ANTHOLOGY

National Coalition for Infusion Therapy Safety
2015–18

AAMI

About AAMI

The Association for the Advancement of Medical Instrumentation® (AAMI) is a nonprofit organization founded in 1967. It is a diverse community of 9,000 professionals united by one important mission—the development, management, and use of safe and effective health technology.

AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals. AAMI helps members:

- Contain costs
- Stay on top of new technology and policy developments
- Add value in healthcare organizations
- Improve professional skills
- Enhance patient care

AAMI provides a unique and critical forum for a variety of professionals including clinical and biomedical engineers and technicians, physicians, nurses, hospital administrators, educators, scientists, manufacturers, distributors, government regulators, and others with an interest in healthcare technology. AAMI fulfills its mission through:

- Courses, conferences, and continuing education, including certification programs.
- Collaborative initiatives, including summits with the FDA.
- A rich array of resources, including peer-reviewed journals, technical documents, books, videos, podcasts, and other products.

About the AAMI Foundation

Over its 50-year history, the Foundation has worked closely with its affiliate, the Association for the Advancement of Medical Instrumentation (AAMI), the world-renowned membership organization driving consensual standards in medical instrumentation.

The AAMI Foundation is committed to reducing preventable patient harm and to improving outcomes with complex healthcare technology. In addition to awarding scholarships, a research grant and its national coalition work, the Foundation works to support and promote the healthcare technology management and sterilization professions to help drive improvements in patient safety.

Anthology

Infusion Therapy Solutions
2010–18

Contents

Infusion Therapy Safety

A History of Accomplishments That Live On

In 2010, the Association for the Advancement of Medical Instrumentation (AAMI) spearheaded an ambitious patient safety initiative focused on a ubiquitous and seemingly intractable problem in healthcare: too many adverse incidents involving infusion devices. The initiative began with an Infusion Device Summit convened by AAMI and the Food and Drug Administration (FDA).

The summit struck a nerve with the 330 people who attended. Notably, the gathering brought together a diverse range of professionals: physicians, nurses, pharmacists, clinical engineers, biomedical technology professionals, human factors engineers, manufacturers, academicians, regulators, and organizations that represent them.

The real achievement ... was galvanizing a critical mass of smart professionals to come to consensus on the most urgent priorities and commit to collaborating in a sustained way.

The real achievement of the event—and the ensuing eight-year journey to improve patient safety—was galvanizing a critical mass of professionals to come to consensus on the most urgent priorities and commit to collaborating in a sustained way. Bringing together a multidisciplinary group to focus concertedly on a complex problem fostered synergy that simply is not as powerful when people work in siloes.

The summit report, *Infusing Patients Safely*, captured clarion themes, priority issues, expert perspectives, and leading practices that pointed the way forward. The report drew national and international attention—and it was meant to spur action.

To keep the momentum going, AAMI entrusted the AAMI Foundation with leading what became a multipronged initiative. Over its 50-year history, the Foundation has worked closely with AAMI, the world-renowned membership organization that leads global collaboration in the development, management, and use of safe and effective health technology. As AAMI's charitable arm, the Foundation is committed to reducing preventable patient harm and improving outcomes with complex healthcare technology.

A Broad Coalition and a Shared Purpose

AAMI and the AAMI Foundation recognized that addressing the challenges identified at the summit would require a sustained interdisciplinary approach. The problems stemming from the use of complex technology cut across many domains—including device design, regulations, standards, systems integration, human factors, medical practice, clinician training, and environments of care.

In short, the scope of work required addressing the entire sociotechnical ecosystem—people, technology, organizations, and processes. For eight years, this is exactly what AAMI and the AAMI Foundation did.

This Anthology traces the history, breadth, and accomplishments from 2010 to 2018—and, most importantly, the recommendations to address the challenges associated with infusion therapy. It showcases the work of a deep bench of AAMI and AAMI Foundation subject-matter experts in infusion device technology and systems.

