the collective knowledge surrounding device-related failures. The colloquium's formal presentations were followed by 4 breakout sessions, during which workgroups were formed to identify problems and propose specific solutions. The workgroups then reported their consensus summaries back to all participants for final analysis. The breakout sessions were well attended and productive in eliciting audience participation, as judged by the submitted reports and positive comments on the evaluation forms.

Representatives of care providers (physicians and nurses), various members of the industry (GE, Cardinal Health, and Emergin), clinical engineers (Texas Children's Hospital, Vermont University Hospital), academia (Texas A&M University, University of Texas, The University of Texas MD Anderson Cancer Center), regulators (FDA), and third parties (ECRI Institute) presented their perspectives and methods for obtaining and processing medical device adverse events data. It is noteworthy that these methods were disparate and unique and do not lead to an integrated data set or to a commonly used taxonomy. All speakers noted a variety of barriers in data collection and/or sharing and commented that full disclosure across stakeholder silos is rare. Speaker-identified barriers included incomplete information, the rapidly growing and duplicative reporting mechanisms (eg, FDA, state, in-house, Joint Commission, and ECRI Institute), and the

perceived fear of disclosure as it relates to licensing, litigation, and public relations. In addition, it was noted that the types of errors are evolving as process complexity and technology are evolving and that the lack of a commonly acceptable dictionary of terms modified by ethnic and organizational cultures are playing an increasingly critical role in risk mitigation. In this context, the real strength of effective organizations is often their resiliency rather than their ability to comply with prescriptive procedures. Dr David introduced the risk reduction strategy used by other industries such as nuclear power and aviation. The aviation industry, for example, significantly reduced the percentage of commercial airline catastrophes and near misses through an increase in simulation training and mandatory shared data collection in part through what is known as the "black box" concept.

The workgroups' reports included barriers and other challenges to effective information collection and sharing. One such challenge is that healthcare organizations have been trying to deal with problems using an incremental/ piece-meal approach and that this approach is not working well. In addition, the groups identified the set of problems as increasingly complex because they are inclusive of the entire healthcare delivery system, rather than just singular point-of-care devices. However, it seems that our healthcare providers do not have a consistent methodology, enough resources and tools, or a sufficient staff who are qualified to rapidly investigate reported incidents and reach realistic and effective conclusions in a timely manner. It was also noted that there are more occurrences of adverse events than are reported. This is especially true when reporting to outside agencies. This is consistent with investigations of the completeness of data found on the FDA Web site for medical device event reporting.

The colloquium was a substantial and successful first step as reflected by the following observations:

- 1) Although the call for papers had been issued just a few weeks before the scheduled colloquium, stakeholders responded positively to the colloquium concept and were well represented. One of the colloquium's successes was that a varied range of stakeholders agreed to publicly discuss and debate issues and to hear each other's perspectives.
- 2) The representation indicated that stakeholders will buy-in to the need for colloquium-like working events that review strategies for better information collection and collaboration across silos, especially in the face of negative incentives. Many of the speakers were able to share knowledge about adverse events that would not have been presented had there not been clear and timely communications from investigators across disciplines.
- 3) It was accepted by most speakers and the audience that 2 major contributing factors to continuing risk are the lack of a uniform taxonomy in reporting and the long time delay between adverse event evaluation and feedback provided to guide proper corrective action. As an example of the taxonomy issue, when a potential adverse event is prevented by an intervention, should it be considered a reportable near miss or as a risk management success that is not reported?

- 4) Systems at the point of care are more complex and intertwined than ever before, leading to secondary errors that may be unknown to direct users. The extent of cross-dependency and the level of systems' integration are not fully appreciated. For example, the ability to completely and wirelessly upgrade the drug library of an infusion pump might be lost and not recognized because of the loss of an access point and, thus, radio communications to the device.
- 5) Caregivers have difficulty learning more than 6 different alarm signals, but a patient in an intensive care unit can have many more than 6 different alarms associated with his or her care (furthermore, several may make identical sounds). This leads to caregivers' experiencing difficulty in discerning the meaning and urgency of an alarm.
- 6) Manufacturers were called upon to improve parameter acquisition and triggering intelligence of alarms to mitigate the large volume of nuisance alarms, which are annoying and can distract from safe patient care.
- 7) Dr David called on leaders across the various healthcare delivery system segments to come together and share experiences that can drive improvements in patient safety. An unbiased data collection system can be placed at the point of care so that many of the conditions leading to adverse events or near misses can be stored and viewed in a near real-time mode--a similar concept to the black box that has been successfully deployed by the airline industry.
- 8) More professionals need to be trained to investigate adverse events and near misses. The colloquium addressed the questions of barriers to the availability of a team of experts to investigate events with the agreement and collaboration of all event stakeholders.
- 9) The workgroups reported a need to develop common methods and measures of success at all of the levels (institution, network, state, and federal) for any patient safety program.
- 10) An example of the general problem associated with the FDA's role of patient safety ally, advocate, and regulatory police occurred when one of the speakers canceled his presentation at the last minute because his company was dealing with an alleged regulatory compliance issue and did not want to participate in the program because regulators (FDA) would be present.

Summary

This colloquium was judged to be a great success based on the number and range of participants, the quality and relevance of the presentations, and the effort of the participants during the breakout sessions. It also provided the first steps toward a broad collaborative effort aimed at developing more effective investigations of medical device incidents and evaluating, reporting, and, most important, acting on the issues.

Key Findings From the Colloquium

- * There are an increasing number of barriers to overcome.
- * The types of events are evolving.
- * The complexity of decisions, systems, processes, standards, devices, and human interactions with machines are all contributing to confusion.
- * The number of device alarms, including "nuisance" alarms, may be defeating their clinical purpose.
- * The delay in beginning an investigation often hampers the ability to gather critical information.
- * A new area under study is the "resilience" of a point-of-care system when challenged.
- * There remain various opinions of who is best qualified to do an after-incident investigation.
- * There is confusion about different processes, what content to include in reports, what to report, whom to report to, and definitions of terms.
- * Reduction in barriers to better dissemination of adverse event analysis and understanding of litigation impact by all stakeholders is needed.
- * Segregation of communication into silos (within device manufacturers, healthcare organizations, and government agencies) needs to be disbanded.
- * Ethnic and organizational cultures are playing an increasingly critical role in risk mitigation.