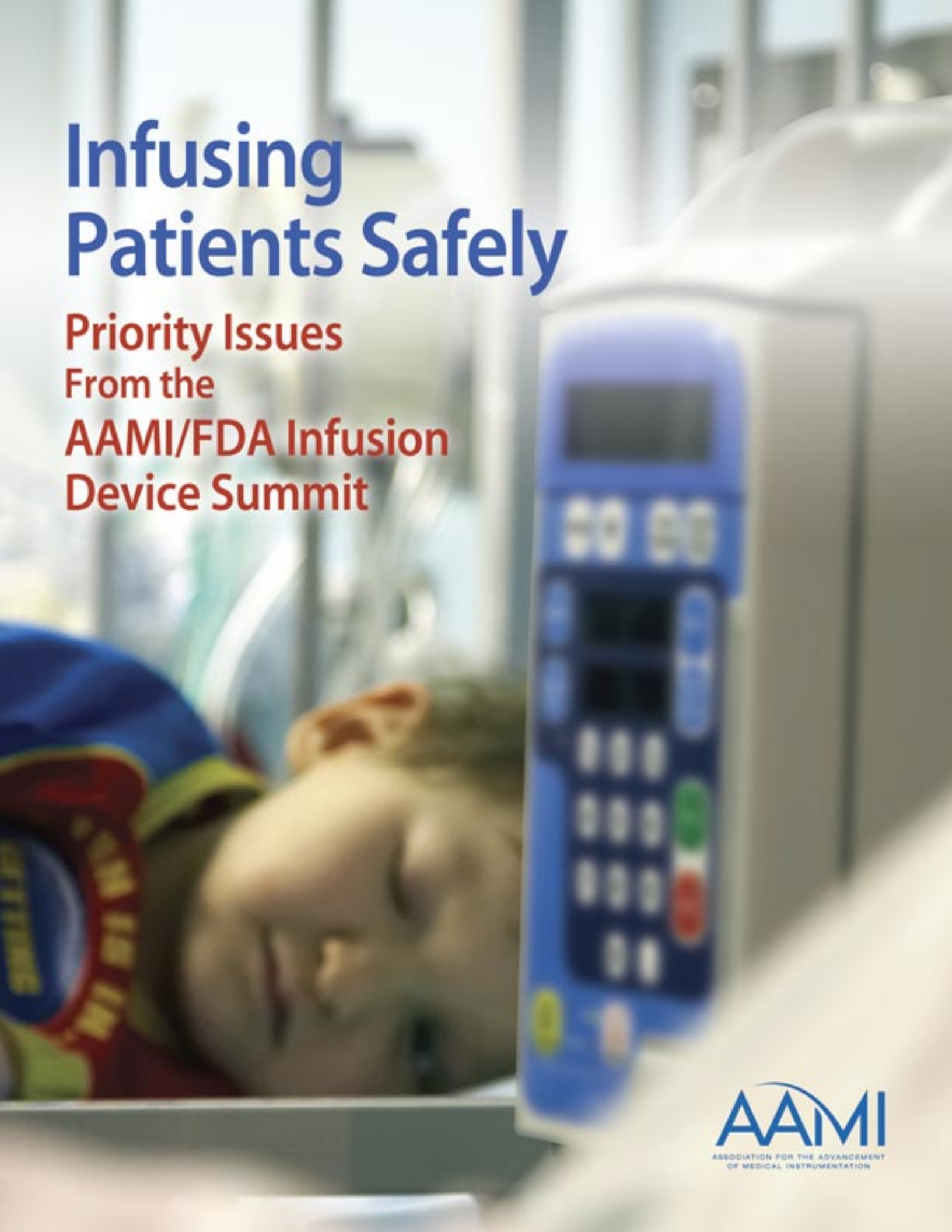


# Infusing Patients Safely

## Priority Issues From the AAMI/FDA Infusion Device Summit

AAMI
ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

## About AAMI

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a diverse alliance of more than 6,000 members from around the world united by one critical mission—supporting the healthcare community in the development, management and use of safe and effective medical technology.

AAMI serves as a convener of diverse groups of committed professionals with one common goal—improving patient outcomes. AAMI also produces high-quality and objective information on medical technology and related processes and issues. AAMI is not an advocacy organization and prides itself on the objectivity of its work.

## About FDA

The U.S. Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution of tobacco products.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health.

# Infusing Patients Safely

## Priority Issues From the AAMI/FDA Infusion Device Summit

# Contents

# A Call to Action


Mary Logan


Carol L. Herman

Dear Colleagues,

On Oct. 5–6, 2010, a remarkable group of diverse experts came together to change the world of infusion devices. The AAMI/FDA Infusion Device Summit opened with this quote from Margaret Mead: "Never doubt that a group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has." Looking back, that quote captured the essence and mood of the summit.

The spark for hosting this unprecedented, groundbreaking event was the result of *listening well*. FDA listened well to the barrage of reports it received about too many adverse incidents involving infusion devices. The academic and industry co-chairs of AAMI's Infusion Device Standards Committee listened well to their instincts: the international standard up for revision needed more work than simply an up or down vote. AAMI as an organization listened well to the need for a neutral convener to bring the right people together from across the entire healthcare community. Industry listened well by answering the call to actively engage in the event. The clinician, clinical engineering, and expert consultant community listened well by giving two days of their time, expertise, and passion for patient safety for the "good of the order." The time was right, and from listening well, the event was conceived and took shape.

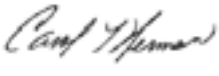
The spark for what happened during the event also was the result of listening well by the 330 people in the room. Attendees heard challenges presented by speakers and amplified by audience discussion. Questions, audience comments, suggestions, frustrations, and opinions were brought to the floor. Participants together fulfilled the challenging assignment of developing a list of priorities—13 in all—that all agreed must be addressed.

What made the event even more remarkable was the overwhelming commitment of attendees that, as a community, they would continue to work together on implementing action plans based on the agreed-upon priorities. Each of these committed professionals, reaching across all parts of healthcare, deserves a round of applause for this great work product. Thank you.

The challenge for all of us will be to keep the momentum going, to nurture the spark that gave us all the energy to conceive and shape the event—and to stay actively engaged in addressing the 13 priorities. The Medical Device Safety Council/Infusion launched by the AAMI Foundation has been tasked with keeping the passion alive by organizing working groups, overseeing the progression of solutions to the 13 priorities, and working with the many people who have already volunteered their time and expertise to infusion initiatives. If the going gets tough, we'll reach out for that common bond we all share: improving patient safety.

Sincerely,

**Mary Logan**
*President*
Association for the Advancement
of Medical Instrumentation



**Carol L. Herman**
*Director*
Standards Management Staff
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
U.S. Food and Drug Administration

# Executive Summary

> **"The most important aspect of the summit is the huge multidisciplinary turnout. There is no way this issue can sink back into obscurity."**
>
> —Nat Sims, M.D., anesthesiologist and physician advisor in biomedical engineering at Massachusetts General Hospital in Boston and co-chair of AAMI's Infusion Device Standards Committee

**THE LEGACY OF** an unprecedented AAMI/FDA Infusion Device Summit could be a more coordinated and focused approach to solving a multitude of challenges with infusion devices—some of the most widely used medical technologies in healthcare. Ultimately, this effort could result in improved patient safety from drug infusions.

That, indeed, is the shared expectation of 330 summit participants who gathered at FDA headquarters outside Washington, DC, in October 2010 to identify and prioritize the most salient issues with infusion devices. The summit drew a broad range of professionals, including physicians, nurses, pharmacists, clinical engineers, biomedical technology professionals, human factors engineers, manufacturers, academicians, regulators, and organizations that represent them.

Framed by expert presentations, summit participants spent two days building consensus for 13 priority issues that they believe are critical for improving patient safety. The range of issues—which encompass incident reporting, design, engineering, manufacturing, and use of infusion devices—calls attention to the increasing complexity of infusion devices. At the same time, these issues gained traction because summit participants believe the healthcare community is capable of addressing them *now* with innovative solutions.

At the summit, AAMI announced the launch of a safety council to spearhead action on the priority issues. Shortly after the summit, AAMI's Infusion Device Standards Committee grouped the 13 priority issues into five clarion themes, which serve as a call to action for improving infusion devices.

## Clarion Themes and Priority Issues

1. **Standardize systems and processes for reporting, aggregating, and analyzing infusion device incidents.**

   *Priority Issues:*

   1. There is a poor (incomplete and inadequate) system for reporting aggregate state and national data about adverse events (e.g., MAUDE [Manufacturer and User Facility Device Experience] and PSOs [Patient Safety Organizations]).
      a. There is a lack of standardization to support data aggregation.
   2. The reported incidents do not convey the bigger picture in terms of the volume of incidents involving infusion devices. User facilities are encouraged, but not required, to report "close calls" and "near misses" and to determine their root causes.
   3. There is often an inability by manufacturers to determine root cause of infusion device incidents due to difficulty accessing and analyzing incident data from all sources. This also applies to continuous quality improvement (CQI) reporting.
   4. There is no process for collaborative failure analysis.
      a. There is no safe space for disclosing or accessing information about infusion device incidents or problems. Patient Safety Organizations (PSOs) should be considered.

2. **Improve the integration of infusion devices with information systems and drug libraries.**

   *Priority Issues:*

   5. There is incompatibility across devices and with systems (e.g., consistent bar coding, wireless, power supply, and health information technology [HIT] systems). The unavailability of wireless in a natural disaster should be considered.
   6. There is a lack of formulary and standards for drug libraries, including standardization of drug concentrations and transparency (e.g., for sharing of drug libraries between facilities).
   7. Uploading, managing, and maintaining drug libraries can be difficult.
      a. There is a lack of coordination between pump requirements and hospital capabilities.
      b. There is a steep learning curve for configuring and managing drug libraries.
      c. There is difficulty in managing the same drug used in multiple units in multiple ways.

3. **Mitigate use errors with infusion devices.**

   *Priority Issues:*

   8. A high percentage of sentinel/adverse drug events (ADEs) are due to use errors. It is imperative to figure out how to develop design safety features that make it easy for the user to do the right thing. Applicable human factors, automatic identification (e.g., bar coding), and the value of all the steps involved in drug administration should be considered.
   9. There is a lack of standardization of terminology used in infusion systems (upstream and downstream devices)—and a clear need for the same wording, same spelling, etc., across the process, devices, containers, etc.
   10. There is a lack of knowledge/familiarity with infusion devices and a lack of effective training in their use—from both manufacturers and facilities.

4. **Improve management of multiple infusions.**

   *Priority Issues:*

   11. There is difficulty in infusion line management—including containers, manifolds, catheters, and transport—reflecting the complexity of multiple infusions, including secondaries, disposables, etc.

5. **Reconcile challenges and differences in the use environments of infusion devices.**

   *Priority Issues:*

   12. Alarm management is not effective.
      a. There are high numbers of false alarms, which also can lead to true alarms being ignored (e.g., air).
      b. Alarms are difficult to prioritize.
      c. It is unclear how to resolve alarm issues.
   13. Injuries are caused by a lack of differentiation between the use of infusion devices in hospitals and in other environments (e.g., home use). Products designed for the hospital environment are being used in home environments (and vice versa). There are design and user issues and differences among home, hospital, and other environments.

## About This Report

By design, this report is not a chronological summary of summit proceedings. Summit participants made clear that the most welcome and productive next step would be concerted action to address the priority issues. Thus, this report is organized around these priority issues, with the expectation that it will serve as a touchstone document for moving forward.

The report does highlight the summit presentations and discussions, along with expert perspectives solicited after the summit and an update of the infusion systems safety council's progress in developing a comprehensive, collaborative, and multidisciplinary action plan to tackle the priority issues.

**An important disclaimer: This publication reports on the 13 priority issues developed by consensus at the summit, summarizes summit presentations, and provides additional context from experts. The 13 priority issues have not been endorsed by AAMI, FDA, or any of the summit sponsors or supporting organizations. The views expressed by individuals in summit presentations and expert perspectives do not necessarily represent these organizations' views.**

### More Summit Information on AAMI Web Site

The summit agenda, PowerPoint presentations of summit speakers, reference materials, and updates are posted on the AAMI Web site. Visit the Web site to view or download this information.

www.aami.org/infusionsummit

# Clarion Themes and Priority Issues

## The Scope of the Problem

The vast majority of patients who spend even a few hours in a hospital encounter one of the most widely used medical technologies in healthcare: infusion pumps. Increasingly, computer-controlled smart pumps can be programmed to deliver controlled amounts of painkillers, antibiotics, insulin, chemotherapy drugs, nutrients, or other fluids. Smart pumps also can keep electronic records of infusions, which are captured in the pumps' software. Infusion devices are used in homes and other healthcare settings as well.

When they work as intended, infusion pumps support the "five rights" of medication safety—right medication, right dose, right time, right route, and right patient. In fact, infusion pumps can provide important health benefits and reduce medical errors, according to summit presenter William Maisel, Deputy Center Director for science at the FDA's Center for Devices & Radiological Health.

But infusion errors and pump failures can cause serious harm, and even death, to patients. Between Jan. 1, 2005, and Dec. 31, 2009, more than 56,000 adverse events and 710 deaths associated with infusion devices were reported to FDA—more than for any other medical technology. During this period, there were 87 pump recalls.

"Adverse events are amplified because of the number and frequency of use of infusion pumps," Maisel said. "Failures can occur wherever pumps are used, with every type of pump, with any manufacturer. Many problems are due to deficiencies in design and engineering. But it's not just an issue of devices, it's about users and user interfaces."