This Anthology documents the work inspired by new partnerships created to solve problems, and it presents solutions developed by the AAMI Foundation's National Coalition for Infusion Therapy Safety, which engaged in the issues from 2015–18. Hundreds of dedicated expert volunteers contributed to the success of the National Coalition, as did dozens of national and international organizations that helped the Coalition build awareness and knowledge about infusion therapy safety.

Sound research methodology ensured rigor as the National Coalition produced major works of research, along with pragmatic, evidence-based, and actionable wise practices. This work is packaged in continuing education as well as in peer-reviewed journals.

This Anthology aggregates the work of the infusion therapy safety initiative in one document, which is freely and publicly available to ensure all healthcare organizations have access to this critical information. We encourage you to take advantage of the published research, collective knowledge, and practical tools and to share them with your colleagues. We hope you will consider this Anthology a living reference to inform your efforts to improve infusion therapy practices in your healthcare organization.

Finally, we celebrate the fact that our knowledge about how to improve infusion therapy continues to grow, as the initiative sparked keen interest in the field. The beacon of patient safety shines on.

Steve Campbell
Executive Director
AAMI Foundation

By the Numbers

AAMI Foundation Infusion Therapy Safety Initiative

Call to Action

Infusing Patients Safely
AAMI/FDA Infusion Device Summit Report

5	Clarion Themes
13	Priorities

AAMI Foundation National Coalition for Infusion Therapy Safety 2015–18

107	Subject-matter experts
21	Healthcare organizations
27	States and the District of Columbia
10	Industry partners
17	Professional societies and agencies
2	International delegations

Deliverables

29	Articles in AAMI's peer-reviewed journal
16	Patient safety seminars
14	Case studies
4	Quick guides
3	Safety Innovations reports
3	Regional Invitational events
1	Toolkit
1	Podcast

The Call to Action

2010 AAMI/FDA Infusion Device Summit

> "The most important aspect of the summit is the huge multidisciplinary turnout. There is no way this issue can sink back into obscurity."
>
> —**Nathaniel Sims, M.D.**, cardiac anesthesiologist and physician advisor to biomedical engineering at Massachusetts General Hospital and associate professor of anesthesia at Harvard Medical School

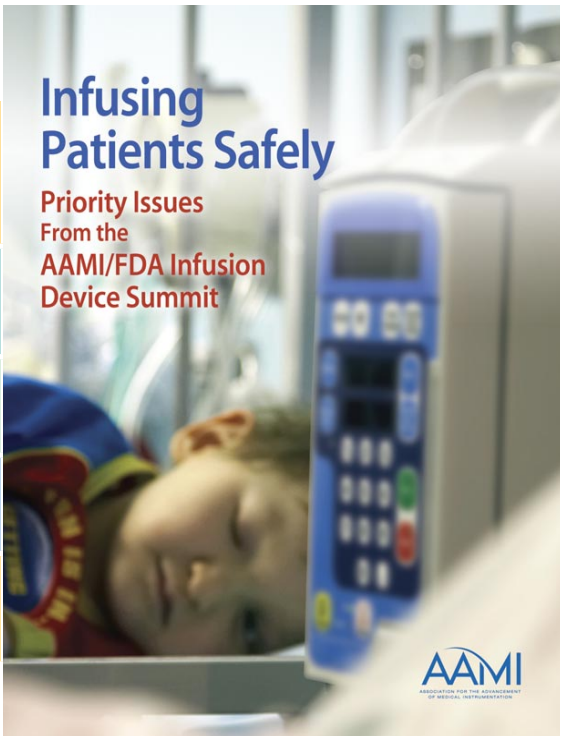
The AAMI/FDA Infusion Device Summit in 2010 was an unprecedented, groundbreaking event. Framed by expert presentations, summit participants spent two days bringing questions, comments, suggestions, frustrations, and opinions about infusion therapy and patient safety to the floor. The diversity of perspectives meant that everyone learned something about how others perceived the problems. As a community with a shared interest in patient safety, participants agreed that the time was right for consensus on major goals and priorities.

