

Colloquium Report...

Overcoming Barriers to Success: Collecting Medical Device Incident Data

Yadin David, William Hyman, Vicky D. Woodruff, and Melita Howell

Over 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 26.¹ 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 from 2003 to 2005. They also reported that the most frequent non-compliant issue observed during FDA inspections of medical device manufacturing facilities was inadequate complaint-handling procedures. In response, FDA is moving to ramp up mechanisms for additional post-market device performance monitoring.

This approach, unfortunately, misses the opportunity to evaluate the resiliency of systems and processes rather than devices one at a time. Further, it is not clear that FDA's collecting ever-greater amounts of information will be particularly effective unless it develops a vastly improved ability to process and respond to this information. Consequently, the need for an integrated platform for event information sharing has become apparent. Clinicians seldom benefit from information collected until a critical level of safety variance—in the form of an adverse event or a recall—has been reached.

To improve system surveillance and assessment, stakeholders must collect and share global information about the environment and conditions that lead to adverse events, near-misses, and even near-near-misses. If such data can be collected and more effectively shared, we will reach a higher level of risk reduction not obtainable otherwise.

The existing sharing of such information by FDA, the Joint Commission, state programs, and ECRI Institute is not fully effective because it is fragmented and inconsistent with respect to thresholds, format, terminology, and reach.

A Call to Leaders

In a 2006 editorial in the industry magazine *MX* ("Failing to Succeed," *MX* July/Aug 2006), Yadin David called on leaders from 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. Yet, there exist specific barriers, as discussed below, to such sharing despite the

many years of discussion of these issues.

This was the theme for the Colloquium on Responding to Medical Device Incidents, held earlier this year in Houston, TX, which brought more than 60 stakeholders together to increase the collective knowledge surrounding device-related failures.

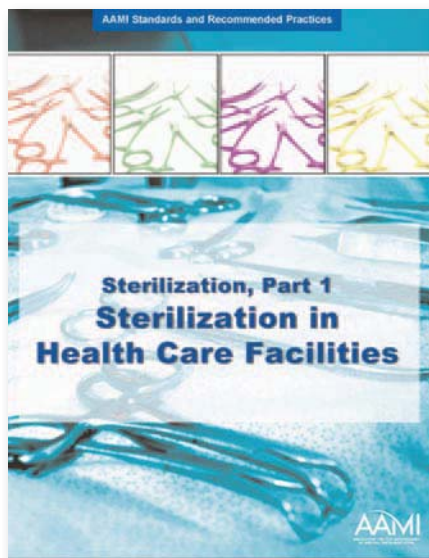
Representatives of care providers (physicians and nurses); industry (GE, Cardinal Health, Emergin); clinical engineers (Texas Children's Hospital, Vermont University Hospital); academia (Texas A&M University, University of Texas); regulators (FDA, Dallas District Medical Device Industry Alliance); and third parties (ECRI Institute) presented their perspectives and methods for obtaining and processing medical device adverse event data. These methods are disparate and unique and do not lead to an integrated data set, nor are they based on commonly used taxonomy.

They do, however, provide a starting point for what will be an ongoing discussion. Certainly a common language is a prerequisite to effective communication where private/governmental sectors (Federal Aviation Administration, National Transportation Safety Board, National Aeronautics and Space Administration) can be brought in to share their expertise and experience in this area.

2 Things

Every Hospital Needs

(In addition to better cafeteria food)