In response to its safety concerns, FDA in April 2010 launched an infusion pump improvement initiative, held a public workshop, published a white paper, issued draft guidance for manufacturers, and created a Web site devoted to infusion safety.

www.fda.gov/InfusionPumps

## A Call to Action and 13 Priority Issues to Address

Framed by expert presentations, summit participants spent two days building consensus on 13 priority issues that they believe are the most critical for improving patient safety. The range of issues calls attention to the increasing complexity of infusion devices and the healthcare environments in which they are used.

At the same time, these issues gained traction because summit participants believe the healthcare community is capable of addressing them *now* with innovative solutions to improve incident reporting, design, engineering, manufacturing, and use of infusion devices. In the words of summit presenter Pat Baird, Systems Engineer at Baxter International, Inc., a manufacturer of infusion devices, and co-chair of AAMI's Infusion Device Standards Committee, going after the "low-hanging fruit" is a viable place to start.

At the summit, AAMI announced the formation of a safety council to spearhead action on the priority issues. Shortly after the summit, AAMI's Infusion Device Standards Committee grouped the 13 priority issues into five clarion themes, which serve as a call to action for improving infusion devices.

The clarion themes and priority issues are presented below, with highlights from summit presenters and expert perspectives on the issues and potential solutions.

"What you don't know, you can't fix."

—Bryanne Patail, biomedical engineer at the Veterans Health Administration's National Center for Patient Safety

## CLARION THEME 1

**Standardize systems and processes for reporting, aggregating, and analyzing infusion device incidents.**

### PRIORITY ISSUES:

1. There is a poor (incomplete and inadequate) system for reporting aggregate state and national data about adverse events (e.g., MAUDE [Manufacturer and User Facility Device Experience] and PSO [Patient Safety Organizations]).
    a. There is a lack of standardization to support data aggregation.
2. The reported incidents do not convey the bigger picture in terms of the volume of incidents involving infusion devices. User facilities are encouraged, but not required, to report "close calls" and "near misses" and to determine their root causes.
3. There is often an inability by manufacturers to determine root cause of infusion device incidents due to difficulty accessing and analyzing incident data from all sources. This also applies to continuous quality improvement (CQI) reporting.
4. There is no process for collaborative failure analysis.
    a. There is no safe space for disclosing or accessing information about infusion device incidents or problems. Patient Safety Organizations (PSOs) should be considered.

## Understanding the Issues: Reporting Systems and Processes

A frustrating aspect of infusion device incidents is the dearth of information about them—answers to the essential "who, what, when, where, why, and how" questions, according to Baird.

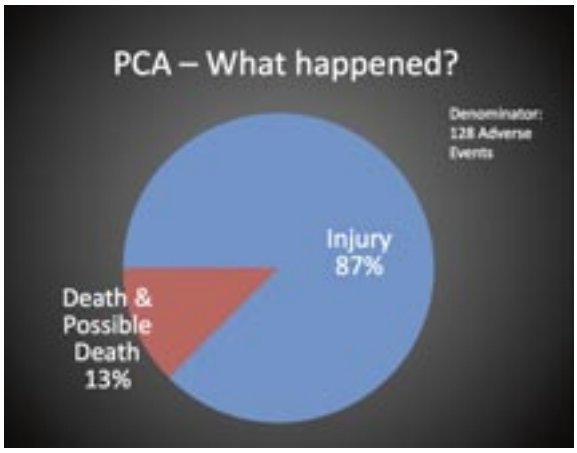
Baird shared findings from his examination of a sample of incident data from public sources, focusing on serious incidents that resulted in patient harm. He sought to answer basic questions about infusion pumps, including how the broad patterns in the public data would inform further investigation into the design, manufacture, and use of infusion pumps. Specifically, Baird reviewed:

- Three years of data from MAUDE (2007, 2008, and 2009), FDA's database of voluntary reports of medical device incidents from users, facilities, distributors, and manufacturers, covering patient-controlled analgesia (PCA), elastomeric, enteral, and general-purpose infusion devices
- More than five years of information from the FDA Class I recall list, the most serious medical device recalls
- 10 years of research literature, including case studies, reports, and conference proceedings on infusion devices

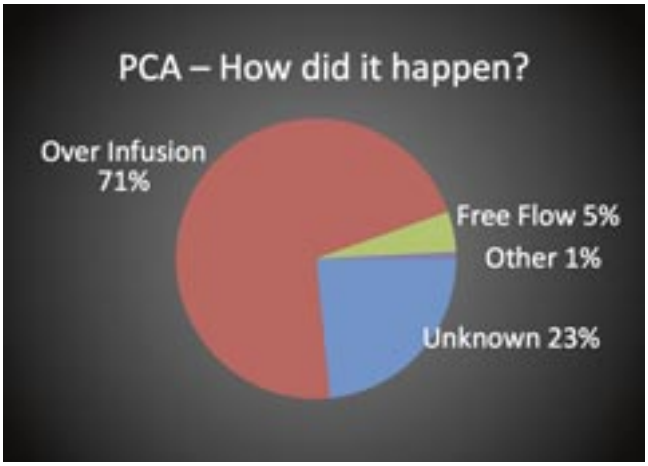
A key takeaway message from this exhaustive investigation is that, even for the most serious incidents, answers to basic questions are sometimes unknown. A sampling of Baird's synthesis of MAUDE-reported incidents with PCA infusion pumps, shown in **Figure 1**, highlights this shortcoming. Baird presented similar findings about other types of infusion devices.

MAUDE is a self-reporting system that might not contain all the necessary information about medical device incidents, Baird noted. In addition, for the incident reports included in his study, MAUDE covers only device-specific issues, which means that related issues—such as misconnections, pharmacy errors, and adverse drug interactions—will not show up. (However, FDA said that related issues such as these are included in other kinds of incident reports.) Rarely is there any "who" associated with device incidents in MAUDE reports, Baird said. The quality of reports varies by device type and by type of incident, with injury reports providing much more information than death reports.

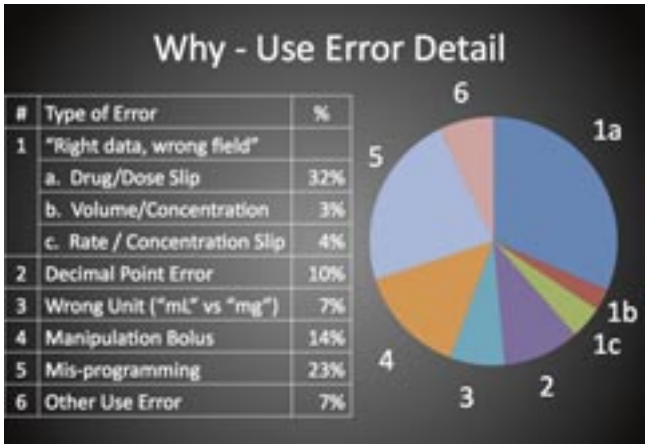
**Figure 1. A Synthesis of Patient-Controlled Analgesia (PCA) Infusion Pump Incident Reports to MAUDE, 2007–09**












Source: Pat Baird, "Incident Data: Filling the Gaps, Identifying the Value, and Prioritizing Needed Information." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 6, 2010.

There are shortcomings to other sources of information as well, Baird said. Published case reports cover specific incidents, with no aggregation or analysis of data into broad categories of information. Conference proceedings often make best-practice recommendations—for unstated problems.

Even with incomplete and inadequate data, however, there is important information to be gleaned from MAUDE data. **Figure 2** shows the identified causes of harm and average yearly tally of adverse patient outcomes for PCA, enteral, and general-purpose devices over the three-year period Baird examined.

Summit participants elaborated on the inadequate and incomplete system and processes for reporting, aggregating, and analyzing infusion device incidents with these observations, which are now priority issues:

- User facilities are encouraged, but not required, to report "close calls" and "near misses." Thus, the reported numbers of incidents do not convey the "bigger picture" of the true volume of infusion device incidents.
- The shortcomings of the incident report system make it difficult for manufacturers to access information from all sources to conduct root cause analysis of infusion device incidents—a problem that applies to continuous quality improvement information captured by smart pumps.
- There is no process or "safe space" for collaborative failure analysis—careful, after-the-fact examination of infusion pump incidents by multidisciplinary teams in which the goal is identifying and resolving issues rather than placing blame.

**Figure 2. Identified Causes of Harm and Average Annual Number of Reported Incidents: Patient-Controlled Analgesia (PCA), Enteral, and General-Purpose (FRN) Pumps, 2007–2009**

| Harm per year | PCA (42.6) | Enteral (13.3) | FRN (79.3) | Total (135.3) |
|---|---|---|---|---|
| Failure / Malfunction | | | 17 - 23.3 | 17 - 23.3 |
| Use: Mis-programming | 5.3 - 9.7 | | 10.3 - 10.3 | 15.6 - 20 |
| Use: Drug / Dose Slip | 7.3 - 13.3 | | 1.3 - 1.3 | 8.6 - 14.6 |
| Use: Decimal Point Error | 2.3 - 4.3 | | 6 - 6 | 8.3 - 10.3 |
| Failed to Alarm | | 4.3 - 8.3 | 4 - 5.7 | 8.3 - 14 |
| Physical Damage | | | 4.7 - 6.3 | 4.7 - 6.3 |
| Use: Manipulation | 3.3 - 6 | | | 3.3 - 6 |
| Use: Wrong units | 1.7 - 3 | | 1.3 - 1.3 | 3 - 4.3 |
| Use: Other | 1.7 - 3 | 1.3 - 2.7 | | 3 - 5.7 |
| Alarm | | | 2.7 - 3.7 | 2.7 - 3.7 |
| Use: Secondary | | | 2.3 - 3.3 | 2.3 - 3.3 |
| Use: Rate / Conc. Slip | 1 - 1.7 | | 0.7 - 0.7 | 1.7 - 2.4 |
| Use: Volume / Conc. Slip | 0.7 - 1.3 | | | 0.7 - 1.3 |
| Total | 23.3 - 42.3 | 5.7 - 11 | 50.3 - 62 | 79.2 - 115.2 |

Source: Pat Baird, "Incident Data: Filling the Gaps, Identifying the Value, and Prioritizing Needed Information." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 6, 2010.

Addressing the shortcomings of the systems and processes for reporting, aggregating, and analyzing infusion device incidents must be a shared responsibility among all stakeholders, not just FDA.

This is because MAUDE is a *reporting* system, intended to signal safety issues, but not to determine or convey root causes of incidents. Not all incidents are required to be reported. And the information in the MAUDE database is only as good as the reporters who submit it. FDA receives two kinds of medical device reports:

- **Mandatory medical device reports**, or MDRs, submitted by the medical device industry and by certain healthcare facilities by three main reporters—medical device manufacturers, medical device importers and user facilities, such as hospitals, which use the devices. The term "user facility" actually describes five types of facilities responsible for mandatory reporting: hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities.

  The federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the authority to collect MDRs. The reporting requirements, which are found in Chapter 21 of the Code of Federal Regulations book at Part 803, are implemented based on the laws in Section 519 of the FD&C Act.

- **Voluntary reports** submitted by reporters who do not have a mandatory requirement to tell FDA about device-related deaths, serious injuries, or malfunctions, but are encouraged to do so.

  According to FDA, near misses and events that could result in harm can be reported using this method. Additionally, the Medical Product Safety Network (MedSun) is an adverse event reporting program launched in 2002 by FDA. The primary goal of MedSun is to work with the clinical community to identify and solve problems with the use of medical devices. FDA also collaborates with MedSun facilities to more fully understand possible emerging public health signals. MedSun participants are educated and encouraged to voluntarily report problems with devices, such as

"close calls," events that could result in harm, and other safety concerns in addition to the death and serious injury events required.

Both voluntary and mandatory reports contain information that helps FDA monitor the safety of medical devices. At any time, if a post-market analyst requires more detail regarding a report, FDA may obtain additional information to fill in any observed gaps or missing pieces in reporting.

FDA encourages manufacturers to engage in active conversations with the agency to obtain guidance about their reporting requirements. In addition, FDA strives to provide outreach through direct communication with manufacturers and through training materials and guidance documents posted on the FDA Web site.

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

FDA also supports medical device reporting by manufacturers, voluntary reporters, importers, and user facilities with training presentations, also available on the FDA Web site. Two presentations provide guidance and technical information about how to use MAUDE, search for adverse event information and submit MDRs to FDA electronically.

www.fda.gov/Training/CDRHLearn/ucm162015.htm

Finally, FDA encourages collaborative action to determine root causes of adverse events. Manufacturers should ensure that staff performing the root cause analysis are communicating and collaborating with their customers and the device users at the time of failure to assist in the identification of the specific cause(s) of the failure. The manufacturer's team performing the root cause analysis should contain knowledge from multiple engineering and relevant clinical disciplines. FDA has posted a number of examples of reported infusion pump problems on its Web site.

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202496.htm

## A Potential Process for Next-Generation Reporting: The National Transportation Safety Board

**SEVERAL SUMMIT PARTICIPANTS** envision a next-generation system for incident reporting, aggregation, and analysis as robust as the National Transportation Safety Board's. NTSB is on the scene of every major transportation incident with a team of trained investigators, who use a standard protocol to get to root causes.

Incident records, preliminary and final reports, and conclusions are accessible on a searchable database on a public Web site.

www.ntsb.gov

## LEAD-USER PROFILE: The Veterans Health Administration

# Root Cause Analysis Shapes Safety Initiatives

**AT THE VETERANS HEALTH ADMINISTRATION** (VHA), root cause analysis is practically an art form. The VHA has conducted more than 12,000 systematic root cause analyses—or more than 1,000 a year—since 1999.