Infusing Patients Safely, the report of the 2010 AAMI/FDA Infusion Device Summit, synthesized the discussions and laid out five clarion themes, which served as the call to action.

Summit participants also developed a list of 13 actionable priorities for each clarion theme. They made clear that the most welcome and productive next step would be concerted action to address the priority issues. Once the work of the initiative started, the list of priorities that follows was refined into a multidisciplinary action plan.

Five Clarion Themes

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



13 Priority Issues

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

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

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.

Mitigate use errors with infusion devices.

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.

Improve management of multiple infusions.

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

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

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.

Supporting the Summit

The AAMI/FDA Infusion Device Summit garnered the support of 12 professional organizations and 15 industry sponsors. Coupled with the hundreds of deeply knowledgeable summit participants and their constituencies, this was an amazing, core group of stakeholders on which to build a movement to address the summit priorities.

Indeed, within the first few months of the summit, nearly 100 people from more than 60 organizations had volunteered to help.

"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."

—**Mary Logan**, president and CEO emeritus of AAMI, and **Carol L. Herman**, senior vice president emeritus of standards policy and programs at AAMI and former director of standards management staff at the FDA's Office of Science and Engineering Laboratories at the Center for Devices and Radiological Health, who led the summit

Summit Supporting Organizations	
1	American College of Clinical Engineering (ACCE)
2	American Society of Health-System Pharmacists (ASHP)
3	Association of periOperative Registered Nurses (AORN)
4	Association of Surgical Technologists
5	Center for Integration of Medicine & Innovative Technology (CIMIT)
6	Diabetes Technology Society
7	ECRI Institute
8	Institute for Safe Medication Practices (ISMP)
9	Integrating the Healthcare Enterprise (IHE)
10	IHE USA
11	National Patient Safety Foundation (NPSF)
12	Parenteral Drug Association

Summit Sponsors	
1	AcelRx
2	Animas
3	Baxa
4	Baxter
5	B. Braun Medical Inc.
6	CareFusion
7	FluidNet
8	Fresenius Kabi
9	Intertech Engineering Associates
10	Kimberly-Clark Healthcare
11	Medical Specialties Distributors
12	Moog
13	Nestle
14	Smiths Medical
15	Zyno Medical

Beyond the Summit

Building a Multidisciplinary Action Plan

The First Five Years: 2011–15

Developing an Evidence Base and Identifying Innovative Practices

Immediately after the summit, AAMI tasked the AAMI Foundation with engaging partners, experts, and supporters to help define the scope of work and shape a wide range of activities to carry it out.

For this first phase of the initiative, the Foundation formed volunteer committees to address the five clarion themes and related priority issues. This work resulted in numerous articles published in AAMI publications (listed on page 21 and included in the Appendix) and in three Safety Innovations reports published online by the AAMI Foundation:

Best Practice Recommendations for Infusion Pump–Information Network Integration

Nine Recommendations to Prevent Multiple Line Infusion Medical Errors

Smart Pump Implementation: A Guide for Healthcare Institutions

A Major Grant and a National Study

In May 2012, the CareFusion Foundation awarded the AAMI Foundation a $328,660 grant to fund a three-year national study on key issues associated with the administration of intravenous medication using smart pumps.

Principal investigator David W. Bates conducted this multi-hospital study with two dozen other researchers. Bates is the medical director of clinical and quality analysis for information systems at Partners HealthCare System, Inc.; chief of the Division of General Internal Medicine at Brigham and Women's Hospital; professor of medicine at Harvard Medical School; and professor of health policy and management at the Harvard T.H. Chan School of Public Health.