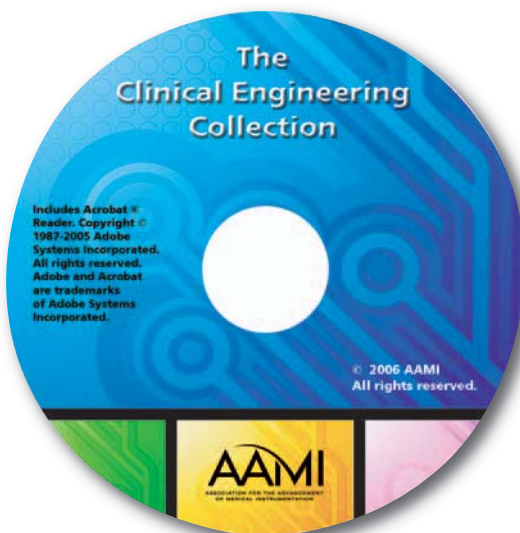


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The Challenge

Speaker-identified barriers in data collection and/or sharing included incomplete information; the rapidly growing and duplicative reporting mechanisms (e.g., FDA, state, in-house, Joint Commission, and ECRI Institute); and the perceived fear of disclosure as it relates to licensing, litigation, and public relations (see sidebar for a sample list of identified barriers). In addition, it was noted that the types of errors and mishaps are evolving as process complexity and technology evolve and that the diversity of organizational culture as well as lack of commonly acceptable terms are increasingly a challenge to risk mitigation. In this context, the real strength of effective organizations may be their resiliency rather than their ability to comply with prescriptive procedures.

Healthcare organizations have been trying to deal with problems using an incremental/piece-meal approach, and this approach is not working well.

David cited the risk reduction strategy employed 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 by an increase in simulation training and mandatory shared data collection through what is known as the “black box” concept (see below). Success in other areas has not been effectively transferred to healthcare for numerous reasons, including greater fragmentation, systems dissimilarity and relevancy, resistance to external approaches, lack of sufficient recognition, and unique liability challenges.

Healthcare organizations have been trying to deal with problems using an incremental/piece-meal approach, and this approach is not working well. The group identified the set of problems healthcare faces as increasingly complex since they are often inclusive of the entire healthcare delivery system, rather than just singular point-of-care devices. Yet, it seems our healthcare providers do not have a consistent methodology, enough resources and tools, or sufficient staff who are qualified to rapidly investigate reported incidents and reach realistic and effective conclusions in a timely manner. There are considerably more occurrences of adverse events than are reported, particularly when reporting to outside agencies. This is

consistent with Government Accountability Office investigations of the completeness of data found on the FDA website for medical device event reporting.

Texas Children’s Hospital: A “Black Box” Case Study

An effective strategy to eliminate preventable device use adverse events must be based on comprehensive data collection and analysis. Although the use of event data recording in healthcare is in its infancy, there are significant benefits to be reaped by committing to a patient black box vision as technology and standards evolve. Texas Children’s Hospital has adopted an enterprise service solution with the long-term vision of enabling

Barriers to Overcome

- Stakeholders are not willing to collect and share device-use-related data.
- The types of events are evolving and often involve teamwork issues.
- 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 is needed, as is an understanding of the litigation impact by all stakeholders.
- 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.

connection of information from all bedside medical devices.

Analyzing the black box data has been instrumental in identifying opportunities for improvement at the bedside. It provides the ability to proactively collect data, analyze and measure trends, anticipate and correct gaps, and share information with all stakeholders.

Data on alarms from a 36-bed pilot unit at Texas Children’s Hospital were analyzed for a 60-day period (see Figure 1). The initial findings quantified anecdotal reports and industry research showing that nurses are barraged by alarms and messages.

Based on the data, cardiac and pulse oximeter monitor alarm frequency and distribution were targeted for improvement. The following steps were taken:

Engage Stakeholders

- Unit-based focus group
- Unit leadership team
- Executive team

Preliminary Research

Conduct a detailed review of monitor alarm black box history.

- Two to five patients (in a 36-bed unit) accounted for more than 80% of monitor alarms.
- On one day, two patients generated 435 alarms out of a total of 508.
- Approximately 33% of monitor alarms are reset within 10 seconds.
- Improve understanding of cardiac and pulse oximeter monitor alarms dynamics via lab simulation.
- Critical alarms are “locked,” requiring a manual reset.
- Alarms caused by movement typically reset in 9 to 12 seconds.

Cardiac and Pulse Oximeter Alarm Survey Tool

Data collected:

- Alarm parameters set to the patient-specific baseline.
- Genuine physiologic or patient safety reason for monitoring exists.
- Discussion with the physician initiated if genuine physiologic or patient safety need is not apparent.

Method:

- Survey conducted on 36-bed unit for seven days.
- Charge nurse completes survey form.