That year, the VHA established the National Center for Patient Safety (NCPS) to develop and nurture a culture of safety, including a non-punitive environment for reporting medical device and other patient safety incidents. Since then, "close call" reports increased 900-fold. "Changing the culture of safety in an organization is like an engine that continues to propel safety," said summit presenter Bryanne Patail, biomedical engineer at NCPS.

The goal of root cause analysis is to find out what happened, why it happened, and what to do to prevent it from happening again. "What you don't know, you can't fix," Patail said.

Some 978 of the root cause analyses conducted over 11 years involve medical devices. More than 13 percent of these, 129 in all, pertain to two types of infusion pumps—60 on general-purpose pumps and 69 on PCA pumps. Based on these root cause analyses, the VA's integrated product team recommended that PCA pumps with an integrated end tidal $CO_2$ monitor is the pump of choice, because use of this technology could have prevented more than 60 percent of adverse events related to PCA pumps.

NCPS has developed a standard protocol, which is spelled out in detail on its Web site and summarized on laminated, spiral-bound, and portable NCPS Triage Cards™, to support patient safety teams in conducting root cause analyses. Triage questions help teams gather information from interviews, documents, and devices and delve into possible (and often multiple) causes for incidents. Probing questions examine relevant issues in key areas:

- Human factors (communication, training, fatigue, and scheduling)
- The environment and equipment
- Rules, policies, and procedures
- Barriers and controls

Based on their findings, the teams recommend actions to prevent or minimize future adverse events or close calls. NCPS tracks the implementation of these follow-up actions—and has enough outcome data to be able to categorize them as "strong, intermediate, or weak fixes." The strongest fix for both general purpose and PCA pumps is standardizing processes—protocols, clinical guidelines, order sets. New device purchases and standardization of equipment make the strong-fix list as well.

Root cause analysis, follow-up actions, and outcome statements indicate that there are opportunities for improvement by all stakeholders. "Opportunities to prevent problems from happening in the first place exist at many levels," Patail said. "I am a strong supporter of 'prevention is better than the cure.' We cannot afford to run to fire calls all the time."

## EXPERT PERSPECTIVE: Improving Reporting Systems and Processes

### Pat Baird

**Baxter International, Inc.**

**Q. What is the "bigger picture" that is missing from reporting requirements?**

**A.** "Healthcare providers are focused on an individual's care—as they should be. It shouldn't be surprising that they sometimes don't have the time to fill out a detailed, free-form incident report. This leads to under-reporting and incomplete reporting. To improve public health, we all need that extra level of detail. We need to find a way to both make reporting easier and to change the perception that reporting is removed from patient safety. This is not just an infusion issue; it affects all medical devices."

**Q. From your investigation, what root causes do you believe deserve more attention?**

**A.** "I believe the industry already knew that 'misprogramming' and 'use error' were significant issues, but those are very broad categories and needed more specificity. This investigation enlightened me to the fact that 'right data in the wrong field' was a significant type of misprogramming. I also was surprised at the number of incidents where physical damage to the device wasn't apparent to the user, but resulted in a death or injury. Other types of use error caused more harm than 'physical damage,' but I don't want us to forget that not all 'use error' is related to device programming."

**Q. What roles do you think manufacturers, FDA, and AAMI should play in improving reporting, aggregation, and analysis of infusion device incidents over the next year?**

A. "There are two things I'd like to see happen:

1) Build confidence in the conclusions from MAUDE.
2) Know what it takes to build a better MAUDE in the future.

"I reviewed three years of MAUDE data and came to one set of conclusions. A review of MedSun* might come to the same or different conclusions. Other databases might have different results altogether. Although I reviewed over 1,000 MAUDE records to be thorough, correlating the MAUDE results with those from other databases would provide an additional level of confidence to the MAUDE data. We need to be sure that we are solving the right problems.

"Although we may be looking specifically at infusion devices in these databases, what we learn is applicable to nearly all medical devices. Infusion systems are a microcosm of the broader medical device industry."

**Q. What could be learned from other reporting systems in the U.S. and abroad?**

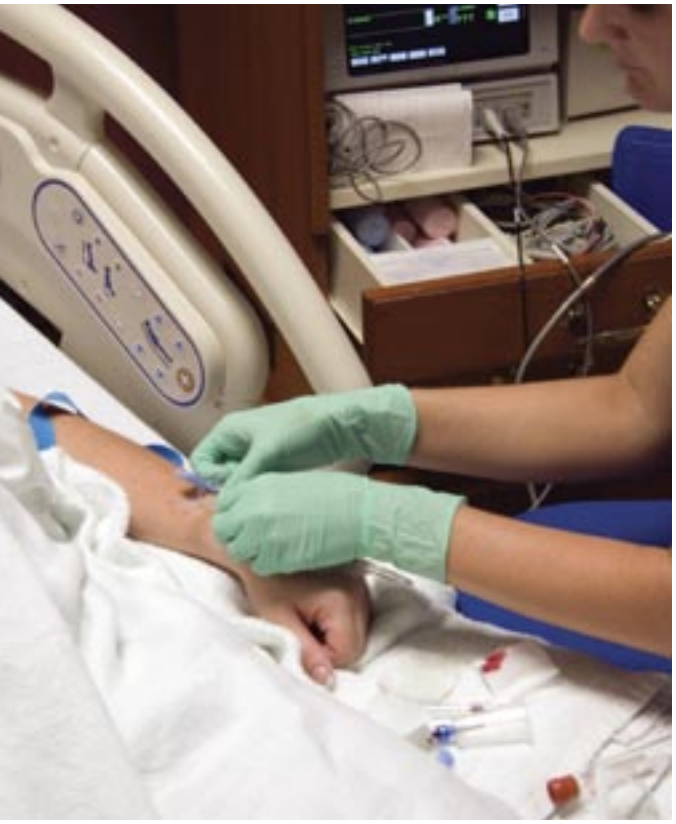
**A.** "Other reporting systems have their own specific goals, strengths, and weaknesses. As we look at pumps, let's also look at how well these reporting systems are working. How do best-practice hospitals track issues internally, and what is the quality of their results? Pennsylvania and Minnesota have statewide reporting systems. How well are those systems working? MEDMARX and MedSun are national-level reporting systems worth looking at. Ontario spends a significant amount of money on healthcare improvement initiatives. How is its reporting system set up? What can we learn from the NHS [National Health Service] in the U.K. and AFSSAPS [French Health Products Safety Agency] in France? Let's take this opportunity to truly understand the capabilities and limits of our collective reporting systems to help design the next-generation reporting system."

In response to Baird's suggestions, FDA cautioned that any conclusions drawn from the MAUDE database might not be sound because, as Baird discovered, the information submitted is not always complete or of high quality. Moreover, incidents reported to FDA do not encompass all incidents that occur. In addition, comparing MAUDE data to data from other databases could be problematic as well, because different reporting systems collect different information.

* Note: Data from the FDA's Medical Product Safety Network (MedSun) is included in the MAUDE database.

**"IV interoperability is cutting-edge technology that we think is really the next additional step for IV medication safety."**

—Amanda Prusch, pharmacist and medication safety specialist at Lancaster General Hospital



## CLARION THEME 2

**Improve the integration of infusion devices with information systems and drug libraries.**

### PRIORITY ISSUES:

5. There is incompatibility across devices and with systems (e.g., consistent bar coding, wireless, power supply, and health information technology [HIT] systems). The unavailability of wireless in a natural disaster should be considered.
6. There is a lack of formulary and standards for drug libraries, including standardization of drug concentrations and transparency (e.g., for sharing of drug libraries between facilities).
7. Uploading, managing, and maintaining drug libraries can be difficult.
    a. There is a lack of coordination between pump requirements and hospital capabilities.
    b. There is a steep learning curve for configuring and managing drug libraries.
    c. There is difficulty in managing the same drug used in multiple units in multiple ways.

## Understanding the Issues: Information Systems and Drug Libraries

Today's infusion pumps are complex systems, connected to wired or wireless networks and information systems, and, increasingly, to drug libraries and electronic medical records. When these systems are well designed and integrated, infusion devices can:

- Improve patient safety
- Reduce medical errors
- Improve charting
- Promote best practices with standardized drug concentrations
- Increase the efficiency of medication use, giving clinicians more time to focus on patients
- Facilitate technical support
- Capture valuable information
- Support information sharing
- Streamline information processing

But the bane of all this connectivity is that, in many healthcare settings, the technology has not caught up to clinical needs. The many kinds of infusion devices and systems are not always interoperable, which can compromise device availability, clinical practices, information collection and use—and patient safety. Healthcare institutions often have to manage the development of device and system integration and interoperability into their own information systems, which can be a major undertaking for large, mid-size, and small institutions alike. Wireless technology adds another layer to this challenge, because robust wireless infrastructures and information security are critical. Summit participants noted that wireless technology is not always reliable—and it could be unavailable in the event of a natural disaster or other emergency.

Incorporating drug libraries into this mix offers an additional set of challenges—and opportunities. Variability among drug formularies (lists of preferred drugs), infusion concentrations, and dosing parameters used by healthcare institutions are key issues. Individual institutions must develop their own parameters for drug libraries—or borrow them from other facilities. This latter solution might not be an appropriate one, summit participants noted. The profiles and needs of different facilities might not match. And it's important for institutions to understand how the drug libraries they use were developed: the considerations and decisions behind drug libraries matter. Institutions need to "own" their drug libraries—by knowing what's in them and why.

Right now, many healthcare organizations allow a wide variety of different infusion concentrations—from five to 45, depending on the drug, according to a survey of pharmacists by the American Society of Health-System Pharmacists (ASHP). ASHP, which represents 35,000 pharmacists in hospitals and healthcare systems, has been focused on this issue since a 2008 summit on achieving fail-safe use of IV medications. ASHP is working on a recommendation from that summit to develop nationally standardized drug concentrations and dosing units for commonly used, high-risk drugs used in infusions. Specifically, ASHP aims to:

- Standardize infusion concentrations that
  - Are limited to as few concentrations as possible
  - Are clinically appropriate for the majority of patients
  - Include the most commonly infused medications
- Standardize terminology for dose and rate
- Provide evidence-based recommendations for upper and lower dosing and rate limits
- Recommend standard procedures for ordering, preparing, and administering drugs

Standard drug concentrations and dosing would reduce errors, facilitate technical support, and increase efficiency, said summit presenter Bona Benjamin, director of medication-use quality improvement at ASHP. Use of standardized infusion concentrations could facilitate faster approval for new drug concentrations and result in an increased number of products available in ready-to-administer form.

There are barriers to this work, however. For starters, "patients are not standardized," Benjamin said, "and we know that it's neither realistic not clinically appropriate to use standard concentrations in all patients." Physicians and nurses, not surprisingly, tend to resist changing established practices—and practices vary in different care environments, facilities, and geographic regions. For this reason, determining "best practice" concentrations on a national level is a challenge.

Some regional groups have succeeded in this effort, Benjamin said, including the San Diego Patient Safety Consortium, which developed countywide standardization for 14 hospitals, and the Indianapolis Coalition for Patient Safety, a similar effort for 13 hospitals in seven healthcare systems.

Still, Benjamin cautioned, even a consensus-developed, evidence-based, open-source reference for drug standardization will not be a magic bullet. "We know that a list of standardized concentrations is not the same as a drug library," she said. "However, it's a necessary first step to give practitioners a common foundation and reference on which to build a smart library."

A drug library should be "a framework for safer practice," according to summit presenter Erin Sparnon, senior project engineer at ECRI Institute's Health Devices Group. Well-designed and integrated technology features can support the "five rights" of medication safety (right medication, dose, time, route, and patient). A drug library can eliminate gross misprogramming or titration errors, allow for efficient and correct autoprogramming, and enable bar code readings of drugs.

"No single safety technology can be perfect, but if you add enough layers of 'Swiss cheese,' you might be able to prevent more errors," she said, referring to British psychologist James Reason's model of system safety. In this model, the holes in a slice of Swiss cheese represent areas where errors or failures could occur. Minimizing the holes and creating multiple overlapping layers of Swiss cheese decreases the likelihood that an error will slip through. To prevent errors, ECRI recommends:

- A comprehensive dose error reduction system (DERS) with both drug library and log-analysis software
- A two-way wireless communication and server system, capable of interfacing to other systems, including pharmacy and documentation
- A pump design that supports future software upgrades

## LEAD-USER PROFILE: Duke University Medical Center, NC

**WHEN DUKE UNIVERSITY MEDICAL CENTER** decided to install smart pumps in its three-hospital system, it began not with the technology but with the people who would use it.

The planning started 18 months before the implementation, with focus and work groups that involved stakeholders throughout the system. "This required a collaborative effort that spanned the entire culture of the medical center," said summit presenter Glenn Scales, certified biomedical equipment technician and patient safety specialist at Duke. "It required buy-in. We engaged people who had typically not been involved."

This extensive planning resulted in a modular smart pump system, with smart pumps that went live in 2005, wireless connectivity added in 2007, and patient-controlled analgesia (PCA) pumps and a wireless expansion in 2008. Since then, Duke has integrated the drug library into a computerized physician order entry (CPOE) system—another benefit that took months of planning—and added hard limits on heparin and insulin infusions, made low-limit adjustments, and minor tweaks and expansions for new therapies.

"Smart pump technology enabled us to get things done that we had not been able to do before," including consolidating the drug library with standardized dosages—most notably in pediatrics, Scales said. "Smart pumps have had a dramatic impact on the severity and number of events we've had over time."

Smart pumps have brought new challenges, however. "The pumps aren't smart enough," Scales said. People can be "extraordinarily inventive" in overriding the checks that are built into the devices. Cross checking of infusion settings remains limited. And there is a sense of information overload from the continuous quality improvement (CQI) data collected by the infusion devices. Data analysis is highly labor-intensive, he said, and staff time for this process is constrained.