The study, published in the *BMJ Quality & Safety* journal in 2017, identified a high rate of error in the administration of intravenous medications despite the use of smart pumps. While relatively few errors were potentially harmful, the results of the study will be useful in developing interventions to eliminate errors in the intravenous medication administration process.

"My work with the coalition gave me a better understanding of the complexities of automation in infusion therapy—manual and barcode programming requirements, tubing requirements, and opportunities for error. I've communicated the work done by others, especially great work by Tony Easty and his staff [at the University Health Network.]"

—Pete Doyle, human factors engineer at The Johns Hopkins Hospital in Baltimore, MD

A Key Collaborator: HumanEra

The AAMI Foundation collaborated with HumanEra at the University of Toronto (formerly the Healthcare Technology Safety Research Team at the University Health Network in Toronto). HumanEra solves healthcare issues in a new way and strives to improve health systems. Rather than focusing on incremental improvements to technology, processes, or environments in isolation, the team investigates these elements holistically as a sociotechnical system.

Central to HumanEra's systems approach is a focus on the needs of people—not technology—first. This unique strategy requires a detailed understanding of cultural and contextual factors. HumanEra is thus able to identify a wide range of issues and contributing factors and to create innovative solutions that span the sociotechnical system, from device and environmental design, to training programs and government policy recommendations. These solutions are developed and refined through the active engagement of the end-user community, often through the use of an iterative design process. This approach distinguishes HumanEra in the health systems quality and safety community, and positions the team to continue to yield impactful, sustained, health system improvements.

Select AAMI and AAMI Foundation Deliverables from HumanEra

Safety Innovations

Nine Recommendations to Prevent Multiple Line Infusion Medical Errors

Toolkit

Intravenous Tubing Labeling Toolkit

Articles

Do Smart Pumps Actually Reduce Medication Errors?

Patient Safety Seminars

Multiple IV Infusion Safety: Where's My Line?

Making the Invisible Visible

Multiple Intravenous Infusions: Education Opportunities

Focus on Multiple-Line "Infusion Confusion" Inspires Innovation

Challenges associated with multiple-line intravenous infusions were a clarion theme at the AAMI/FDA Infusion Device Summit, a focus of AAMI Foundation committee work, and a priority for the National Coalition for Infusion Therapy Safety. Multiple sets of infusion tubing can be difficult for clinicians to distinguish, making medication errors related to multiple-line infusions a top safety hazard.

In an AAMI Foundation Safety Innovations report, *Nine Recommendations to Prevent Multiple Line Infusion Medical Errors*, researchers at HumanEra identified a number of interventions that could mitigate the risks. An AAMI Foundation Quick Guide shared the recommendations as well.

MedLite ID, a Utah-based company, is now marketing a product by the same name that responds to some of the challenges and recommendations. The MedLite ID solution is a disposable medical device that lights up the primary medication infusion line, from pump to bag to injection port, using built-in wireless technology. This allows clinicians to accurately and efficiently identify the safe medication push line, day or night.

"The coalition educated me about challenges I was not fully aware of or didn't fully understand. We've had discussions during our medication safety committee meetings and we have educated nurses. Excellent work!"

—**Nathaniel Sims, M.D.**, cardiac anesthesiologist and physician advisor to biomedical engineering at Massachusetts General Hospital and associate professor of anesthesia at Harvard Medical School

The Final Three Years: 2015–18

Establishing a National Coalition to Promote Safe Practices

> "The AAMI Foundation's work in the area of infusion therapy safety supports pharmacists, nurses, and others involved in the infusion pump administration workflow. The videos and documents generated by the AAMI Foundation's coalition filled a knowledge gap and identifies safe practices for multiline infusions, smart pump compliance, drug library management, and more that allow clinicians to better care for their patients."
>
> —**Richard J. Zink**, managing director of REMEDI Operations at the Regenstrief Center for Healthcare Engineering at Purdue University

As the focus of the infusion therapy safety initiative shifted to education, communications, and promotion of evidence-based practices, the AAMI Foundation incorporated the work of the committees into a larger, three-year effort—the National Coalition for Infusion Therapy Safety, which launched in 2015.

