Executive Insights on Healthcare Technology Safety

2014 Report

A Joint Report from...

AAMI
Advancing Safety in Medical Technology

ECRI Institute
The Discipline of Science. The Integrity of Independence.

A MESSAGE TO HOSPITAL AND MEDICAL DEVICE INDUSTRY EXECUTIVES

As executive leaders, it's impossible to stay on top of everything we need to know in order to manage, plan, and execute well in a world dominated by fast-paced change. Monitoring issues and trends is essential, and yet we don't always have time to make real sense of all of the data or verify whose data we can trust. We know you share this challenge.

This first ever report from our C-suites to yours will present AAMI's and ECRI's collective insights and perspectives on key technology safety issues to help you monitor, think, and act. The topics were carefully selected by the two of us with a focus on C-suite executives from both healthcare delivery organizations and medical device companies.

Why do we care enough to prepare this unique report for you? And, why should you care enough to read it? Because medical technology is complex, expensive, and indispensable to healthcare delivery organizations. It's too important to simply delegate and hope for the best.

AAMI and ECRI are nonprofits with deep expertise on healthcare technology. We have unique and complementary knowledge that is trustworthy.

Our goal was to:

- Synthesize key insights on safety issues that tell an important story
- Share our wisdom on key technology-related issues that merit your attention and help you understand why you should care and why you should act
- Move you to the front end of issues, so you aren't caught off guard when you have no time left to "think" about the implications.

We are sharing what *we* would want to know if we were in your shoes, but it's still our perspective. We encourage your questions, comments, frustrations, suggestions, and advice on what's missing that would help make this unique report even more valuable in the future.

Mary Logan
President
AAMI

Anthony J. Montagnolo, M.S.
Executive Vice President and COO
ECRI Institute

THE TOP SAFETY ISSUES

Safety issues selected for this report come from recalls, safety notices, complaints, adverse incident reports, FDA priorities, and analyses of recurring problems identified by technology experts. Patients are at risk, responding is expensive, and reputations are at stake—for industry and healthcare delivery systems alike.

Healthcare delivery and device industry executives may have different perspectives on these issues and who should be responsible. But shared responsibility is critically important.

Questions Executives Should Ask

1. For healthcare delivery executives, do you know where your organization is most vulnerable from a technology safety perspective?

2. For industry executives, are you offering solutions to address top technology safety concerns?

ALARM SYSTEMS: NATIONAL PATIENT SAFETY GOAL

Alarm safety is being driven by new accreditation requirements from The Joint Commission (TJC). Technology plays a major role in alarm safety.

Questions Executives Should Ask

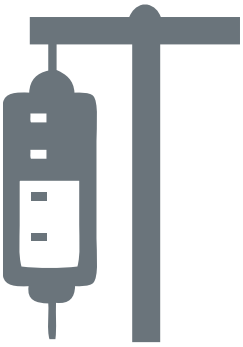
1. For healthcare delivery executives, has your multidisciplinary team been established to meet TJC's National Patient Safety Goal? How is your technology helping to prevent or contribute to alarm safety concerns?

2. For industry executives, how is your technology impacting the alarm management issues in healthcare delivery? What solutions are you providing or can you provide to help healthcare delivery organizations address alarm safety concerns?

HOW WE CAN HELP

- AAMI's "Hot Topics" web page on Alarm Systems (free)
- AAMI's Webinar Series on Compliance with TJC's NPSG (free)
- Priority Issues From the AAMI/FDA Medical Device Alarms Summit (free)
- ECRI's Top Ten List of Health Technology Hazards (free)
- ECRI's Alarm Safety Resource Site (free)
- ECRI's Alarm Management Safety Reviews (consulting service)

Find these resources at www.aami.org/aami-ecri



LUER CONNECTORS

The CEO of one of the largest U.S. health systems heatedly asks why industry hasn't solved the Luer connector issue more quickly, noting how impossibly painful it is to explain an avoidable death to the family of a patient who died from a Luer misconnection. The beauty of the Luer connector is that it is universal, like a USB stick: a single connector has as many as 16 different uses on various medical devices, from enteral feeding sets to blood pressure monitors. The deadly danger of this connector is also that it is universal. Numerous deaths have occurred from misconnections (e.g., an infant's feeding tube inserted into an IV line). Industry has been working with regulators on new design standards for connectors to minimize the risk of misconnections. In late 2014, new enteral sets with a brand new, standardized connector are expected to enter the market in the United States. In 2015 and beyond other new connectors will enter the market.