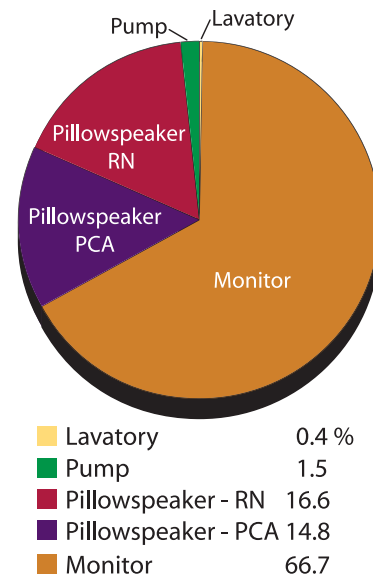


Figure 1. Alarm type summary

- Target patient population with high volume of alarms escalated to charge nurse.

Outcomes:

- Training deficiencies identified and corrected.
- Holistic review of clinical monitor use reached.

System Configuration Changes

- Delayed secondary alarm notification on non-critical alarms by 10 seconds.
- Discontinued resend (x3) of alarms not acknowledged by caregiver.
- Redesigned wireless telephone message management keyboard interface based on focus group direction.

Measuring the outcomes of this initiative is still in process, but early results show a significant drop in nuisance alarms (more than 30%) from cardiac and pulse oximeter monitors, improved staff awareness of factors contributing to clinical alarm generation, and higher staff satisfaction on the pilot unit. This example demonstrates that knowledge gained via the black box can be used to direct improvements in patient safety, staff satisfaction, and clinical workflows.

Summary

The Colloquium on Responding to Medical Device Incidents 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. Stakeholders agreed

to continue to investigate strategies for improving data collection and data sharing to eliminate preventable adverse events, perhaps by using similar methodologies to those that led to the achievements made by the airline industry.

An effective strategy to eliminate preventable device use adverse events must be based on comprehensive data collection and analysis.

The Colloquium participants offered the following observations:

1. Interest in the topic is widespread. A varied range of stakeholders agreed to publicly discuss and debate issues and to hear each other's perspectives—a step toward improved cross-disciplinary communication.
2. Stakeholders will likely 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 the existing 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. Two major contributing factors to continuing risk are the lack of a uniform taxonomy in reporting and the long delay time between adverse event occurrence, evaluation, and feedback 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 a risk management success that is not reported as adverse event?
4. Systems at the point of care are more complex and intertwined than ever before, leading to secondary errors and delayed outcomes that are unknown to 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 the loss not recognized because of the failure of an access point and thus radio communications in the pump's location.
5. Caregivers have difficulty learning more than six different alarm signals, but a patient in an intensive care unit can have many more than six alarms associated with his or her care (additionally, 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 can distract from safe patient care.
7. David called on leaders across the various health-care 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 stakeholders.
9. The workgroups reported a need to develop common methods and measures of success at all levels (institution, network, state, and federal) for any patient safety program. ■

Reference

1. **David Y, Clark JT.** "Improving Patient Safety Through Clinical Alarms Management." Proceedings of the 11th Mediterranean Conference on Medical and Biological Engineering and Computing, MEDICON 2007, Ljubljana, Slovenia, June 2007.

Yadin David has served as the director of the Biomedical Engineering Department at Texas Children's Hospital in Houston since 1982, where he directs the comprehensive hospital-based technology management program. William Hyman is a professor of biomedical engineering at Texas A&M University in College Station, TX. Vicky D. Woodruff is a writer based in Houston, TX. Melita Howell is a senior project manager for information technology at Texas Children's Hospital.

For more information on this colloquium, contact David at 832-824-1810 or ybdavid@texaschildrenshospital.org.

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Two New Sterilization TIRs Nearing Completion

Sonia Balboni

In response to member and industry requests, AAMI is developing two new technical information reports (TIRs), which are expected to be approved and published in late 2007/early 2008 and subsequently available on the AAMI website.

Radiation Sterilization for Tissue Industry

AAMI will soon publish its first-ever guidance on sterilization for human tissue-based products, AAMI TIR37, *Sterilization of health care products — Radiation — Guidance on Sterilization of Human Tissue-Based Products*.

The new TIR is intended to be used with the ANSI/AAMI/ISO 11137 series of standards on radiation sterilization. While the requirements of the 11137 standards apply to all products, regardless of whether they contain living cells or tissue, the AAMI Radiation Sterilization Working Group felt that additional guidance would be helpful for users in the tissue industry for such areas as determining sampling and testing requirements. Therefore, as the 11137 series approached its final stages of development in early 2005, AAMI members proposed development of this new guidance document.