The kickoff event, held in March 2015, brought together clinicians, biomedical engineers, hospital experts, researchers, patient advocates, representatives from national associations and societies, and industry partners to build consensus.

This National Coalition promoted the adoption of specific safety practices in four critical areas of infusion therapy to help ensure patient safety during intravenous infusions:

1. Safe implementation of multiple-line intravenous (IV) infusions
2. Increasing compliance with the use of smart-pump drug libraries, including migration to wireless systems to upload the libraries
3. Reducing non-actionable infusion pump alarms
4. Promoting questions senior hospital leaders should ask about infusion therapy safety

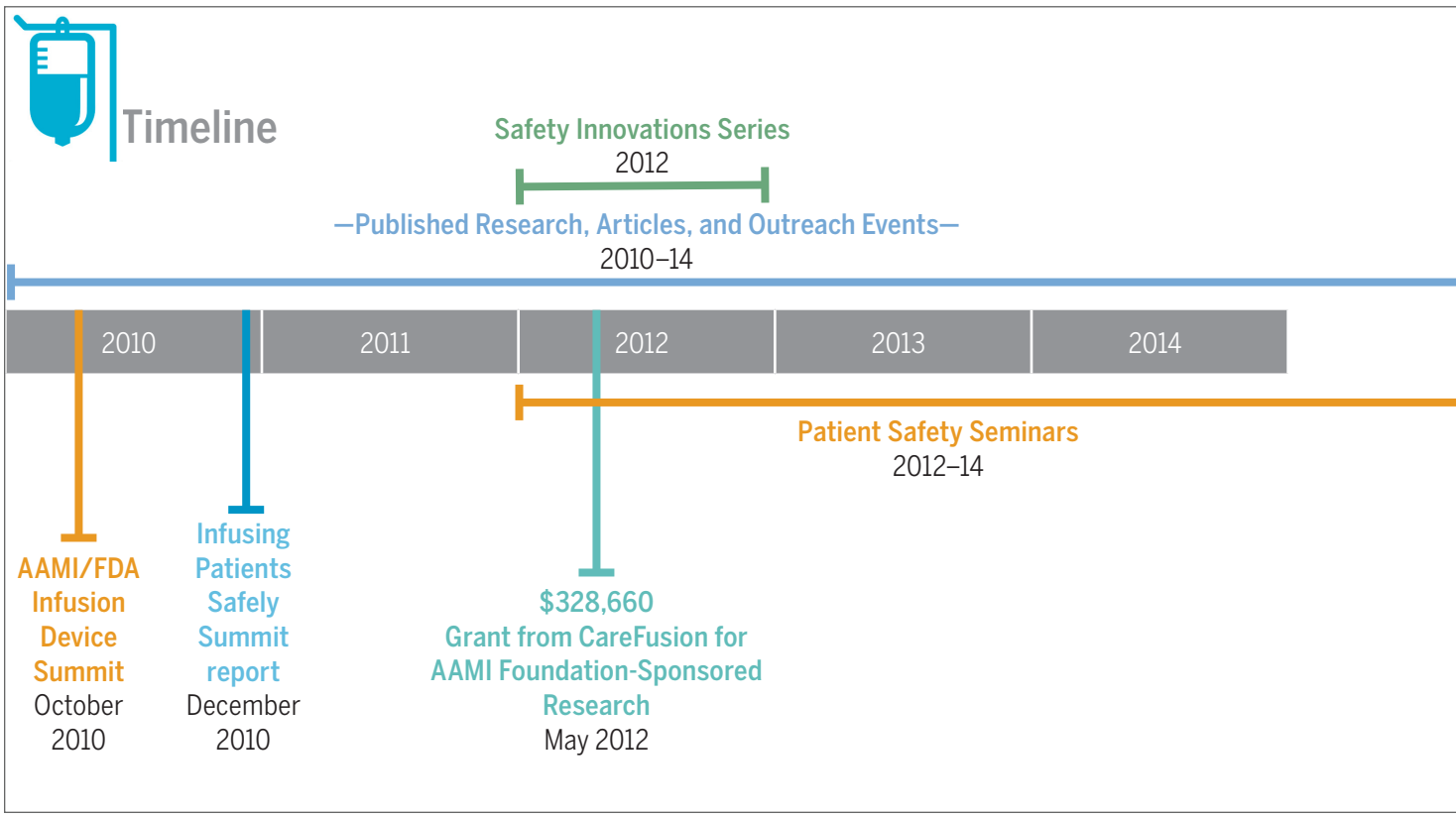
Through this multidisciplinary approach, the Foundation and the numerous Coalition volunteers produced high-quality education on infusion pump safety.

