What’s the Prognosis?
Making Infusion Systems Safer

Martha Vockley

Two years ago, more than 300 people gathered outside Washington, D.C. to tackle one of the most pressing challenges in healthcare—making infusion devices and systems safer.

What’s changed?

The AAMI/FDA Infusion Device Summit in October of 2010 has proven to be a catalyst for healthcare professionals who care about one of the most important safety issues of our time—infusing patients safely. Two years out, the ripple effects from the summit and the events that prompted it are only increasing in magnitude and impact. Today, more people are talking, working together, and committing to making the system of delivering intravenous (IV) therapy safer.

What’s different now? Here’s a look at some of the progress to date:

A systems approach. Champions of infusion safety are taking into account the entire technological, medical, institutional, and human system in which infusion devices are used, rather than focusing narrowly on pumps alone. That’s a sea change in defining and working through the problem comprehensively—and with a clear recognition of its complexity. “Infusion pumps are only part of the problem, and IV infusions require a system, of which pumps are a part,” says Tim Vanderveen, PharmD, vice president of The Center for

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“For the most part, when errors do occur, it is a system issue and not a singular event.” By way of example, Vanderveen compared infusion pumps to automobiles. “Accidents are not typically [due to] the car, but more the driver, the conditions, the maintenance, and so on.”

Tony Easty, senior scientist at the University Health Network in Toronto, agrees. “I see more of a systems approach being taken,” says Easty, who is also team leader of the Health Technology Safety Research Team at the Centre for Global eHealth Innovation. Scientists there are conducting groundbreaking research on multiple line management. “Manufacturers are more aware of the difficulties that occur in implementation and clinical use, and healthcare organizations and clinical engineers are looking at infusion safety in a more comprehensive way than before.”

Easty doesn’t minimize the effort and practices required for systems thinking, but he’s encouraged by the increasing exchanges of information and collaboration. “I think many institutions are trying hard to make an integrated plan for the various components of a medication safety system, but this is not easy to do,” he says.

“It is time-consuming and requires a multidisciplinary approach. I think we have come to realize just how much effort is required to develop and implement a truly effective medication safety system. Also, there is a large commitment required for ongoing analysis and feedback. Staff need to be given time to focus on quality and safety assessment, so this is definitely an additional load for institutions to bear.”

**Multidisciplinary collaboration.**

Manufacturers, healthcare organizations, pharmacists, clinical engineers, nurses, and other patient safety specialists are working together much more actively and collaboratively to improve the system.

Pat Baird, systems engineer at Baxter Healthcare Corporation and chair of the AAMI Infusion Systems Steering Committee (ISSC), says “many manufacturers” are involved in standards work as it relates to infusion pumps and are also active in developing other solution-focused resources. “People have asked the team, ‘Aren’t they your competitors? Why are you working together? Isn’t it in your best interest to have an advantage over another company?’ Our response has always been, ‘We won’t compete on basic safety,’” Baird says.

Easty says he sees a new mindset and approach at work among the various players. “There is a growing realization that to achieve improvements in infusion safety, technology needs to be combined with careful planning and implementation,” he says. “We also know that we still have a long way to go in this regard. There are major challenges in standardizing drug ordering practices, compliance with pre-programmed drug libraries, and other patterns of use that bypass some of the safety features built into modern smart infusion pumps. These behaviors are often based on the pressure of work faced by nurses in busy clinical units, and so we need to understand these pressures better and work with them to design systems that are safer and more convenient to use.”

Still, there are advances on the pharmaceutical front. Bona Benjamin, director of Medication-Use Quality Improvement at the American Society of Health-System Pharmacists and a member of the AAMI ISSC, reports “significant progress” in standardizing the nomenclature for medication administration via infusion devices, as well as recommendations for standardized concentrations for high-risk, high-volume medications. “Once we achieve consensus on the final formulary, we

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**Clarion Themes From 2010 Infusion Summit**

1. Standardize systems and processes for reporting, aggregating, and analyzing infusion device incidents.
2. Improve the integration of infusion devices with information systems and drug libraries.
3. Mitigate use errors with infusion devices.
4. Improve management of multiple infusions.
5. Reconcile challenges and differences in the use environments of infusion devices.
to key stakeholders emboldened to take action, which is creating an environment that is more conducive to change.