## LEAD-USER PROFILE: Intermountain Healthcare, UT

# Developing a Smart System of Pump Alerts

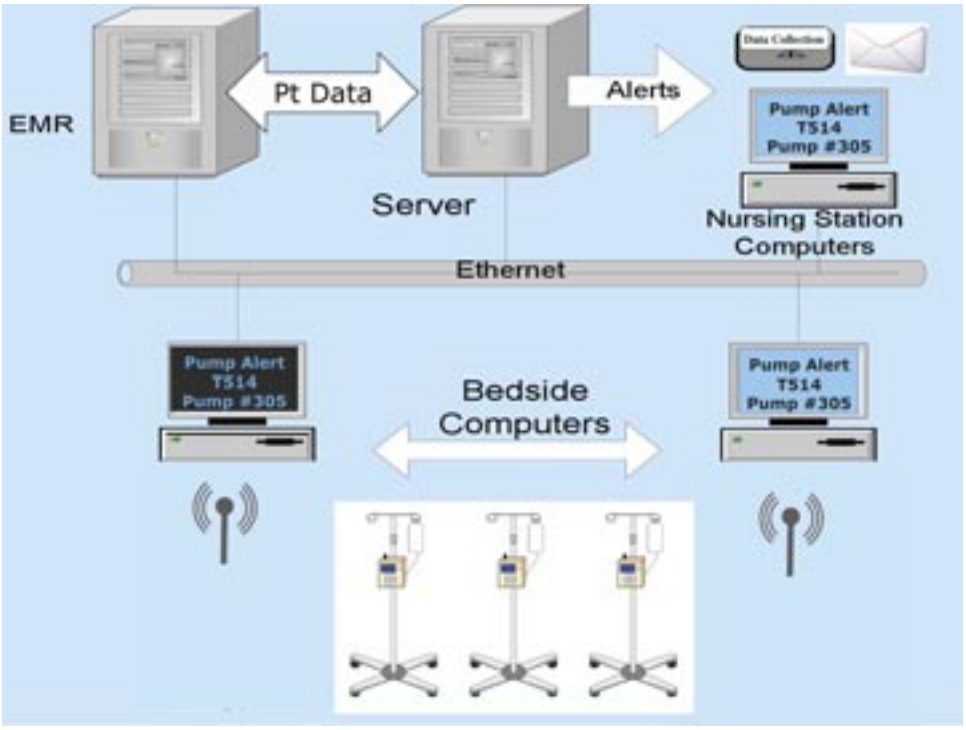
**IT TAKES MORE THAN SMART PUMPS** to produce the greatest benefits to patient safety. It takes a smart *system*. At Intermountain Healthcare, which serves the medical needs of Utah and southeastern Idaho in 22 hospitals, a smart system developed in-house is producing results and helping people work smarter as well.

The smart system features wireless connectivity of infusion pumps, bedside computers, and nursing station computers into a central database, which is connected to electronic medical records, as shown in **Figure 3**.

The system sets pump alerts for high-risk medications, including initial start limits—typically set limits—and rate change limits that take into account unit protocols, patient work flows, and patient variables, such as nutrition and insulin therapy. Simple or complex pump alerts can be developed, with information about the alerts delivered via e-mail, pages, or text messages to computers or mobile devices, according to summit presenter Rick Carlson, pharmacist and board certified pharmacotherapy specialist at Intermountain Medical Center. Rules for the alerting database can be modified easily with the help of medical informatics and computer programmers.

Analysis of the smart system over almost two years showed that 137 alerts saved patients from harm.

**Figure 3. Intermountain Healthcare's Smart System**




Source: Rick Carlson. "Enhanced Notification of Infusion Pump Programming Errors." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 5, 2010.

## LEAD-USER PROFILE: Lancaster General Hospital, PA

### Interoperability: The Next Step in Medication Safety

**LANCASTER GENERAL HOSPITAL** harnessed the power of emerging technologies—and its vendors—to create a seamless, interoperable system that supports medication safety. The übersystem links infusion pumps and the people who use them with a host of data systems, including medication orders, a drug library, electronic medical administration (eMar) records, bar code medication administration (BCMA), and reporting, as shown in **Figure 4**.

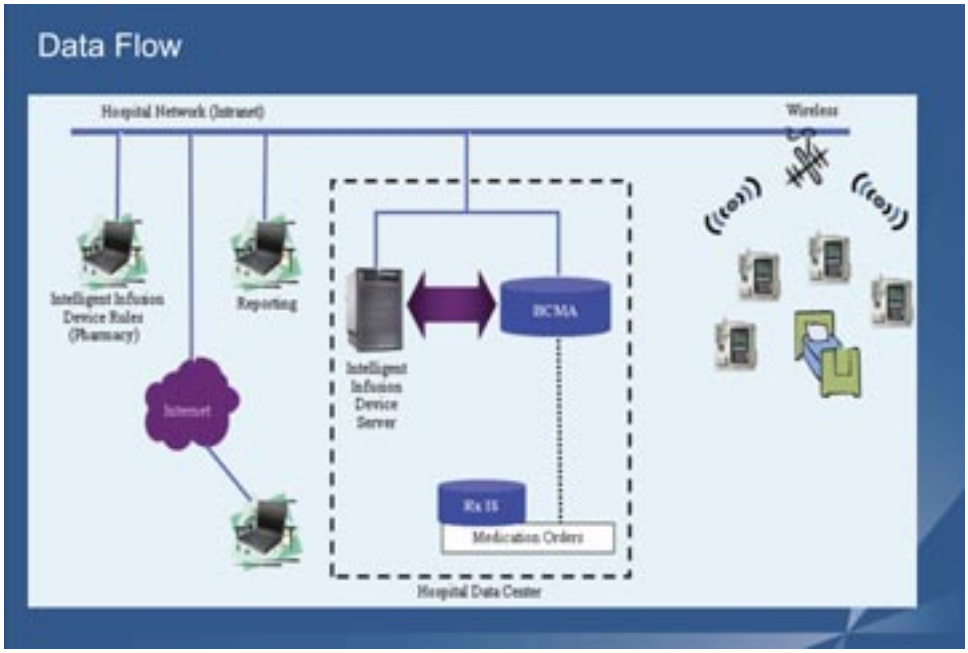
"It's all wireless—and hospitals, if you're not already there, you should be," said Amanda Prusch, pharmacist and medication safety specialist at Lancaster General. The two-way system builds in checks and counter-checks in the clinical workflow to satisfy the five rights of patient safety (right medication, dose, time, route, and patient), as shown in **Figure 5**.

"Drug library compliance pretty much doubled after introducing IV interoperability," Prusch said. "We think IV interoperability is really the next additional step for IV medication safety. It is cutting-edge technology and it's still evolving. This was a huge collaborative effort with our pump vendors, bar coding vendors, pharmacists, information services, and biomedical engineering."

The system also streamlined the workflow and potential for errors by moving from manual to automated programming, reducing a 17-step process to seven steps and reducing nursing time for pump setup by 24.8 percent, said summit presenter Tina Suess, a nurse and system administrator at the hospital. The hospital conducted a validation study comparing manual and automated programming by nurses—and found that manual programming was replete with errors. "We wanted to make it safer for our nurses to administer IV medications," she said. "And we wanted to prove that this was worth our time and money."

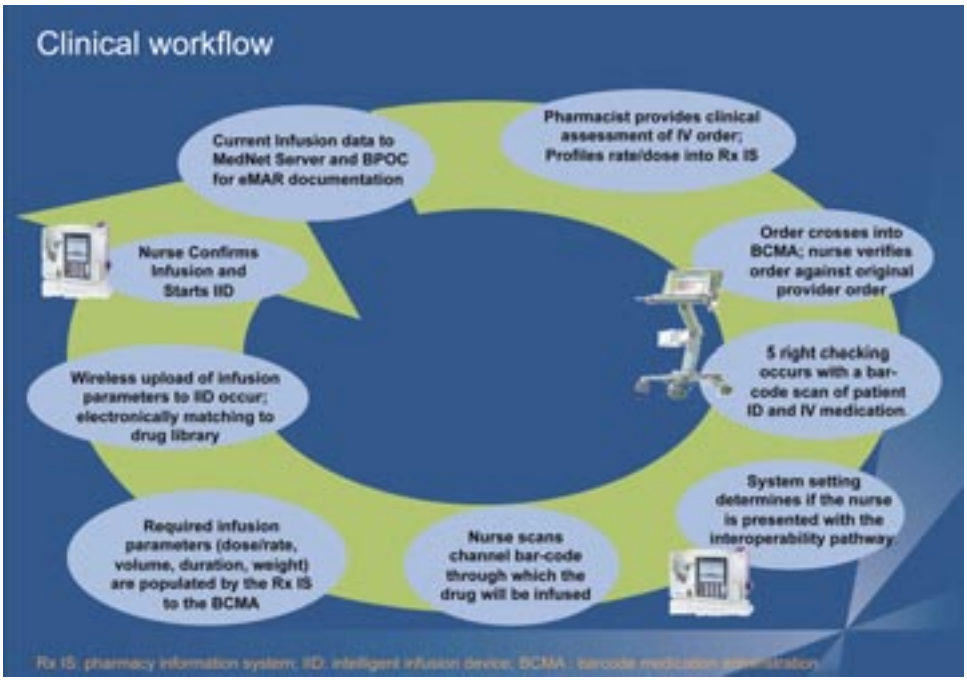
**Figure 6** shows the challenges of manual pump programming and the advantages—no longer in question—of the interoperable system.

**Figure 4. The Data Flow in an Interoperable System**




Source: Amanda Prusch and Tina Suess. "IV Interoperability: Smart Pump and BCMA Integration." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 6, 2010.

## Figure 5. Clinical Workflow Builds in Medication Safety Checks




Source: Amanda Prusch and Tina Suess. "IV Interoperability: Smart Pump and BCMA Integration." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 6, 2010.

## Figure 6. A Comparison of Manual Programming and IV Interoperability

Comparison: Manual versus IV Interoperability

| Challenges of Manual Pump Programming | Advantages of IV Interoperability |
|---|---|
| Manual input process | Pump programming parameters (dose/rate, weight, volume to be infused) populated by order |
| User must opt into safety features | Magically occurs; guarantees correct medication is selected |
| Complex workflow on limited real estate | Streamlined workflow<br>Nurse must focus on one IV task<br>Pump alerts display on computer screen |
| Limited drug library size | Can program rate and volume to be infused off the order for medications NOT in the drug library |
| Pump settings are influenced by the user | Standardization is introduced; pump is programmed according to order |
| Disconnect between what occurs on the pump and medical record | Pump settings are documented in the medical record |
| Process totally owned by the nurse | Pump is populated with clinically appropriate, evidence-based, safe infusion rates as profiled by pharmacist |

Source: Amanda Prusch and Tina Suess. "IV Interoperability: Smart Pump and BCMA Integration." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 6, 2010.

## EXPERT PERSPECTIVE: Automate, Standardize, Expedite

### Alan Lipschultz
**Christiana Care Health System**

**WHAT COULD THE HEALTHCARE COMMUNITY DO** to improve infusion device safety? Alan Lipschultz, director of clinical engineering at Christiana Care Health System in Delaware, pointed to the common themes of mitigating use error and making it easy for people to do that right thing in offering these three recommendations:

- **Automate processes.** Every step in the infusion process should be examined, from the moment a physician writes a drug order until the drug is delivered to the patient, with an eye toward making each step less dependent on humans alone. "The more you can streamline and automate processes, the more effective the system will be in meeting the five rights of medication safety," Lipschultz said, referring to the right medication, dose, time, route, and patient.

  Ideally, bar coding technology should be used on drugs, drug orders, drug bags, pumps, healthcare providers, and patients to ensure correct matches. Interoperability of systems, "the Holy Grail that people have been chasing," should be the gold standard.

- **Standardize devices and protocols.** Infusion devices should be intuitive to use. "As an example, when you rent a car, you can be sure that the accelerator is to the right of the brake," Lipschultz said. Standard layouts for the most important device features would make it easier for people to use different devices as well.

  Likewise, he said, "physicians and clinicians have been learning that there are benefits to standard protocols. When a patient has chest pain, there are standard things that you do—and if you do them, outcomes go up." Clinicians and pharmacists could apply this same mindset to every step of the drug ordering and delivery process. "Standards are doable if people are willing. Clinical engineering can act as a facilitator, making sure that the right people are talking, but it has to come from clinicians and pharmacists."

- **Expedite fixes.** A software glitch in Christiana Care's infusion pumps illustrates Lipschultz's concern that problems are solved too slowly. The healthcare system, which has more than 1,100 patient beds in two hospitals, rolled out new infusion pumps between February and May of 2009. By July of 2009, the healthcare system had identified a problem. The pump software sometimes crashed, resulting in what Lipschultz termed "the blue screen of death," which requires restarting the pump to get it back into service, or, worse, "the white screen of death." For the latter failure, "We're hosed. We can't reboot," he said.

  Christiana Care reported these problems in July 2009. By October 2009, the manufacturer told the healthcare system that it had resolved the problem with a software fix. However, because of FDA's stepped-up static analysis of software changes in infusion devices, the updated software might not be released until mid-2011. In the meantime, Christiana Care has documented more than 100 pump crashes, Lipschultz said.

  The pump does sound a loud alarm when it crashes, which so far has helped avert any adverse patient incidents beyond delay of medication—which for some patients could be risky. Still, this doesn't make it easier for Lipschultz to sleep at night. He advocates releasing the software that fixes the known bug before the thorough software analysis is completed.