The Foundation employed a multimedia strategy to convey key messages to healthcare professionals at every level, from frontline clinicians to managers to C-suite senior leaders, as well as to those who deploy and service infusion pumps—biomedical engineers and technicians and IT specialists:

- Patient safety seminars (webinars) for targeted professional learning and continuing education
- Publications, including a Safety Innovations series, case-study articles, and Quick Guides
- Outreach events for key opinion leaders in well-recognized markets
- Social media

The Foundation disseminated coalition proceedings freely and publicly to the nation to ensure all hospitals had access to this critical information around infusion therapy safety.

The National Coalition helped the Foundation engage the entire healthcare community in multidisciplinary safety initiatives that would strengthen the development, management, and use of infusion therapy for improved patient outcomes.



How the AAMI Foundation Selects and Builds National Coalitions

Select Critical National Initiatives

- Conduct comprehensive review of current and emerging issues
- Engage stakeholder communities
- Vetting process with AAMI Foundation partners

Convene Critical Stakeholders

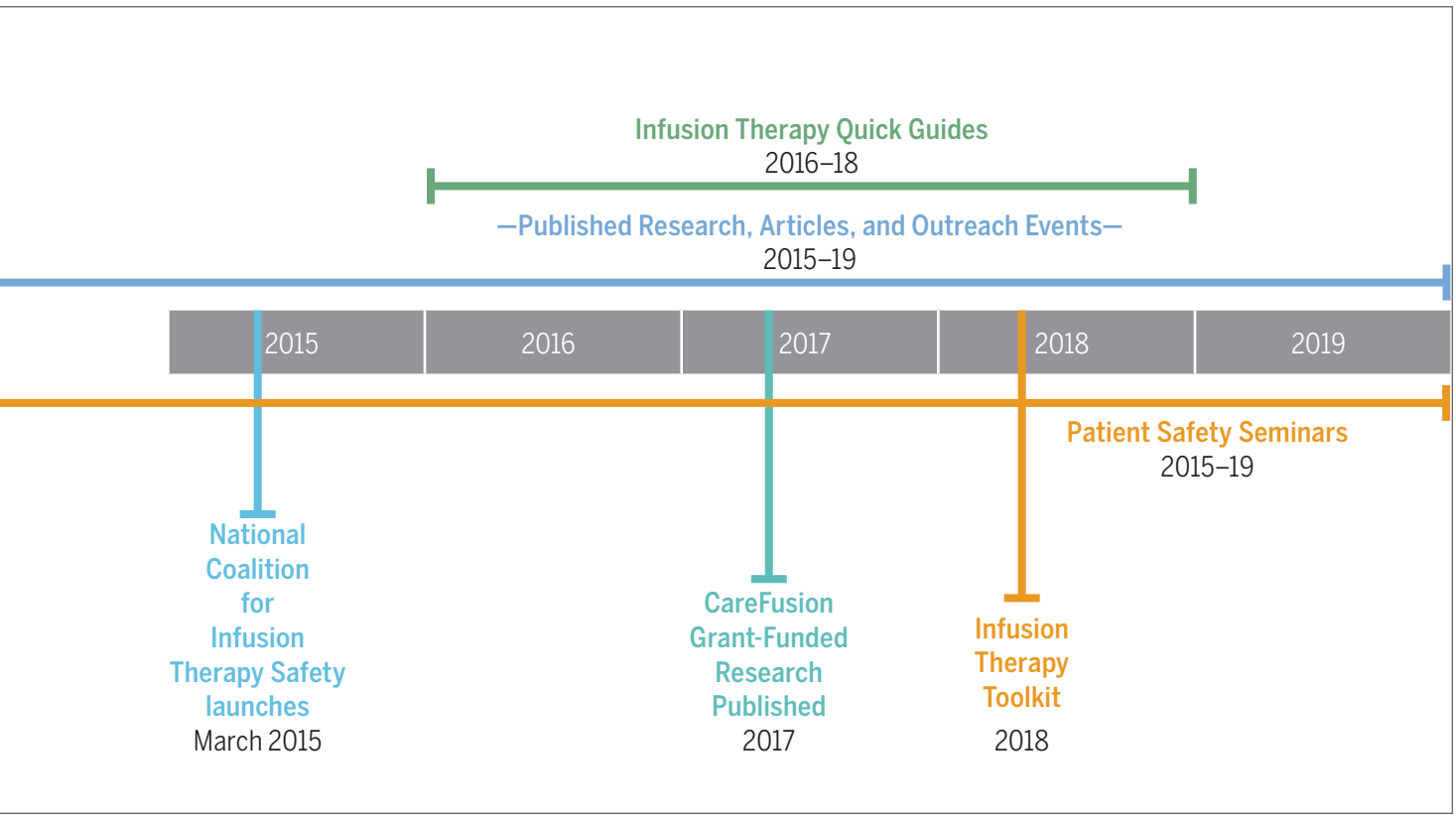
- Engage stakeholder organizations
- Host think tank meeting
- Ensure collaborating partners are involved
- Create teams for deliverables

Publish Deliverables

- Peer-reviewed manuscripts