For example, Benjamin says, pharmacists in hospitals and elsewhere “have become integral” in initiatives aimed at medication-related technology challenges. “By involving users of infusion devices in policy and clinical decision-making, applying their clinical knowledge and systems thinking skills, and leveraging support from technology vendors, pharmacists can help ensure that a safe medication use process is planned and implemented,” Benjamin says.

‘The Start of Something’
The unprecedented AAMI/FDA Infusion Device Summit produced a focused agenda that highlighted both the extraordinary challenges facing the entire healthcare community and best practices by leading organizations.

Framed by expert presentations, summit participants built consensus on 13 priority issues that they believe are crucial to improving patient safety. Shortly after the summit, AAMI’s Infusion Device Standards Committee grouped the 13 priority actions into five clarion themes, which serve as a call to action.

Indeed, the summit turnout—which included physicians, nurses, pharmacists, clinical engineers, biomedical technology professionals, human factors engineers, manufacturers, academicians, regulators, and organizations that represent them—scored an overarching key message of the event: It would take a comprehensive, collaborative, and multidisciplinary effort to improve infusion device safety.

At the end of 2010, AAMI published Infusing Patients Safely, a report of the summit’s clarion themes, priority issues, best practice presentations, and expert perspectives. The report was widely distributed to healthcare organizations and stakeholders.

Perhaps what made the summit most remarkable was the overwhelming commitment of attendees that, as a community, they would continue to work together on the development and implementation of action plans based on the agreed-upon priorities,” says AAMI President Mary Logan.

Moreover, the clarion themes continue to resonate, according to professionals who are deeply involved in improving the state of
practice. “As a comprehensive set, they provide an excellent basis for developing strategies to address the issues of pump safety,” Doyle says.

“Yes, the themes from the summit remain,” says the FDA’s Anthony Watson, director, Division of Anesthesiology, General Hospital, Infection Control, and Dental Evaluation at the Office of Device Evaluation at the Center for Devices and Radiological Health (CDRH). “The infusion pump team at the FDA is still highly motivated and recognizes change takes time.”

Alan Lipschultz, president of Healthcare Technology Consulting LLC in Wilmington, DE, attended the summit and sees its impact. “The summit was the start of something,” he says. “The conversation has changed because the document is a door opener to get some of the issues on the table and talk about the bigger picture within institutions, within which clinical engineers function.”

Gaining C-Suite Attention

The summit report served that purpose for Glenn Scales, who put it in the hands of leaders who make strategic decisions and set priorities on behalf of Duke University Health System in North Carolina. Scales, who serves on the ISSC, recently retired as a patient safety specialist with Duke’s Department of Clinical Engineering. To get the attention of people who have “hundreds of priorities that are priority number one,” Scales distributed handfuls of copies of the report and follow-up publications. He also forwarded e-mails and electronic information related to infusion devices to keep the issues on the radar screen of institutional leaders and key staff members, such as the chief nursing officer and patient safety officer.

“It helped people to understand that they needed to get a little more galvanized at looking at this institutionally, rather than just being reactive when a problem occurs,” Scales says. “The good news is that in this institution and in many others, you’ve got people who know the right people and have the right kinds of

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influence to help them see the bigger picture and understand how our developmental practices need to change and evolve.”

In practice, that has meant changes in business as usual in the two years since the summit, with more thoughtful, multidisciplinary approaches to improving the use of infusion systems. “We’re doing things differently now,” Scales says. “We’re collaborating better. Committees that are beginning to look at how we make errors and how we can improve our processes and drug libraries and settings are much more multidisciplinary than they used to be. It used to be that it would just be pharmacists and maybe a few nurses. Now it’s a much broader cross-section of people across the institution. Some of the work product from the summit is helping us think about different ways of how to use the tools that we have more effectively.”

Challenges and Opportunities For Manufacturers

The recall two years ago has had manufacturers scrambling to supply new infusion pumps to replace the 200,000 recalled devices. Baxter turned to SIGMA, a small firm in Medina, NY, and others to supply replacement pumps. At the time, Baxter had a 40 percent ownership stake in SIGMA; this year, Baxter completed its acquisition of the company.

SIGMA and other firms had to ramp up production quickly and dramatically. There have been bumps along the way, including additional recalls of the replacement pumps. Still, the industry and healthcare institutions seem to have risen to this immediate challenge.