  In response to this recommendation, FDA said: "It would be a premature move to approve an unfinished product without a thorough software analysis. Our role is not to jump to quick fixes, but to actually make sure a fix fixes something. We've had unfortunate experiences where we have tried to be speedy and the fixes were not beneficial."

## EXPERT PERSPECTIVE: Develop Artificial Intelligence to Analyze Data

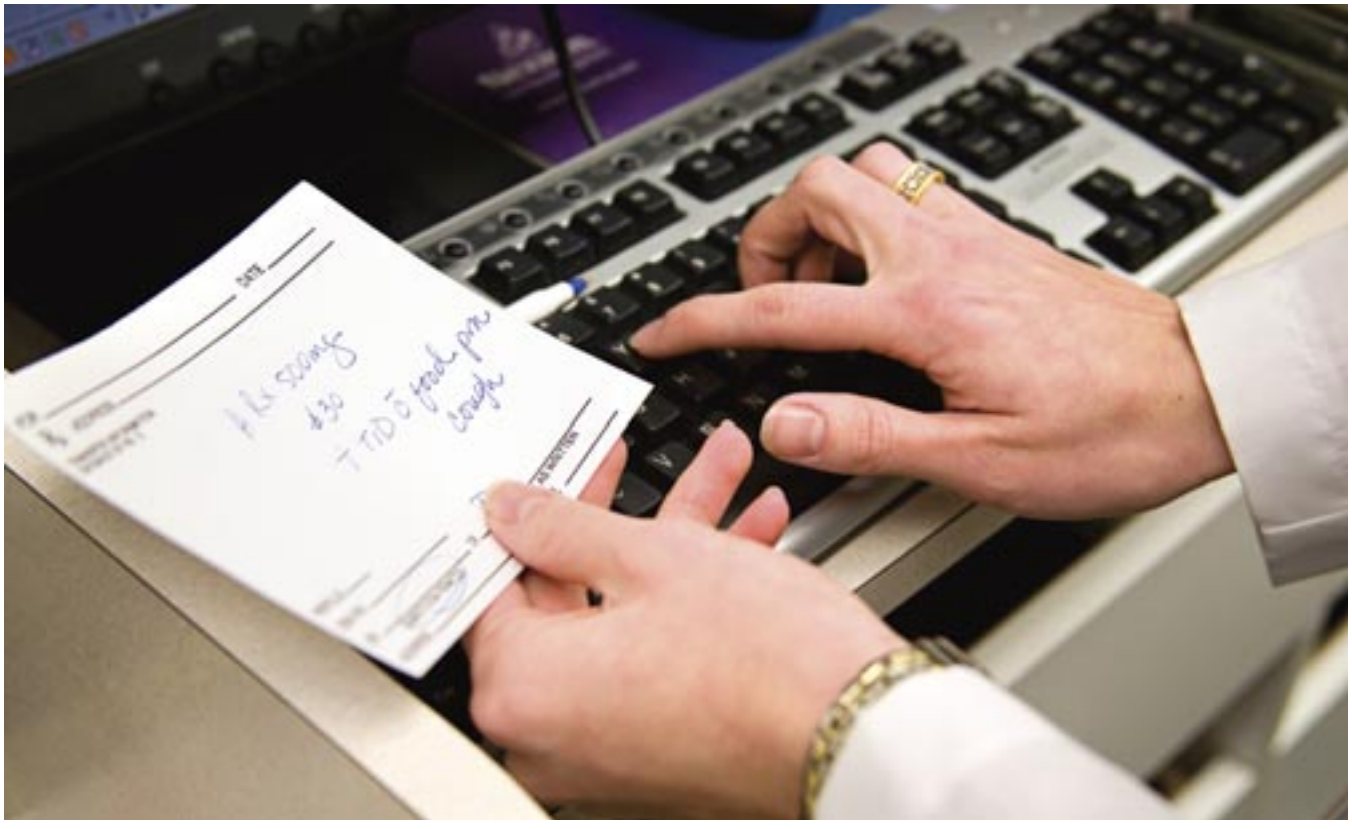

### Glenn Scales
**Duke University Medical Center**


**SMART PUMPS COLLECT A TROVE OF DATA.** But they don't yet provide adequate tools for analyzing this data, according to Glenn Scales of Duke University Medical Center.

Healthcare systems can review the continuous quality improvement (CQI) data accumulated by smart pumps on a regular basis. Making sense of this data is a challenge, however.

"When we pull the data out of the pumps, we get a spreadsheet that's about 30 columns wide with 85,000 rows of data," Scales said. "It's hard to find time with the right kind of people to pull the data together and analyze this information. We spend hours trying to find patterns in this data."

While there are some software tools that support data analysis, they're not yet powerful enough, he said. It takes human beings—physicians, nurses, pharmacists, and other healthcare professionals with an understanding of clinical practices in specific settings—to spot institutional issues. Even then, "the data is interesting, but it never really answers the question, why? The software hasn't kept up. There's not enough artificial intelligence to do what the human brain can do."



> **"We need to design safety features that make it easy for the user to do the right thing."**
>
> —Matthew B. Weinger, M.D., Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, biomedical informatics, and medical education at Vanderbilt University School of Medicine

## CLARION THEME 3

**Mitigate use errors with infusion devices.**

### PRIORITY ISSUES:

8. A high percentage of sentinel/adverse drug events (ADEs) are due to use errors. It is imperative to figure out how to develop design safety features that make it easy for the user to do the right thing. Applicable human factors, automatic identification (e.g., bar coding), and the value of all the steps involved in drug administration should be considered.
9. There is a lack of standardization of terminology used in infusion systems (upstream and downstream devices)—and a clear need for the same wording, same spelling, etc., across the process, devices, containers, etc.
10. There is a lack of knowledge/familiarity with infusion devices and a lack of effective training in their use—from both manufacturers and facilities.

## Understanding the Issues: Use Errors

Smart pumps are neither as ingenious as humans nor as simple for intuitive use as they should be in demanding healthcare environments, summit presenters and participants emphasized.

Consequently, "use errors" in relation to infusion devices is a contentious topic in the healthcare community, especially for clinicians. Their point: the majority of use errors are made unwittingly, not with malice or willful disregard of potential patient safety risks.

"I don't think there are many people who come to work saying, 'I'm going to try to disable the safety features,'" said summit presenter Matthew B. Weinger, co-chair of AAMI's Human Factors Engineering Committee; professor of anesthesiology, biomedical informatics, and medical education at Vanderbilt University Medical Center; and staff physician at the VA Tennessee Valley Healthcare System.

Thus, summit presenters and participants argued for more user-friendly infusion devices that make it easier for people to do the right thing. Summit presenter Peter Doyle, human factors engineer at The Johns Hopkins Hospital, shared a sampling of findings from a user interface study, culled from a task analysis of nurses using large-volume infusion pumps, interviews and discussions with experts, field observations, and a literature review. Inclusion of a systems engineer from The Johns Hopkins Applied Physics Lab, Alan Ravitz, and clinical personnel in this study helped to assure a broad range of issues was addressed. The findings are presented below:

- **Medication labeling** varies in format and content from pumps to IV bag labels to medical record documentation. Such variation increases risk of programming errors.
- **Hardware design** enables incorrect tubing installation and removal of cassettes in a manner that invites risk.
- **Controls** are not standardized. Keypad controls, including number layout and decimal point placement, vary from device to device. "Soft" controls such as channel selections are not properly associated with labels in some instances. Functional grouping of controls and displays via color, for instance, is not used to best effect. Pump controls are difficult to read in dark environments.
- **Information displays** are hard to read and the marquee style display takes too much time to present needed information. While dose information is more important, rate is displayed rather than dose. Pressure history is not provided for fluid delivered. Indications of occlusion are overlooked because they are not intuitive. Cues to distinguish between similar drug names are insufficient.
- **Battery status** is only indicated when there is a low-battery alarm.
- **Drug lists** showing multiple concentrations may require more than one screen to display all options. Without a strong cue that there are more options on subsequent screens, selection of wrong concentrations has become a common error.
- **Programming prompts** can result in wrong doses. Prompts to enter rate or volume to be infused (VTBI) come before prompts on dose, which have resulted in incorrect rate calculations. Sufficient confirmation information is not displayed.
- **Failure to power the pump down or select a new patient profile** could result in incorrect drug delivery.

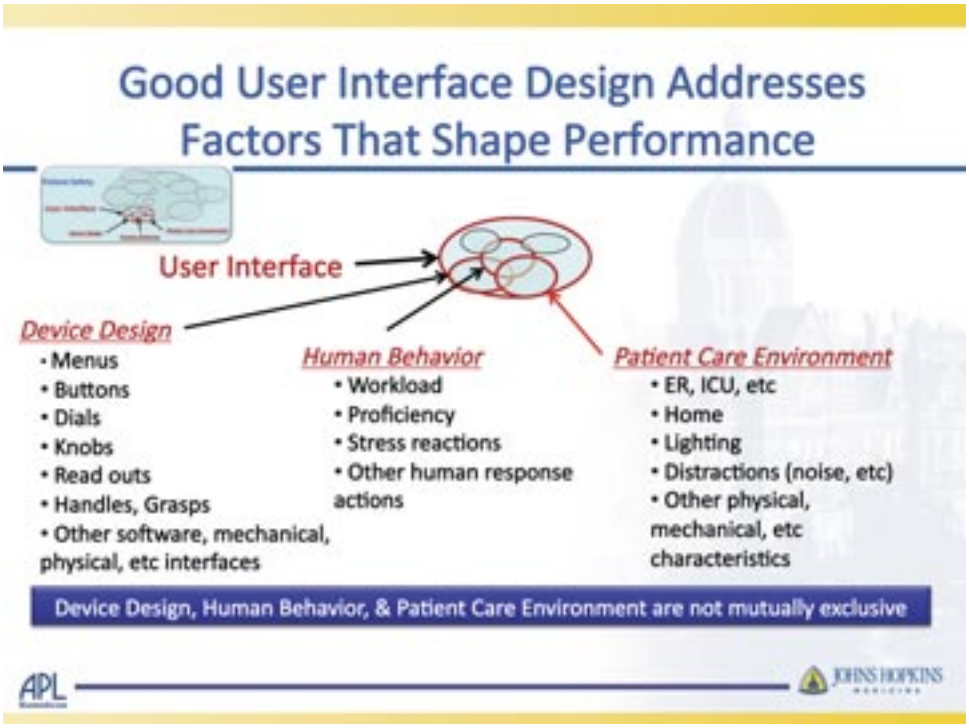
### A Definition of 'Use Error'

- Any device-related event in which the user–device interaction did not conform to either the user's expectations or the designer's intentions.
- The only use errors that are outside the scope of discussion are criminal intention or intentional negligent misuse.

Consistent with ANSI/AAMI/IEC 62366:2007, *Medical devices: Application of usability engineering to medical devices*, an FDA-approved document

- **Drug calculations** required of clinicians introduce the potential for errors in rates. Programmable rates do not allow those needed for bolus dosing of specific drugs.
- **Timing issues** can impede drug delivery. The power-up cycle and input of user recognition data can delay pump startup and drug administration. Pump menus do not include options to select smaller bag sizes so that the time of alerts is accurate for those bag volumes. There is no timely notification for preparation of subsequent medication bags. There is no delayed start option to support nurses' workflow. Sequences to correct programming errors may delay drug delivery.
- **Error checking** may be inadequate in some instances. A dose error reduction system (DERS) is not a fail-safe means of controlling dose. While it prevents extreme programming errors, it does not take patient factors into account. The pump display can be deceptive in indicating which medication is being delivered; the drug programmed might not match the bag. Bar coding the bags or networking the physician order entry (POE) system to the pump could provide this check. Pumps do not support programming checks by requiring a second clinician to repeat (match) the inputs. Procedural controls to assure the five rights of medication safety are not always sufficient. Errors in weight-based calculations could be reduced if patient weights from smart patient beds were communicated to the electronic health record.
- **Drug library options** may differ among hospital units, according to the level of care and patient needs, but not all options are appropriate for all units. The range of available patient profiles should be limited, depending on the unit.

**Figure 7. Good User Interface Design Addresses Factors That Shape Performance**




Source: Peter Doyle and Alan Ravitz. "Standardization of the User Interface." Presentation at the AAMI/FDA Infusion Device Summit, Oct. 5, 2010.

- **Alarm volume changes** affect signal tones (pitch). No notification is provided when an audio signal is locked out. Only one alarm signal is provided for all alarms, regardless of differences in criticality. Timing for "callback" notification is after, not before, infusion completion. Screen test and alarm test functions are not provided.

Doyle recommended a systems engineering approach to addressing these and other safety issues. The user interface, device design, human behavior, and the patient care environment are not mutually exclusive, as shown in **Figure 7**, indicating a need to address issues via a comprehensive systems engineering approach. "It would be much preferred," he said, "not to have to rely on training to compensate for interface issues that could be accomplished with design."

Weinger elaborated on user interface considerations from a clinician's perspective. He noted that a user interface is any aspect of a device with which a human can interact, including software, hardware, documentation, labeling, and packaging. Users include clinicians, lay care providers, cleaning and maintenance staff, and patients.

User interfaces should be informed by human factors—the formal study of human interactions with tools, devices, and systems to enhance safety, efficiency, and satisfaction. Human factors research is commonly applied in a wide range of domains, such as the airline, energy, and consumer products industries. Use errors, Weinger said, are often due to violations of human factors design principles, as shown below.