Questions Executives Should Ask

1. For healthcare delivery organization executives, what is your patient safety team doing to prepare your organization for the massive effort that will be required to implement the new connectors?

2. For medical industry executives, do any of your products use Luer connectors and are you ready to implement the new standards for connectors?

HOW WE CAN HELP

- AAMI's "Hot Topics" Web Page on Small-Bore Connectors (free)
- AAMI's FAQs on Small-Bore Connectors and Tubing Misconnections (free)
- ECRI Guidance on Preventing Misconnections of Lines and Cables (free)
- ECRI's Top Ten Health Technology Hazards (free)

Find these resources at www.aami.org/aami-ecri

CYBERSECURITY

A security expert working in the field writes, "Medical device manufacturers and hospitals are not telecom providers, but they are building telecom networks with telecom equipment without understanding that doing this the right way requires huge amounts of resources to test and secure the networks and devices before deployment. The security failures in healthcare are mistakes of a long gone era in other verticals." He adds, "We recently tested a bunch of devices on a major hospital network and destroyed some devices and the device manufacturer claimed that the attack was not possible if the network was 'correctly' configured. We had them 'correctly' configure the network, and it still killed the devices. We had the hospital try their hand at configuration, and they still killed the devices. This included secure VLANS (virtual local area networks) and all the bells and whistles." White hat or not, hackers are highly skilled at getting through firewalls, VLAN devices, and the like.

Questions Executives Should Ask

1. For both healthcare delivery organization and medical industry executives, what security best practices from other industries should you follow and what are the consequences if you do not adopt those best practices?

2. For healthcare delivery executives, to what depth are you testing and securing networks and devices before deployment?

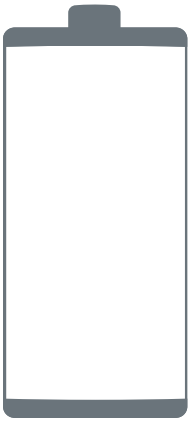
3. For both healthcare delivery organization and medical industry executives, what kind of assessment are you doing before making purchasing decisions?

4. For healthcare delivery executives, how high a priority have you made device/network security in your organization, and where should this fit in your overall priorities based on a risk/cost/benefit analysis?

HOW WE CAN HELP

- AAMI's Healthcare Cybersecurity Risk Management: Keys to an Effective Plan (free)
- AAMI's Chronicles of Interoperability: Failures, Safety, and Security (free)
- ECRI's Webinar on Medical Device Cybersecurity (for purchase)

Find these resources at www.aami.org/aami-ecri



BATTERIES

The FDA has made medical device batteries a priority, because of the quantity and severity of reports of problems in the field. The quality of batteries is a patient safety issue for both industry and healthcare delivery executives. The challenges range from undercharging and overcharging to confusing error messages, leakage, and loose connections. Short-term gains (the cheapest battery source) can create long-term pain (recalls, failed devices that put patients at risk).

Questions Executives Should Ask

1. For healthcare delivery executives, are you considering the type and life of batteries as part of your pre-purchase assessment for medical devices? Are you inadvertently pressuring supply chain and healthcare technology management (biomed) staff to buy the cheapest batteries available, without considering the use and the past performance of the potential replacement?

2. For medical industry executives, how are you assessing and testing the quality of batteries from your suppliers? Are you inadvertently pressuring supply chain staff to cut costs in an area where you will pay later if you don't pay up front?