“A concern among clinical engineers was that overly rapid, FDA-mandated implementation of 200,000 new smart pumps in hundreds of hospitals, together with user training and all the necessary support systems, could create inherent dangers,” says Nathaniel Sims, an anesthesiologist, medical device inventor, and physician advisor to Biomedical Engineering at Massachusetts General Hospital (MGH) in Boston. “Happily, to the best of our knowledge, the rapid replacement of the recalled systems, has significantly improved the patient safety net and did not create unintended consequences of change.” Sims also serves on the ISSC, which is part of the AAMI Foundation’s Healthcare Technology Safety Institute.

At the same time, manufacturers had to learn how to follow the new FDA regulatory process with infusion pumps. That includes the new safety assurance cases and design controls. In addition, pump manufacturers and healthcare institutions recognize that the advent of electronic medical records, computerized physician order entry (CPOE), and other technologies requires their attention as well. They’re working on new partnerships with information technology (IT) companies that specialize in healthcare IT to connect infusion systems with other IT systems. In short, manufacturers have a lot on their plates. “Even if we have all the answers, change takes time,” Baird says. “I think people in the industry realize this.”
THE BACKSTORY

In April 2010, the U.S. Food and Drug Administration (FDA) took steps that, taken together, amounted to an across-the-board indictment of the state of practice for delivering medications, nutrients, and other fluids to patients via infusion systems.

First, the FDA ordered Baxter Healthcare Corporation to recall as many as 200,000 infusion pumps because of what the agency called “numerous flaws” in the devices. The FDA told Baxter it had to provide its customers with replacements or refunds for the recalled devices.

Second, the FDA stated that conditions in the industry as a whole were unsatisfactory, citing 56,000 adverse events reported between 2005 and 2009, at least 700 deaths, and 87 manufacturer-initiated product recalls associated with infusion devices. Such data underscored “that the problem in the infusion device industry was not a problem involving just one manufacturer … but it was a pervasive problem affecting everybody,” says Nathaniel Sims, an anesthesiologist, medical device inventor, and physician advisor to Biomedical Engineering at Massachusetts General Hospital (MGH) in Boston. Sims also serves on the Infusion Systems Steering Committee (ISSC), which is part of the AAMI Foundation’s Healthcare Technology Safety Institute.

The FDA made the processes by which manufacturers design infusion devices and submit information for approval to sell them more stringent. Rather than seeking approval of new devices based on the “predicate device concept” of substantial equivalence—likening the safety of new devices to that of previously approved devices—manufacturers are now encouraged by the FDA to provide a “safety assurance case” to demonstrate that new devices are safe on their own merits.

The FDA’s rationale for this change is that new or changed devices will have different technological characteristics than predecessor devices. Safety assurance requires a claim about a device property (or properties), evidence that demonstrates the validity of the claim, and an argument that links the evidence to the claim.

In concert with its major announcements, the FDA’s Center for Devices and Radiologic Health (CDRH) launched an Infusion Pump Improvement Initiative to establish additional requirements for infusion pump manufacturers, proactively facilitate device improvements, and increase user awareness.

“What the FDA did was stunning,” says Glenn Scales, also a member of the ISSC. “It had never been seen before at that scale. It sent a chill through the industry about how serious the FDA was about the scope of the problem that they were seeing. It was perceived by me and others that the FDA had finally just had enough, that they’d seen far too many recalls, too many issues, too many anecdotal reports and actual SMDA [Safe Medical Devices Act of 1990] MedWatch reports of medication errors and patient harm and patient death. It was like, ‘enough is enough. We’re putting our foot down and putting a stop to this and getting the industry’s attention.’ It was a shocker.”

Related to the FDA changes in the device approval process, manufacturers now have to adhere to new guidance for medical device design. “There’s more to that than just saying that devices should be designed according to a better quality system,” Sims says. “FDA recognizes that human users of medical devices are just that, human users, and that there can be a potential for error. Users may not have been completely trained in how to use a device, or might not have quick access to a manual, online resource, or a mentor. Therefore, since safety assurance cases no longer assume a perfect front-line-caregiver, and because drug infusion therapies are more complex than ever before, manufacturers must test new designs in clinical or simulated environments—in every type of care environment where the device may be used, and under realistic circumstances in which caregivers may be tired and under pressure from meeting competing priorities for numerous acutely-ill patients.”