Originally, it was proposed that the TIR focus broadly on biologic-based products. After consideration, however, the working group recommended that the scope of the document be narrowed to human

tissue-based products only, and this scope was ultimately approved by the AAMI Standards Board in 2005.

The first draft was prepared by a task group initially led by committee member Martell Winters (Nelson Laboratories), and later by Trabue Bryans (Apptec Laboratories). After the task group completed the drafting work, the document was voted on by the full Radiation Sterilization Working Group and was then submitted to the AAMI Standards Board for final approval, which was received on Oct. 15, 2007. TIR37 will be published by the end of 2007.

Materials Qualification for Manufacturers

AAMI TIR17:200x, *Compatibility of materials subject to sterilization*, is intended to provide manufacturers with guidance on the qualification of polymeric materials, ceramics, and metals in healthcare products that will be sterilized. It covers products that are delivered sterile as well as those intended for re-use that will be sterilized multiple times by the end user, and is intended to help manufacturers choose materials and sterilization modalities that work optimally together.

The project was initiated through a proposal to expand AAMI TIR17:1997, *Radiation sterilization material qualification* to provide guidance on material qualification for all sterilization modalities, not just radiation sterilization. A new working

group was established, comprising medical device sterilization experts in radiation, ethylene oxide, moist heat, dry heat, hydrogen peroxide, and ozone. Led by Byron Lambert (Abbott Laboratories) and Jeff Martin (Alcon Laboratories), the working group is developing a comprehensive document that includes process and design considerations and elements of material testing, as well as individual annexes specifying guidance for each sterilization modality.

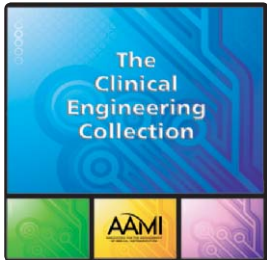
The document will be a useful tool for manufacturers who need to consider what effects the method(s) of sterilization that they intend to use or recommend for use with their products will have on the materials used in their medical devices and packaging. For example, a product that is ideally suited for one method of sterilization may experience degradation or other undesirable outcomes when sterilized by other modalities. Or, if a manufacturer changes his product makeup to incorporate a new type of polymer, the product may suddenly experience discoloration if the same sterilization method continues to be used.

The working group will review and resolve ballot comments in December 2007 and, provided a second ballot is not needed, the document is expected to be approved and published in spring 2008. ■

Sonia Balboni is a standards manager at AAMI.

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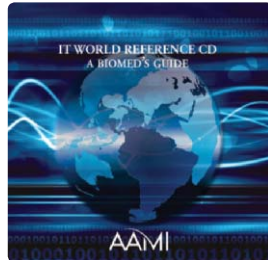


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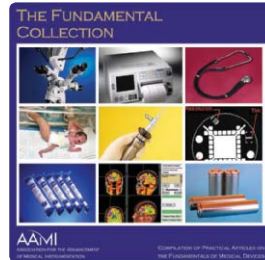
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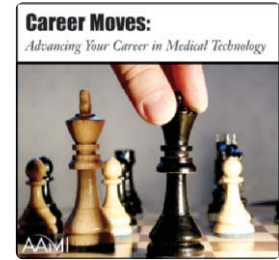
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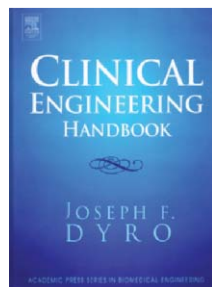
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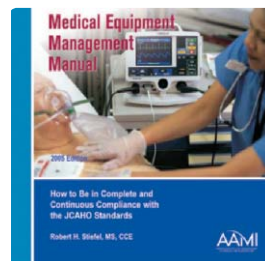
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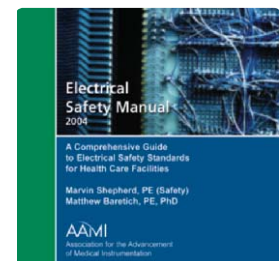
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