## Some Human Factors Principles

- Meet users' needs
- Be visible
- Design for error
- Keep it simple
- Be consistent
- Communicate
- Fail gracefully
- Minimize workload
- Automate wisely
- Focus on core tasks

In practice, these principles should be used to satisfy clinicians' needs and requirements with infusion devices—doing actual work, accommodating the complexity of care, and accounting for the context of use, such as interactions with other technology. Weinger offered these recommendations to manufacturers and other stakeholders for improving infusion pump design:

- **Develop a meticulous understanding of the user profile and user workflow.** "We spend too much time adapting our workflow to the pump," he said.
- **Make the pump configurable.** Add options to the software design to meet local cultural and workflow needs. "Users are different," he said. "We need to be able to tweak the options."
- **Use bar code technology.** Bar code standards are available today—and bar coding connected to the pump and the rest of the system provides a safety check and a backup when wireless systems fail.
- **Use design standards.** Manufacturers can't make a different pump for every hospital, but they could simplify and standardize the design. "Predictability is more important than configurability," he said. "Nurses work in more than one unit. The pumps might look the same on the outside, but they don't work the same on the inside. That's a big problem."

Still, a one-size-fits-all pump would invariably be a compromise suitable to no one, he said. Usability tasks and criteria, reporting of usability test results, and core and high-risk user interface features are aspects of infusion devices for which standardization makes sense.

The ANSI/AAMI standard, *Human factors engineering—Design of medical devices* (ANSI/AAMI HE75:2009), is an FDA-approved tool with human factors engineering design guidance, case studies, and checklists. Another FDA-approved tool, *Medical devices—Application of usability engineering to medical devices* (ANSI/AAMI/IEC 62366:2007), is intended primarily for manufacturers and technical committees preparing medical device standards.

## EXPERT PERSPECTIVE: Studying User Interfaces

**Peter Doyle**
**The Johns Hopkins Hospital**

**Q. What prompted you to undertake your user interface study of large-volume pumps?**

**A.** "Dr. Peter Pronovost of The Johns Hopkins University envisions a Public-Private Partnership to Promote Patient Safety (P5S). This partnership is modeled after an aviation safety initiative that included all system stakeholders in the pursuit of safety. Because the Johns Hopkins University Applied Physics Lab (JHU APL) has expertise in systems engineering, we invited them to participate with us in a study as a means to grow and develop the P5S methodology. Infusion pumps were identified as a good place to start because we recognized the risks of use and they constitute a relatively discrete device with many external 'arms and legs,' if you will, deserving attention for the sake of safety. Those arms and legs include programming interface design, drug libraries, labels, user skill and training, and environmental considerations. We recognized pumps are a good subject for partnering with stakeholders in the pursuit of safety. It was not long after that we learned of the FDA's initiative with AAMI's collaborative efforts.

"Systems engineering is a professional discipline that addresses the increasing difficulty of designing all aspects of complex new products. The goal is to produce products that meet all performance requirements—to include safety, operability, reliability, and supportability—over the life cycle of the system. A very broad, interdisciplinary team uses a variety of engineering processes and methodologies to control and coordinate diverse development tasks, manage risks, and ensure performance."

**Q. Your study identified a number of design and user issues. Are you collaborating with manufacturers or any other stakeholders to address the issues you raised? How?**

**A.** "For more than two years a diverse team at The Johns Hopkins Hospital has met monthly with one pump manufacturer to share clinical experiences and obtain and review safety data. We also conducted a hazard analysis (a failure modes and effects analysis, or FMEA) and communicated the results to the manufacturer. Realizing the issues identified were not unique to one manufacturer prompted us to look more broadly at the challenge to affect design industry-wide. Then, as the FDA initiative developed, we rolled our efforts into the FDA/AAMI undertaking."

**Q. How widely used is the systems engineering approach in healthcare? Is it becoming more important as medical devices and IT converge and become more complex?**

**A.** "While I am not sure how widely it is used, I suspect that it is used in varying degrees by different organizations. It is our opinion that the very detailed and all-encompassing systems engineering processes practiced at JHU APL would add value to the methods used by commercial healthcare developers. We hope to progressively demonstrate the value of employing these techniques as we develop the P5S approach.

"Systems engineering is absolutely more important given the increased electromechanical, IT, operation and maintenance complexity of devices, the support systems required, and the training and skill demands of the users, who conduct their tasks in a fast-paced environments where failures have severe consequences."

**Q. You noted in your presentation that task analysis could be used to analyze additional tasks, such as anesthesia use and maintenance, and other pump devices. Do you plan to undertake such studies? What additional issues do you anticipate you could discover?**

**A.** "We have a plan to do a comprehensive user requirements analysis and develop simulation tools to evaluate many aspects of pump use with some prototype designs—we're waiting to hear on funding. Anesthesia use differs in that the pump is not monitored so remotely. Also the users have different training, skill sets, and objectives. Maintainers can identify and prevent failure modes. Each user/maintainer may provide beneficial input for new design requirements."

**Q. Could the systems engineering approach and usability studies that you employ be undertaken at smaller facilities, or those that are not focused on research?**

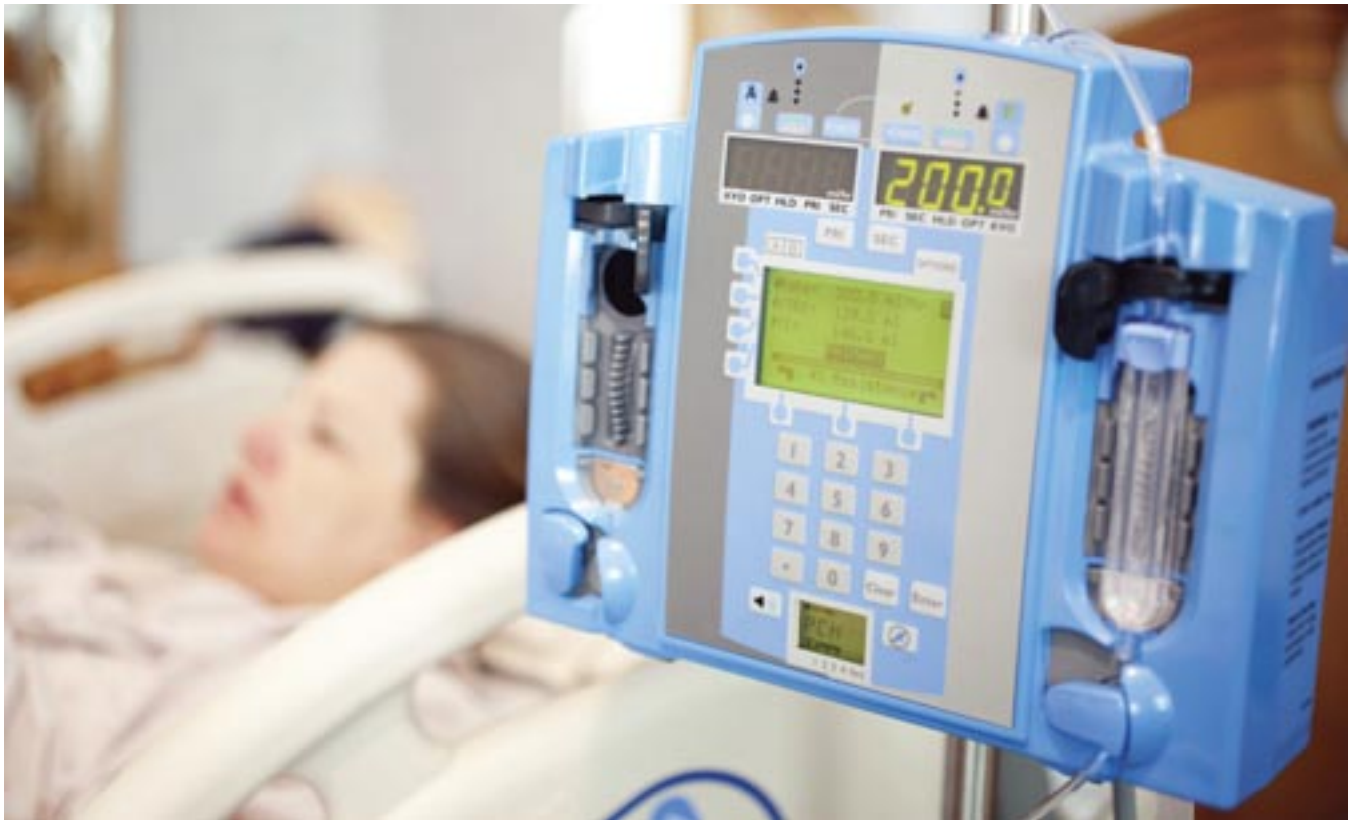
**A.** "The depth or breadth of studies would not deny the possibility of learning valuable information. I would encourage anyone to engage in identifying failure modes and improvements. Sometimes the best findings come from unexpected sources."

**Q. If you were on a design team for infusion pumps, what would you ask designers and engineers to do to create safer pumps? What specific experiences with pumps would you share?**

**A.** "Specifics are many, but I would encourage the iterative use of usability testing of many operation protocols, from device concept on paper—yes, you can test that—to final and post-production models."

**Q. What are the education and training challenges that you, or the nurses on your team, face in working with infusion devices?**

**A.** "A very significant challenge is the time available for training. Production pressures and staffing limitations put the hurt on training opportunities. I believe that training technologies, such as computer-based multimedia training and embedded training (pumps with built-in means to provide training and feedback), are not used to their best advantage. These means can be very effective in the time-stressed environment we face."



## EXPERT PERSPECTIVE: User Interfaces and Use Environments

### Matthew B. Weinger
**Vanderbilt University School of Medicine and VA Tennessee Valley Healthcare System**

**Q. As a clinician, what prompted you to become active in promoting greater use of human factors principles in medical device design?**

**A.** "I have been interested in human–technology interactions in healthcare since college (30 years ago) when I was a dual electrical engineering and biology major at Stanford with an interest in the relatively new field of biomedical engineering. When I was a first-year medical student at UC San Diego, I worked with John Brimm on a decision support system in the cardiothoracic ICU. I was struck by the sheer amount of technology around the fresh post-op heart and the demands that technology made on the nurses."

**Q. In your presentation, you argued passionately for greater consideration of clinicians' needs in the design of user interfaces. Is the medical device industry behind other industries you mentioned, such as the airline, energy, or consumer products industries, in using human factors design principles? If so, why?**

**A.** "Yes, in general, healthcare is behind other industries in adopting state-of-the-art quality and safety interventions. It is also behind the consumer products industries in its ability to be customer-centered and customer-driven—meaning patient-driven. With regard to human factors, I'd estimate that healthcare is still on average 20 years behind other complex, high-risk, technology-oriented industries like aviation and energy."

**Q. Are there special barriers to studying human interactions with infusion devices? If so, how could these barriers be addressed?**

**A.** "The devices are actually quite complex as are the diverse environments in which they are used. I'd speculate that infusion pumps are the most widely used, complex, computer-based technology in healthcare today. They are much more ubiquitous than equivalently complex devices like ventilators, have a wider range of uses than most devices, and are used by a wider range of users (including patients). Obviously, the use of an infusion pump at home by an elderly, far-sighted, tremulous arthritic diabetic patient will be worlds apart from use of the same pump by an anesthesiologist in an operating room. So it is perhaps not surprising that it is challenging to design effective, safe, usable, efficient, and satisfying infusion pump user interfaces.

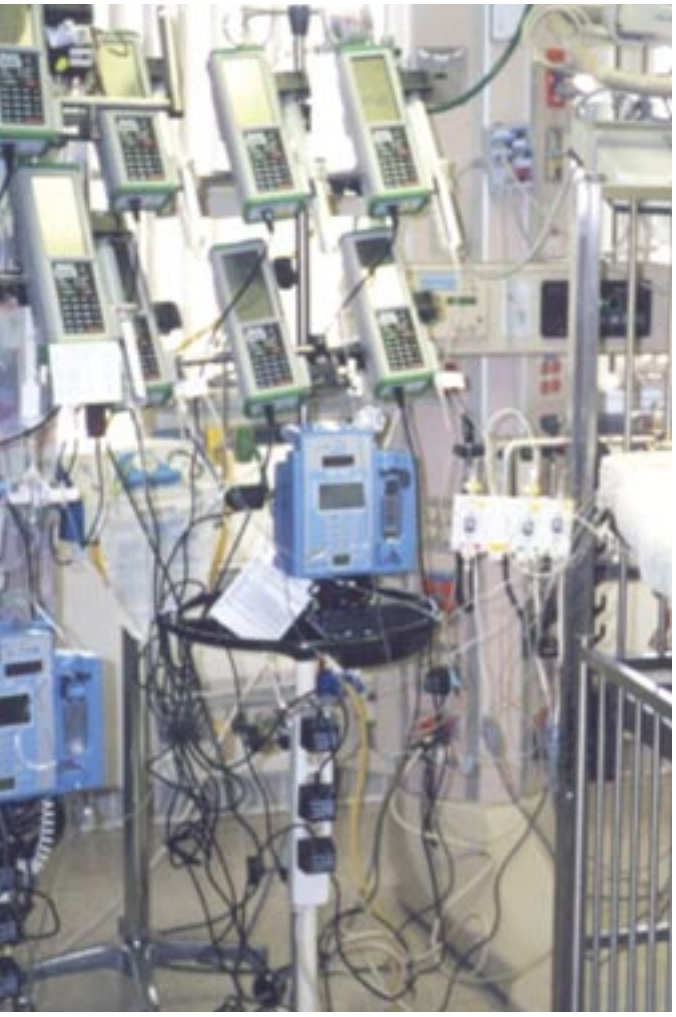
"High-fidelity simulations of infusion pump use are more challenging and expensive to create. However, high-fidelity simulation has become much more available in the last 10 years."