“There were questions about whether that meant the device had to be tested in a clinical trial with real patients, in real hospitals with real nurses, or whether that meant it was acceptable to do it in a real simulation environment,” Sims adds. “In general, the latter has occurred and that’s actually a better place to test.”
THE FDA PERSPECTIVE

Progress in Incident Reporting and Device Approvals
Since the FDA signaled its intent to take a more hands-on approach to improving infusion device safety, the agency, through its Center for Devices and Radiological Health (CDRH), reports progress in incident reporting, device approvals, and collaborative efforts with industry and many other stakeholders.

“As expected from the increase in stakeholder awareness from the center’s Infusion Pump Initiative, CDRH has received more voluntary and user facility reports for external infusion pumps,” the FDA reports. A complete analysis of adverse event reports has not been completed.

Over the past two years, CDRH says it has cleared 16 infusion pumps, which represents most of the submissions the agency has received. “Most of these 510(k) submissions voluntarily included a safety assurance case,” the FDA states. “These safety assurance cases included the results of static analysis testing performed on their infusion pump software.” (Static analysis is a relatively new technique that automates the process of finding bugs and potential design errors in software code.)

“Through recent experience, CDRH believes that infusion pump submissions that contain a safety assurance case provide significantly improved information that helps us make a more complete and timely decision.”

Challenges and Support for Manufacturers
While the approval process is improving, CDRH has noted a few common deficiencies in infusion pump submissions:

• Failure to address issues associated with medical device reports (MDRs) and recalls
• Arbitrary safety specifications with no supporting justification
• Uncorrected software anomalies
• Human factors studies that do not validate safe and effective use
• Claims with no evidence
• Missing biocompatibility and sterilization information—or information included is not applicable to the intended use
• Failure to comply with standards, despite claims to the contrary

“CDRH continues to move forward on its Infusion Pump Initiative, laying the groundwork for safer pumps and more consistent review,” the FDA states.

“At the time of the initiative, CDRH started a risk-based inspection program that focused on two of the major problems with many infusion pumps: manufacturers’ design controls and corrective and preventive action systems. CDRH inspects each infusion pump manufacturer at least once every two years.”

CDRH continues to participate in the Generic Infusion Pump (GIP) Project, which is a collaboration of the center’s Office of Science and Engineering Laboratories and a number of academic institutions. The project goals are to:

• Establish an infusion pump safety reference standard that can be used by both manufacturers and CDRH to measure a specified degree of pump safety, and that can rapidly incorporate both operational experience and new technology developments.
• Provide academia with a moderately complex real-world problem (free from intellectual property and confidentiality issues) to use in refining their theories.
• Demonstrate to manufacturers “state of the art” product development methods.
• Train the next generation of engineers on real-world problems using “state of the art” software development methods.

Thus far, the project has published:

• A list of hazards and their causes for a Generic Insulin Infusion Pump (GIIP) and a Generic Patient-Controlled Analgesic (GPCA) infusion pump
• Safety requirements for both the GIIP pump and GPCA pump
• Preliminary hazard analysis for the GPCA pump
• A Simulink®/Stateflow® simulated safety model of a GPCA pump (one for a GIIP is under development)

CDRH continues to closely monitor infusion pumps. The FDA worked with AAMI to develop a technical information report (TIR) educating infusion pump manufacturers on the development of assurance cases. The FDA is an active participant in the AAMI Infusion Device Standards Committee and the AAMI Infusion Systems Steering Committee. Lastly, several FDA members participated in The Johns Hopkins University Applied Physics Laboratory Infusion Pump Workshop, “A Systems Engineering Approach for Human Factors Solution,” in January 2012. This was a gathering of national stakeholders to aid the development of prototype design of future infusion pumps.
But the new forums in place for collaborative efforts to improve practices are easing the way. “I see that the concept of a cross-functional safety council like the ISSC can work to improve areas where medical device safety overlaps with medical practice safety,” Baird says.

The shift toward integrated systems is impacting healthcare institutions as well. At Duke University Health System, for example, “the very best of the IT talent has been taken away from their day-to-day operations to focus on new IT projects such as CPOE and integrated electronic medical record systems and the things that MDDS [the FDA Medical Device Data Systems rule] is beginning to mandate that we do,” Scales says. Eventually these new integrated systems will incorporate data from infusion devices, which Scales believes will be the beginning of safer medication delivery at bedside.