- Best practices and guidance documents
- Patient safety seminars

Communicate and Enlist Support

- Engage stakeholder organizations in publicizing and disseminating deliverables



A Robust Collection of Knowledge

2010–18

"The coalition helped bring more visibility to the issue of infusion therapy safety. My organization is looking at ways to improve usability, safety, and unnecessary alarms on smart pumps. I used all of the deliverables. Keep it up! This is a really important area of patient safety for AAMI."

—**Karen Giuliano,** associate professor at the University of Massachusetts at Amherst's Institute of Applied Life Sciences and College of Nursing

The Call to Action

Deliverables from the AAMI/FDA Infusion Device Summit 2010

Summit Report, Presentations, and Priorities

Infusing Patients Safely: Priority Issues from the AAMI/FDA Infusion Device Summit
AAMI (2010)

This report issues a call to action to address the challenges around infusion therapy. It includes clarion themes, priorities, summaries of presentations, expert perspectives, and leading practices.

13 Priorities Generated by Participants of the AAMI/FDA Infusion Device Summit

Beyond the Summit

AAMI Foundation Safety Innovations Series 2012

Best Practice Recommendations for Infusion Pump–Information Network Integration
AAMI Foundation Infusion System Working Group (2012)

Pump integration requires pervasive and reliable wireless coverage—if pumps can't communicate with the server via a wireless network, no integration can occur.