**Q. You are an editor of a new book, *Handbook of Human Factors in Medical Device Design*. What topics in the book are pertinent to infusion device design and mitigation of use errors?**

**A.** "Much of the book is relevant to infusion pump user interface design. The book is intended to complement the new ANSI/AAMI HE75 national standard on the design of medical device user interfaces. For example, chapters of direct relevance include Controls, Displays, and Environment of Use."

**"Multiple IV infusion errors are both prevalent and harmful."**

—Andrea Cassano-Piché, human factors engineer
at the University Health Network Centre for
Global eHealth Innovation, Toronto



## CLARION THEME 4

**Improve management of multiple infusions.**

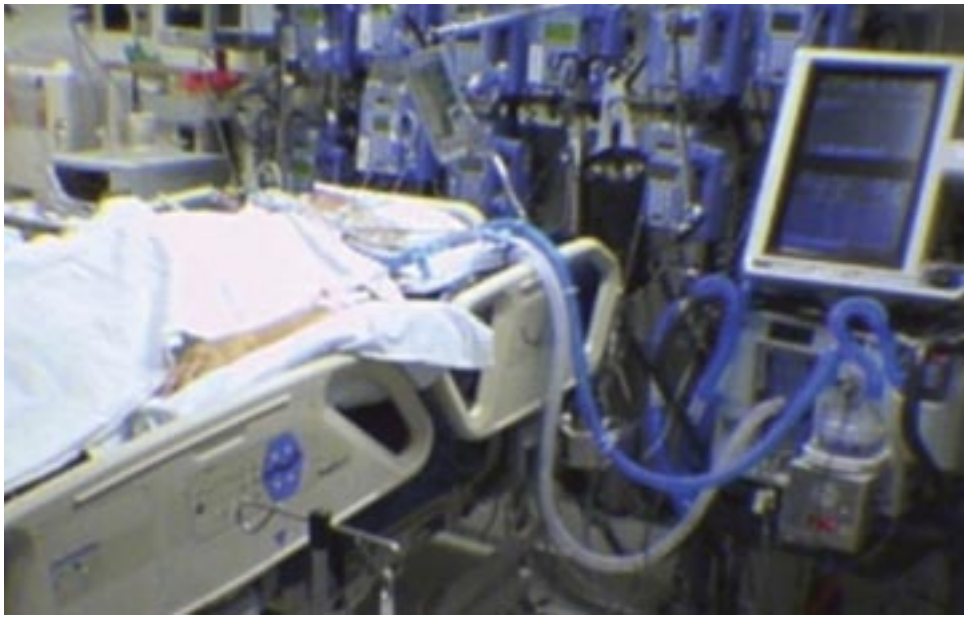
### PRIORITY ISSUE:

11. There is difficulty in infusion line management—including containers, manifolds, catheters, and transport—reflecting the complexity of multiple infusions, including secondaries, disposables, etc.

## Understanding the Issue: Multiple Infusions

All of the human factors and user interface issues that summit presenters and participants identified with infusion pumps are compounded with multiple infusions. This priority issue makes such an impact on patient safety—and raises an even different set of concerns—that both summit participants and AAMI experts believe it needs its own call to action.

Working with multiple pumps simultaneously, each of which could be very different, escalates the potential for errors. The ancillary medical equipment associated with many different devices is difficult to manage as well. The expert perspectives below elaborate on the challenges.



## EXPERT PERSPECTIVE: Managing Multiple Infusions

**Matthew B. Weinger**
**Vanderbilt School of Medicine and VA Tennessee Valley Healthcare System**

**Q. What are the clinical challenges of multiple infusions?**

**A.** "Managing multiple lines and pumps adds appreciably to the complexity for clinical users. But it also makes it challenging for manufacturers to assure patient safety because they currently have no control over what happens after a drug leaves their pump. For example, a pump currently cannot tell where the pumped drug is going or whether any incompatible drugs or fluids are being intermixed.

"To address these important safety issues, we are going to need some innovative technologies. I believe that we will need technologies at the IV site to measure what and how much is actually going into the patient's vein (as opposed to infiltrating). We will need better ways to manage all of the plumbing, with clear correct linkage to medication, pump, and patient. I like to say that what we'll have in the future is way to 'teleport' the drugs directly into the patient from the pharmacy à la Star Trek."

## EXPERT PERSPECTIVE: A Human Factors Approach to Studying Multiple Infusions


### Andrea Cassano-Piché

**Human Factors Engineer, University Health Network Centre for Global eHealth Innovation, Toronto**


**Q. Can you describe the study of multiple infusions that you are conducting? Why did you undertake it?**

**A.** "We are conducting a study on the nature and frequency of errors related to the administration of multiple IV infusions. Our objective is to better understand the types of risks contributing to errors and then identify and validate potential risk-mitigation strategies.

"The study came about in response to a heightened level of awareness of multiple IV infusion risks after performing a human factors study on smart IV pumps. When comparing user performance on traditional large-volume IV pumps versus smart IV pumps, it became apparent that errors associated with administering multiple IV infusions to a single patient were not mitigated by current safety technology, and had potentially severe outcomes. A review of two independent incident databases confirmed that multiple IV infusion errors are both prevalent and harmful, and a review of the literature showed that this problem has not been systematically studied and that mitigation strategies currently in use have not been validated."

**Q. When will you have results to share?**

**A.** "We expect to have results to share in early 2012."

**Q. What are the confounding issues in hospitals and other healthcare settings for managing multiple infusion lines?**

**A.** "The most prevalent issue is the overall complexity of the medication administration system. A large number of components—including an order, a prepared and labeled drug container, tubing, a pump, connectors, and patient access—all need to be arranged in exactly the right way for an infusion to be administered safely. There are a lot of decisions and actions that have to be made correctly by several different clinicians. As the number of IV infusions on a patient increases, so does the complexity. More complexity leads to more errors."

**Q. How could human factors studies and design principles be used to help clinicians avert incidents with infusion devices?**

**A.** "Human factors studies aim to understand the level of complexity in the system and identify opportunities to reduce it to a level that is appropriate for humans to manage safely. That is, they identify the required complexity needed by the users to support their role and the extraneous complexity that can be reduced using a variety of approaches, such as standardization, reducing the total number of steps in a task, automation, and the application of usability principles to the design of user-technology interfaces.

**Q. You've contributed to the development and presentation of Human Factors 101, a course offered monthly to healthcare workers at the University Health Network. What kinds of healthcare workers take this course? What do they learn? Should all healthcare workers take a course like this?**

**A. "**Human Factors 101 is a course aimed at clinicians and healthcare administrators to get them thinking from a broader systems perspective about system safety and safety culture. We use case studies to highlight foundational human factors principles, such as limitations on attention and memory and cognitive biases. We also discuss more controversial topics such as culpability and team dynamics. We've had just about every type of hospital employee as well as representatives from industry and other types of healthcare organizations participate in our course.

"It is surprising that human factors concepts that have been talked about by quality and safety practitioners in healthcare for over a decade are still new for most attendees. This is probably because human factors education is not an integral part of medical training. I think all clinicians need to be exposed to human factors education both in their academic training and throughout their professional development."

"What could go wrong? Let me count the ways."

—Christine Kessler, R.N., M.N., nurse practitioner
at Walter Reed Army Medical Center's
Diabetes Institute

## CLARION THEME 5

**Reconcile challenges and differences in the use environments of infusion devices.**

### PRIORITY ISSUES:

12. Alarm management is not effective.
    a. There are high numbers of false alarms, which also can lead to true alarms being ignored (e.g., air).
    b. Alarms are difficult to prioritize.
    c. It is unclear how to resolve alarm issues.
13. Injuries are caused by a lack of differentiation between the use of infusion devices in hospitals and in other environments (e.g., home use). Products designed for the hospital environment are being used in home environments (and vice versa). There are design and user issues and differences among home, hospital, and other environments.

## Understanding the Issue: Use Environments

The healthcare settings in which infusion devices are used are enormously diverse, ranging from hospitals to alternative care and mobile facilities to homes. In each of these environments are more facets of diversity—in terms of such variables as size, location, infrastructure, services, staffing, professional capacity, and patient profiles.

Infusion devices do not always mesh well with their environments. This plays out in ineffective alarm management, inappropriate uses of infusion devices in some environments, and design and use issues that differ, depending on the use environment, summit presenters and participants said.

Ineffective alarm management encompasses a number of serious problems. False alarms abound. Alarms are too soft or too loud. Alarms from different devices cannot be distinguished. Alarms do not always indicate the severity of the problem, making it difficult to prioritize alarm responses. Not all infusion complications prompt an alarm. Alarms can be turned down or turned off inappropriately. Alarms fail. And these uncertainties can lead to alarm fatigue—and inadvertent failure to notice and respond to true alarms.

For this priority issue, summit presenters and participants suggested these starting points for action to reconcile challenges and differences in use environments:

- Standardize alarms.
- Clarify roles and responsibilities of manufacturers and users.
- Build protocols for alarm responses into alarms.

Several summit presenters addressed issues with insulin pumps, which are widely used in home and mobile environments and exemplify challenges and differences in different use environments.

FDA is investigating infusion device safety through the lens of software, a key device component, according to summit presenter Paul L. Jones, senior systems/software engineer at FDA's Center for Devices and Radiological Health. FDA is piggybacking on its Generic Infusion Pump Project, which began with PCA pumps, to develop model-based software that incorporates safety principles, properties, and methods for insulin pump use.

"We are in the process of putting together a safety analysis, guidelines, and user computer science tools to reason about the safety of devices," Jones said. Manufacturers will be able to use or adapt these safety models and reference specifications to verify the safety of different classes of infusion pumps. Academic and clinical researchers are collaborating with FDA on this project.

"Our interest is to gain knowledge from technology to regulate more effectively and efficiently," Jones said. "We hope to have a regulatory and public health impact," including an infusion pump guidance document, an insulin pump standard, and insulin pump safety.

Improving insulin pump safety could, indeed, have a significant public health impact. "Thirty-eight percent of all medication errors are made with insulin," said summit presenter Donna Jornsay, B.S.N., R.N., a diabetes educator and clinical specialist at Long Island Jewish Medical Center in New York. "These numbers are particularly relevant to the increasing number of children with diabetes."

Clinicians who treat diabetic patients with insulin pump therapy make an impact on public health one patient at a time. The challenges and differences with insulin pump use environments vary with every patient. "What could go wrong? Let me count the ways," said summit presenter Christine Kessler, R.N., M.N., a nurse practitioner at Walter Reed Army Medical Center's Diabetes Institute. She catalogued a litany of errors associated with pumps, clinicians, and patients, including:

- Selecting the wrong pumps for particular patients, based on such patient factors as health, literacy, vision, ability, mobility, activity, and responsibility levels, as well as the availability of caregiver support
- Errors in setting up basal and bolus doses and rates
- Errors in calculating the duration of insulin action and "bolus on board," which differ with different pumps

- Errors in reminders and alerts
- Errors in guestimating and manually inputting carbohydrate intake

Smart pumps are making it easier to manage some of these issues. However, Kessler said, "The pump is only as good as the patient education. True risk management is follow-up, follow-up, follow-up."

## EXPERT PERSPECTIVE: Alarm Management

**Matthew B. Weinger**
**Vanderbilt School of Medicine and**
**VA Tennessee Valley Healthcare System**

**Q. How can alarm management be improved?**

**A.** "Alarm management will only improve when we have fully integrated alarm systems that are truly 'intelligent.' This will require a uniform plug-and-play standard for all medical devices and centralized alarm management so the information about patient status can be shared and utilized."

## LEAD-USER PROFILE: Massachusetts General Hospital

### Alarm Fatigue: 'An Issue Across the Country'

**WHEN AN 89-YEAR-OLD MAN** died in his bed at Massachusetts General Hospital, the alarms that should have gone off—but didn't—set off a different kind of alarm throughout the hospital, the city of Boston, the state, and regulatory agencies.

An investigation revealed that the volume on the patient's bedside monitor alarm and the alarm default setting for lethal arrhythmia had been turned off, according to summit presenter Lela Holden, Ph.D., R.N., and patient safety officer at Massachusetts General. Plus, 10 nurses on duty that day had not detected a lower-level, two-beep audio alarm at the central nurses' station or on scrolling tickertape messages on three hallway signs. This alarm signaled that the patient's oxygen and heart rate were critically low.

How was this possible? No one knew when or why the bedside alarm had been disabled. Very few people knew it was even possible to turn off the alarm default setting for lethal arrhythmia. Further investigation revealed staff confusion regarding monitoring and alarm system settings in a complex environment—one with two central systems, multiple models of devices and software versions, a large number of patients on monitors, and a lack of standards for monitoring. Alarm fatigue and desensitization were uncovered as well.

The hospital drew attention from all corners for this fatality, including coverage in *The Boston Globe*, and scrutiny from state and federal regulators and The Joint Commission. Their collective questioning actually helped the hospital staff learn from the event and come together in cross-functional teams to make improvement, Holden said. Now, clinical staff and monitor manufacturers do a double-check when devices are rolled out. There are standard defaults on monitors and a comprehensive process to review defaults. And the biomedical engineering department reports greater trust from clinicians for its independent validations of equipment, Holden said.

"Everyone has a role to play—clinicians, clinical engineers, vendors, journalists, and regulators," she said.

The tragedy underscored the fact that infusion pump problems can occur at even the best and most innovative hospitals. *U.S. News & World Report* ranked Massachusetts General, which pioneered the use of drug libraries in infusion pumps in 1996, fifth on its 2010 list of best hospitals.