Scales is concerned that U.S. manufacturers have been so overwhelmed meeting production demands—and uncertain about FDA requirements—that the next generation of infusion systems is in jeopardy. “Fortunately, at this point the infusion devices we are using are meeting our current needs,” he says. “But we also know that if we decided that we wanted to replace this fleet, we have about a 30-month timeline ahead of us. We don’t see any truly innovative, earth-shattering device development in the near future that’s worthy of our attention. We’re just seeing little, incremental changes in the equipment base that we already have.”

With these challenges, however, come opportunities for innovation. Sims believes the next wave of innovation could come from abroad, as manufacturers everywhere work toward new infusion platforms with global reach. “I’m convinced that the next innovative leaps will come from sourcing best clinical practices, engineering insight, and business models from around the world” says Sims.

Still, foreign manufacturers must go through the FDA approval process as well—and that’s unfamiliar territory for them. And they have to tailor their products to American user expectations. That could pose hurdles not just in device development and approval, but also in medical practice. For example, Lipshultz says, many non-U.S. manufacturers base their technology on syringe pumps, rather than the large-volume infusion pumps that are used in most U.S. clinical settings.

Laying a Foundation With Research
The summit showcased a handful of leading organizations and individuals whose research and innovative practices inspired summit participants and continue to serve as exemplars to the healthcare community. Since then, there has been more progress, which is laying a foundation for broader improvements in infusion device design, human factors, evaluation, manufacturing, and use.

For example, in the case of device design and usability, The Johns Hopkins University Applied Physics Laboratory and Johns Hopkins Medicine have collected more than 900 candidate usability solutions and other comments from a diverse set of pump experts. “We are in the process of reducing these to identify the most helpful and most feasible solutions for later prototype evaluation in a simulation setting,” says Doyle, whose team includes Alan Ravitz, program manager, biomedical systems, at the Applied Physics Lab and Julius Pham, MD, of Johns Hopkins Medicine. The prototype capabilities will enable a degree of flexibility for test activities—and they will be made available for others to use once the project is completed.

A three-year grant from the U.S. Department of Health and Human Services Agency for Healthcare Research and Quality is funding some of this work.

“Research conducted on human factors issues related to pumps continues at a good pace,” Doyle says. “What is really beneficial, I believe, is that now there is more dialogue between human factors specialists and others in the pump community. This helps to point human factors research better to feed design activities. While progress may seem incremental, one must acknowledge both the complexity of this challenge and the need for a discerning scientific approach. It should be recognized that the unprecedented cooperation of stakeholders is proving most advantageous in providing guidance and direction.”

On another research front, the Health Technology Safety Research Team at the University Health Network in Toronto, in collaboration with the Institute for Safe Medication Practices Canada, has unearthed a number of risks and challenges in what until recently had been an understudied topic: multiple IV infusions. This research has identified and described the “considerable cognitive demands...
Helping to improve infusion systems is one of the top priorities of the Healthcare Technology Safety Institute (HTSI), which is part of the AAMI Foundation. Here’s a look at some of HTSI’s work.

**National Study on Intravenous Medication Errors:** The institute received a three-year $328,660 grant from the CareFusion Foundation to fund a study of the nature of infusion system errors across multiple hospital settings. The study is being led David W. Bates, MD, an internationally renowned expert in patient safety.

**Multiple-line Management:** AAMI published nine recommendations for safely administering multiple-line infusions from a study conducted by the University Health Network Research Team in Toronto, Ontario. To read those nine recommendations, go to: www.aami.org/htsi/infusion/index.html and look for Multiple IV Infusions Summary Recommendations.

**Multiple-line Management Webinar:** This past May, HTSI hosted a webinar on the nine recommendations featuring speakers from the University Healthcare Network Research Team and the Institute for Safe Medication Practices-Canada. Access the recorded webinar at: www.aami.org/htsi/infusion/index.html

**Safety Innovations:** HTSI has launched a series of white papers highlighting innovative healthcare organizations’ solutions to specific technology challenges. Two of the papers focus specifically on infusion pumps. The papers, which are free, can be downloaded at: www.aami.org/htsi/safety_innovation.html

**LinkedIn Group:** HTSI started a LinkedIn group in early 2012 for the healthcare technology community to discuss issues surrounding patient safety issues. To join the group, go to: www.linkedin.com/groups/Healthcare-Technology-Safety-Institute-HTSI-4284508