HOW WE CAN HELP

- AAMI's "All Charged Up: The Many Challenges of Battery Maintenance" (free)
- ECRI's price benchmarking and product selection services for medical products – including batteries (for purchase)
- The FDA's Battery-Powered Medical Devices Workshop (free)

Find these resources at www.aami.org/aami-ecri

RECALLS

According to a recent FDA report, the number of annual *reported* medical device recalls has nearly doubled, from 604 to 1,190, from 2003 to 2012. There is much more to the story than the numbers convey.

The Rest of the Story

— The increase in recalls is in part due to FDA vigilance about industry's obligation to *report* recalls. For example, the reporting of radiology device recalls more than doubled from 100 per year to 250 per year following the 2010 public attention to radiation exposure. For this reason, it's impossible to know from the FDA report how much recalls overall increased, versus how much the reporting increased.

— It's the Class I and II reported recalls that went up so dramatically, see graphs below.

— The most frequent Class I recalls were for:
- Infusion pumps
- Automated external defibrillators
- Continuous ventilators
- Blood glucose test systems
- Catheter introducers
- Implanted infusion devices

— The most frequent Class I and II combined recalls were for Linear accelerators, with 176 recalls. The vast majority related to software issues.

— The most common cause of all reported recalls: Software design (approximately 15% of all recalls from 2010-2012).

Questions Executives Should Ask

1 For healthcare delivery executives, do you consider recall history as part of your pre-purchase technology assessment? Do you have an efficient, effective, system for managing recalls?

2 For industry executives, have you compared the full cost of recalls versus the cost of additional validation, verification and other testing up front, particularly for software?

3 For both healthcare delivery organization and medical industry executives, do you have an efficient, effective system for monitoring, communicating, and taking appropriate action on technology safety issues?

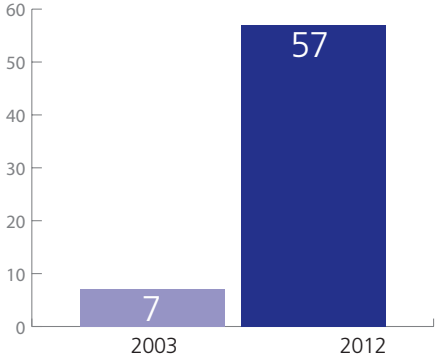
4 For both healthcare delivery organization and medical industry executives, are you spending more on fixing technology safety issues than on solving them?

HOW WE CAN HELP

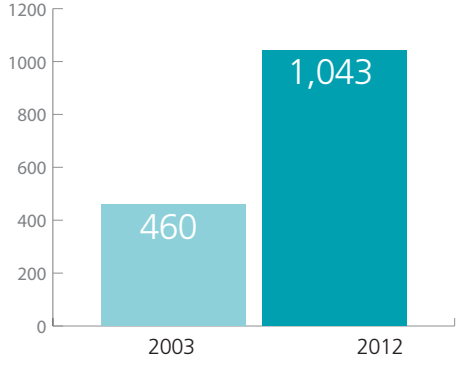
- Video on ECRI Institute's Alerts Tracker Hazard and Recall Management Service (for purchase)
- ECRI's Health Devices Safety Alerts (paid service)
- The FDA's Medical Device Recall Report (free)

Find these resources at www.aami.org/aami-ecri

Class I Reported Recalls



Class II Reported Recalls



About AAMI

The Association for the Advancement of Medical Instrumentation (AAMI) is the world's leading organization for advancing the development, safety, and effective use of medical technology. AAMI's membership is comprised of a diverse group of nearly 7,000 key decision makers in the healthcare technology field—clinical engineers, biomedical equipment technicians, clinicians, manufacturers, sterile processing professionals, quality assurance/regulatory affairs experts, and other professionals. Visit **www.aami.org.**

About ECRI

ECRI Institute is an independent, nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care. As pioneers in this science for more than 45 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. Visit **www.ecri.org.**

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