## EXPERT PERSPECTIVE: Insulin Pump Use Environments—and Patients

**Robert Bernstein, M.D.**
Southwest Clinical Research Center and Regional Endocrinology Associates

**Suellen Minturn, R.N.**
Regional Endocrinology Associates

**DEPENDING ON PATIENTS** and their use environments, portable insulin pumps can be a veritable game changer with a dramatically positive or negative impact on life. "Virtually all of the patients whom we have helped get started on pump therapy think it's a big improvement for them," said summit presenter Robert Bernstein, principal investigator at the Southwest Clinical Research Center and an endocrinologist at Regional Endocrinology Associates in Santa Fe, New Mexico. "What they've told us is that they are less hypoglycemic and have less variability in their blood sugars with the pump. A lot say they just feel better."

At the same time, he said, "The great majority of problems we have encountered are due to patient error." At the summit, he offered several case studies that indicate the range of challenges—patients dropping pumps in water, exposing them to heat in hot tubs or saunas, reusing disposable equipment, and failing to securely reconnect tubing after disconnecting it. Such incidents can damage pumps or degrade insulin.

"To use an insulin pump requires a lot of attention," Bernstein said. When patients run into trouble, they tell him, "'I thought the pump would take care of everything.'"

But insulin pumps, like other infusion devices, aren't yet tough enough to stand up to patient neglect or misuse—or smart enough to rectify all user shortcomings or use errors.

Thus, clinicians share the responsibility with patients for successful insulin pump use, beginning with selecting patients for pump therapy, Bernstein said. Not all patients are candidates for insulin pumps, including patients who are not committed, interested, or capable of managing therapy and patients with literacy, vision, or hearing problems.

Clinicians who provide training and ongoing support to patients on insulin pump therapy have a similar—but magnified—challenge as hospital clinicians: working with a variety of pumps that do not have standard features. "They all run in a slightly different way," said Suellen Minturn, a nurse and certified diabetic educator at Regional Endocrinology Associates. If a patient calls her for help when she is not in her office, she has to recall the layout and functionality of a particular pump from memory. "I can picture the one or two preferred pumps. More than that, I don't know that I could."

From her experiences with patients, Minturn offered these suggestions for pump manufacturers:

- Offer a magnifying lens that fits over the screen, larger print, and brighter screens for patients with vision problems
- Make icons more intuitive—and offer a print option for patients who find it difficult to memorize "random" icons
- Translate the text into more languages
- Design a safety feature that alerts patients when the cannula—a small, soft tube that goes under the skin and connects to the pump—is partially occluded (not just completely occluded)
- Include sensors that can tell when there is resistance or hardened tissue at the infusion site
- Test alarm tones on a variety of age groups
- Offer a strong vibrating alarm so patients who are hard of hearing or asleep will notice it
- Build educational features into the pump, so patients can learn how their nutritional and exercise habits affect their blood sugars

# Where We Go From Here

> "Do or do not. There is no try."
>
> —Yoda

**NO ONE INDIVIDUAL,** working group, or organization can address the 13 summit priorities well in isolation. Prior to the summit, there was no coordinated, collaborative, multiple-stakeholder mechanism for addressing the challenges with infusion device systems. Many of the complex issues do not lend themselves to standards; FDA regulations cannot and should not address everything; and no single stakeholder has enough context or perspective to see the issues from the perspective of other stakeholders.

At the conclusion of the summit, Pat Baird, co-chair of the AAMI Infusion Device Standards Committee, and AAMI President Mary Logan announced the concept of a medical device safety council to serve as *the body that coordinates implementation of the action plans that result from the summit*. The vision for the safety council's first initiative, infusion device systems, is to convene, cajole, coordinate, collaborate, and celebrate specific clarion theme projects, with the success measure being *safer infusion*.

Nearly 100 summit participants signed up to participate on specific priority issues, and they will be invited to populate the working groups for each of the clarion theme projects.

## The Medical Device Safety Council/Infusion

The Medical Device Safety Council/Infusion is being established *within The AAMI Foundation*, which is a 501(c)(3) charitable and educational organization, thus supporting the overall goal of *improving patient outcomes by making infusions safer*.

While the initial, purposeful focus of the safety council is infusion device systems, there will be a next medical device challenge, flowing from the next summit(s) and other sources. For this reason, the structure is intended to be fluid, nimble—and ready to jump into the next issue if and when the time is right, as shown in **Figure 8**.

The AAMI Foundation expresses its gratitude to the following organizing committee members for their time, expertise, and passion for launching this work:

- Pat Baird, Baxter International, Inc.
- Bona Benjamin, American Society of Health-System Pharmacists (ASHP)
- Andrea Cassano-Piché, University Health Network, Centre for Global eHealth Innovation
- Glenn Scales, Duke University Health System
- Dennis Schneider, Baxa Corporation
- Nat Sims, Massachusetts General Hospital
- Erin Sparnon, ECRI
- Tony Watson, FDA

## Funding

The AAMI Board of Directors in November 2010 approved the transfer of the approximately $15,000 in income left after paying all direct expenses from the summit to help get the safety council off the ground. AAMI absorbed all indirect expenses from the summit. As advised to all summit participants, AAMI will not be providing funding for the safety council going forward. The safety council was formed *by the will of the community* and thus must be supported financially *by the will of the community*. Contributions by individuals, hospitals, and other healthcare organizations, patient safety groups, consultants, industry, and others will be *essential* if the safety council is to be successful.

To make a donation, mail your check or money order to:

AAMI Foundation
Medical Device Safety Council/Infusion
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22201-1633

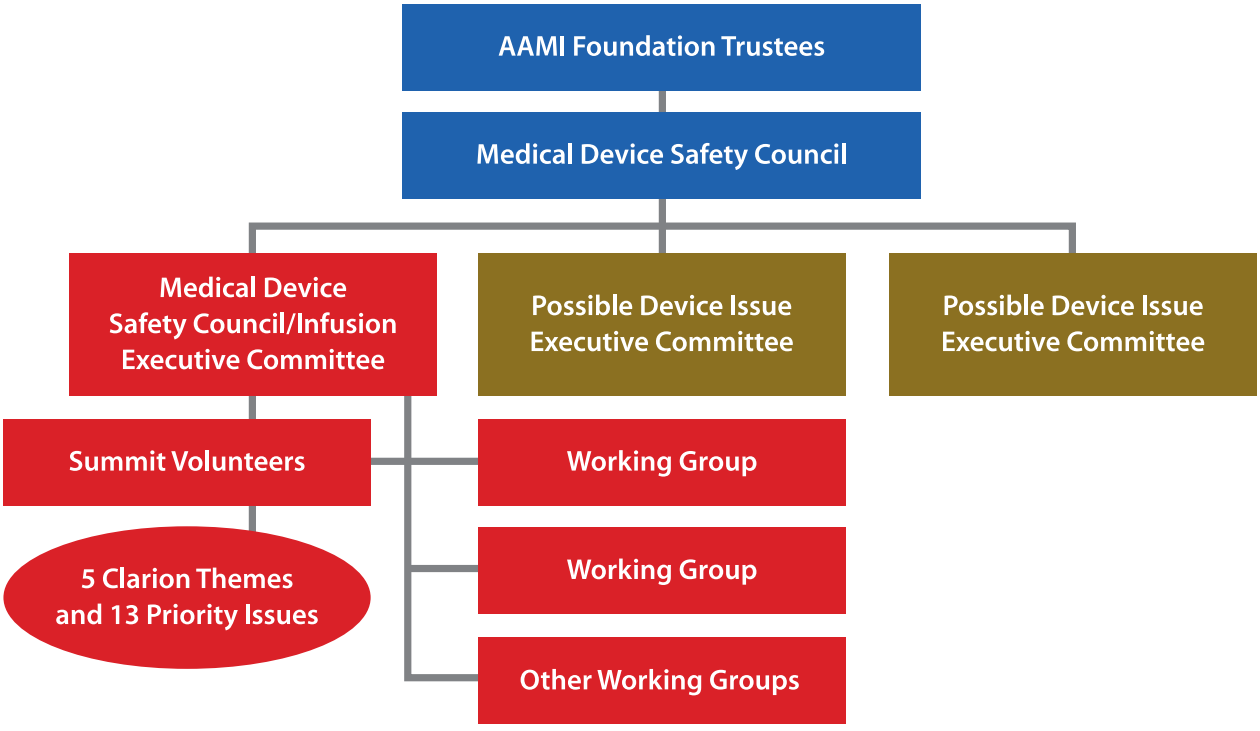
For funding questions, contact Lauren Healy at AAMI: 703-253-8290.

## Next Steps

The organizing committee met on Dec. 8, 2010. Their primary work product is working group assignments based on the five clarion themes at the summit. The assignment "grid" will be posted at www.aami.org/foundation by the first week of January 2011. Updates will continue to be posted there and at www.aami.org/meetings/infusionsummit/

Let the projects begin—let's do!

**Figure 8. Organizational Chart for the Medical Device Safety Council/Infusion**




Source: Association for the Advancement of Medical Instrumentation.

# Conclusion

> **"The AAMI/FDA Infusion Device Summit was a productive first step in fostering an open environment where collaboration and open discussion is encouraged."**
>
> —Anthony Watson, director of the Division of Anesthesiology, General Hospital, Infection Control and Dental Devices in FDA's Office of Device Evaluation at the Center for Devices and Radiological Health

**THE AAMI/FDA INFUSION DEVICE SUMMIT** issued a call to action for improving infusion device safety: five clarion themes and 13 priority issues that resonate with urgency.

AAMI, FDA, and summit participants from across the spectrum of the healthcare community issued a renewed pledge to address the issues with innovative solutions. Many of these solutions could be informed by *systems* approaches, such as:

- Thinking systemically about incident reporting, root cause analysis, and continuous improvement
- Designing with a systems engineering perspective
- Transitioning from smart pumps to smart infusion systems
- Connecting medical technology and information systems
- Systematizing drug libraries and protocols
- Responding to the diverse use environments and user needs within healthcare systems

Lela Holden, patient safety officer at Massachusetts General Hospital, opened the summit with a keynote about healthcare being a team sport. She emphasized that putting patient safety first requires a willingness by all of us to be completely open about glitches, near misses, and adverse incidents. Some summit participants expressed curiosity about how these two messages about teamwork and openness relate to the task before us.

By the end of the event, it was clear that Holden's message had hit home. Not one of the five clarion themes has a single "owner" among industry, hospitals, clinicians, clinical engineers, biomedical equipment technicians, independent experts, IT professionals, or FDA. These are *systems* issues, requiring the whole healthcare community to continue to work together as a team. For example, Clarion Theme 1 will not be solved with a new "MAUDE." Users and user facilities must make accurate, clear, and detailed reporting of glitches, near misses, and adverse incidents to manufacturers a priority; manufacturers must make root cause analyses a priority; FDA must listen to the needs of hospitals, industry, and outside subject experts about MAUDE. Listening well must continue to be an ongoing theme by everyone in the healthcare community if real progress is to be made.

Summit presenters and participants shared insights and examples of progress on infusion safety, which could inform more widespread and comprehensive improvements to infusion systems. Other experts generously contributed their perspectives—and recommendations for moving forward.

The AAMI Foundation's new Medical Device Safety Council has been charged with sustaining the momentum from the summit with an action plan for addressing the priority issues. Like the summit itself, the action agenda will require multidisciplinary, collaborative efforts. No single group can do it alone. With collective action, smarter infusion systems and improved patient safety are within reach.

Already, nearly 100 people from more than 60 organizations have volunteered to help. To volunteer for this work and to monitor summit follow-up activity, visit AAMI's Web site dedicated to infusion device safety.

www.aami.org/infusionsummit/index.html

# Resources

AAMI Infusion Device Summit

www.aami.org/infusionsummit

ASHP IV Safety Summit

www.ashp.org/iv-summit

FDA Infusion Pump Improvement Initiative

www.fda.gov/InfusionPumps

## AAMI Resources

Visit www.aami.org for these and other infusion-related publications.

ANSI/AAMI/IEC 62366:2007, *Medical devices: Application of usability engineering to medical devices*

ANSI/AAMI HE75:2009, *Human factors engineering—Design of medical devices*

Brady, Jody L. "First, Do No Harm: Making Infusion Pumps Safer." (September/October 2010). *Biomedical Instrumentation & Technology.* Association for the Advancement of Medical Instrumentation.

*Home Healthcare Horizons*, a supplement to *Biomedical Instrumentation & Technology*. (2010). Association for the Advancement of Medical Instrumentation.

## Other Resources

Evans, R.S., Carlson, R., Johnson, K.V., Palmer, B.K., & Lloyd, J.F. (2010). "Enhanced Notification of Infusion Pump Programming Errors." *Studies in Health Technology and Informatics, 160:* 734–8.

*Getting Started Kit: Safe Administration of High-Risk IV Medications*

www.nichq.org/pdf/AppendixDSanDiegoPatientSafetyConsortium.pdf

*HPM2:2 Medical Instrumentation: Infusion Pump Connectivity to Clinical Systems.* (February 2010). Partners Healthcare.

Indianapolis Coalition for Patient Safety

www.indypatientsafety.org/focus_areas.aspx

"Intermountain Healthcare, Baxter Integrate SIGMA Spectrum Infusion System with Intermountain's Electronic Medical Record System." (Dec. 1, 2010). *Business Wire.*

www.businesswire.com/smp/intermountain-and-baxter-integrate-sigma-spectrum-infusion-system-with-electronic-medical-record-system/

Weinger, Matthew B.; Wiklund, Michael R.; & Gardner-Bonneau, Daryle J. (Eds.) (2010). *Handbook of Human Factors in Medical Device Design.* CRC Press.

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Diabetes Technology Society
ECRI Institute
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