**Library of Resources:** A library of links to articles on infusion systems has been developed and can be accessed at: www.aami.org/htsi/infusion/library/index.html

**National Quality Forum Report:** The institute’s work on infusion system has been cited in a draft report, Critical Paths for Creating Data Platforms: Patient Safety. That report is being prepared for the U.S. Department of Health and Human Services. The report aims to assess “the current state of electronic data readiness for quality measurement and current gaps in data exchange that, if filled, would allow for more robust infusion pump safety measurement and improvement.” To view the draft report, go to: www.qualityforum.org/ WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71730

**Work in Progress**

**Ideal Reporting System:** The Incident Reporting/Listening Systems Working Group is defining and describing the ideal reporting system and its requirements.

**Drug Formulary:** The Drug Library Working Groups are developing a formulary of medications with standardized data elements and developing checklists on maintaining and updating drug formularies in infusion systems.

**Matching Environments With Safety Features:** The Working Group on Environment of Use is developing a tool that will help match use environments with specific device safety features to help reduce the risk of prescribing inappropriate equipment.

**Research and Project Agenda**

1. Education on the Principles of Infusion: Objective of this project is to develop an online, intuitive learning platform to improve clinicians’ knowledge of key infusion principles. The “Why” of Clinical Workarounds: The objective of this study is to better understand the reasons for working around infusion pump libraries.

2. Standardizing the Infusion System Vocabulary and Drug Libraries

**Would You Like to Participate?**

The success of HTSI initiatives depends on the participation of experts from many fields and disciplines. To learn more about how you can get involved, go to: http://www.aami.org/htsi/getinvolved.html.
and time pressures present where many patients receive multiple IV infusions, with some IV infusions “particularly prone to error.”

The research team identified six themes that are of concern, with 22 primary issues (“actions or omissions that can lead directly to patient harm”) related to these themes of management of multiple IV infusions:

1. Secondary line infusions
2. Line identification
3. Line set-up and removal
4. Dead volume management (the volume in the IV tubing between the point where multiple IV agents are connected and share volume in the IV tubing) and the patient’s vein
5. IV bolus administration
6. Pump-specific issues

While the multiphase project is still under way, members of the ISSC are particularly impressed with the research to date, which takes into account factors related not just to front-line healthcare staff, but also factors at the organizational, regulatory, and government levels. Moreover, the project is moving from research to best practice by making recommendations for improvements to infusion and infusion-related technology, education standards, clinical best practice guidelines, hospital policies, and unit work practices required to reduce the risk potential.

For Scales and other biomedical technology professionals, the Toronto team’s insight that clinicians need a working knowledge of the fundamental principles of infusion therapy—how and why the devices work—has practical value. “It's simple things, like the higher you hang a bag of fluid, the fluid pressure that it exerts on the pump and on the patient is greater,” he says. “The fluid flows more easily the higher the bag is hung. But a lot of times the bag is hung too low for a lot of reasons. It's rarely hung any higher than it has to be to clear the door frame of the room. Or a particularly short nurse wants to reach the bag and read the label.”

Clinicians sometimes neglect to put the fluid back at an optimum height after lowering it to get through the door, reach the bag or read the label, Scales says. “If they don’t understand fluid pressure and why it’s important, why the bag works better if it’s hung higher, then they don’t make the effort to make the height adjustment,” he says.

Many of the principles of infusion therapy, and the special risks of multiple IV infusions, are not formally and explicitly taught in nursing education programs, according to the Toronto team’s research. Once they are in clinical settings, nurses typically learn how to use specific infusion devices in orientation and training programs provided in-house or by manufacturers. But the principles are taught unevenly—and it’s difficult to learn these fundamentals on the job. “You’ve got a limited amount of time and they just want the basics,” Scales says. “It’s what I call ‘knobology’—what knob do I need to turn to get the right result?”

Adds Lipschultz: “I am surprised at how much progress has been made on the issue of multiple line safety, real progress, not just people sitting around talking about it. I am also surprised at the scope of things going on. People aren’t just sitting around letting the grass grow. There is real movement that’s still continuing—and enthusiasm.”

A New Convener and Coordinator
The AAMI Foundation quickly followed up on the infusion summit, as well as the AAMI Medical Device Alarm Summit of 2011, by launching the Healthcare Technology Safety Institute (HTSI). HTSI has identified infusion device safety as its first priority and now spearheads an Infusion Systems Safety Initiative guided by the multidisciplinary ISSC.

In this leading role, HTSI serves as a convener, messenger, and coordinator of all stakeholders in infusion device safety. The steering committee periodically brings stakeholders together to share progress, identify and prioritize needs, and forge partnerships to advance research and best practices.

In the spring of 2012, HTSI was awarded a $328,660 grant by the CareFusion Foundation to fund a three-year national study on key issues surrounding the administration of IV medications using smart pumps. The goal of this first-ever study, to be coordinated by Brigham and Women’s Hospital in Boston, is to evaluate the types of errors that may occur when using smart pumps to administer IV medications, and what can be done about them.

“Medication errors are probably the most common type of mistake in hospitals, and IV
medications carry especially high risk," says David Bates, MD, the study’s lead investigator who has researched problems surrounding smart pumps before. Bates is senior vice president for quality and safety at Brigham and Women’s Hospital.

“IV medication errors represent one of the most significant safety and cost threats for hospitals, and studies have shown that many of these errors are preventable,” Vanderveen says. “The adoption of smart IV pumps has yielded a treasure trove of new information that has helped us understand the high degree of variability in the IV medication process. This study will deliver even more insight to drive best practices in IV therapy and help clinicians better leverage technology to avoid errors and improve patient care.”

The study will analyze smart pump usage at 10 hospitals across the country. A team of two observers at each facility will compare the medication orders against the actual administration of drugs using smart pumps to find any discrepancies. In the second year, the team will analyze the results and develop safety solutions to help prevent future errors. After those solutions are implemented, observers will measure IV medication errors at the facilities again to track improvement. The research team will then publish the error rates, results of the solutions, and best practices for smart pump use.

“The progress made by AAMI, HTSI, and, more importantly, by the healthcare community in less than two years is remarkable,” Logan says. “I’m reminded again of the Margaret Mead quote that captured the essence and mood of the summit: ‘Never doubt that a group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has.’ Is our work done and can we go home and ‘declare victory’ now? Absolutely not. Our work will not be done until we achieve our vision: that no person should be harmed by a drug infusion.”

Reference

What You Can Do Now

Research is longer term, as are some other needed actions to improve infusion safety. However, based on research and best practices available now, the AAMI Infusion Systems Steering Committee recommended 10 steps that healthcare organizations can take now:

1. Hold weekly morbidity/mortality conferences—not punitive, but problem-solving—around a real-life issue that has occurred:
   - Identify process changes needed.
   - Integrate into training.
   - Identify workarounds and understand the “why.”

2. Use continuous quality improvement (CQI) data:
   - Identify the top 10 low-hanging fruit items to address.
   - Use CQI data to help standardize practices, processes, and systems in place.

3. Standardize:
   - Standardize the system (policies, processes, practices, checklists, and devices)
   - Standardize and limit the number of drug concentrations and dosing units used in the hospital. Use the Institute for Safe Medication Practices (www.ismp.org) checklist of what should be in the drug library as a model.

4. Include wireless as an essential requirement in purchasing decisions.

5. Maximize the use of smart pump features and capabilities.

6. Assess competency on IV principles and use of devices.

7. Engage the C-Suite to create an imperative for a hospital-wide strategy for change.

8. Collaborate:
   - Encourage more collaborative meetings among front-line clinicians, nursing, clinical engineering, and pharmacy on use of IV pumps, training, and so on.
   - Conduct a collaborative clinical assessment at the nursing level for comprehensive competency assessments so pharmacy understands what is needed at the clinical level.
   - Encourage collaborative training.

9. Reinforce one practice:
   - “Mind the gap” between research, training, and practice.
   - “Do one thing at a time.”
   - “Mind the drip.”
   - Attend to “one pump at a time” for multiple infusions.
   - Learn the 3Ms—Method, Mechanism, Mindfulness:
     - What are you doing? (Method or “mental model”)
     - How does it work? (Mechanism)
     - How could it go wrong? (Mindfulness)
   - Photograph the screen of the pump; make a 15-second video to get data on what is happening versus what should happen.
   - Identify infusion device training and retraining.

10. Evaluate pump alarm systems based on the clarion themes from the 2011 AAMI Medical Device Alarm Summit.