Nine Recommendations to Prevent Multiple Line Infusion Medical Errors

The Health Technology Safety Research Team (HTSRT), University Health Network, Toronto, Canada (2012)

The study, *Mitigating the Risks Associated with Multiple IV Infusions*, was conducted by the Health Technology Safety Research Team at the University Health Network in Toronto, Canada, in collaboration with the Institute for Safe Medication Practices Canada. The nine

recommendations in this paper are from an interim report, *Multiple Intravenous Infusions Phase 1b: Practice and Training Scan.*

Smart Pump Implementation: A Guide for Healthcare Institutions

Health Technology Safety Research Team (HTSRT), University Health Network, Toronto, Canada (2012)

This document guides healthcare institutions through the purchasing and implementation phases of smart infusion pumps and helps institutions that are currently using this technology to assess successful adoption.

Practical Strategies for Executives, Risk Managers, and Clinical Leaders

Deliverables from the AAMI Foundation's National Coalition for Infusion Therapy Safety, 2015–18

Infusion Therapy Quick Guides

Improving the Safe Use of Multiple IV Infusions
AAMI Foundation (2016)

This guide provides evidence-based, actionable strategies and leads clinicians, especially nurse educators and nurses, through a set of tools for safe use of multiple IV infusions.

What You Need to Know about Smart Pump Compliance and Drug Libraries
AAMI Foundation (2017)

This guide introduces key concepts and identifies requirements for a successful infusion therapy safety program. It leads hospital staff through a series of questions about their smart pump usage, policies, and practices.

Optimizing Patient Outcomes: Questions Senior Hospital Leaders Should Ask about Infusion Therapy Safety
AAMI Foundation (2017)

This guide informs hospital senior leadership on the importance of supporting efforts to improve patient safety—and reduce cost—through the use of smart pump technology.

Managing Smart Pump Alarms: Reducing Alarm Fatigue
AAMI Foundation (2018)

This guide provides a starting point for healthcare institutions to begin to explore their large-volume and syringe pump alarms and understand potential strategies to mitigate nonactionable alarms.

Toolkits

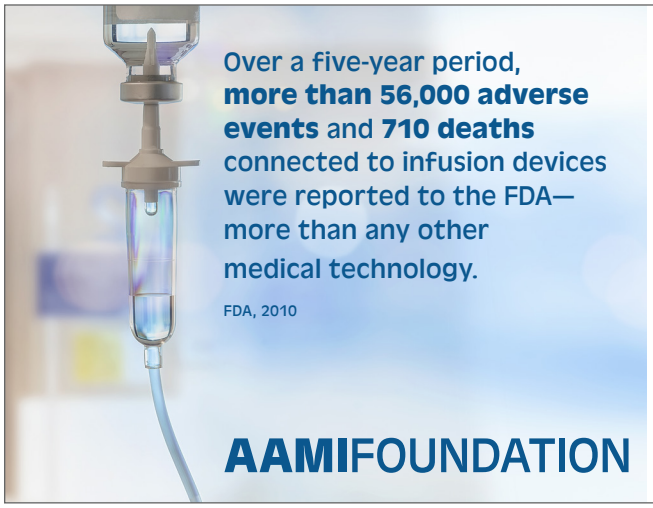
Intravenous Tubing Labeling Toolkit
Cassano-Piché, A., Pinkney, S., & Trbovich, P. (2018)

CareFusion Grant-Funded Research Sponsored by the AAMI Foundation

The Frequency of Intravenous Medical Administration Errors Related to Smart Infusion Pumps: A Multihospital Observational Study.

Schnock, K.O., et al. (February 26, 2017). BMJ Qual Saf 2:131–140. doi: 10.1136/bmjqs-2015-004465.

Spreading the Word



Social media is key to informing all those who are concerned about patient safety that there are tools developed by national experts to assist in reducing harm with infusion therapy. Over the eight years of this effort, AAMI and AAMI Foundation have made use of Facebook and Twitter to get the word out about the recommendations and solutions available to the clinical community.

Education and Knowledge Sharing

AAMI Foundation Annual Regional Events

2015–17

The AAMI Foundation provided live, interactive learning experiences during three annual regional events, where sessions highlighted infusion therapy and work by the Foundation's National Coalition on Alarm Management and National Coalition to Promote Continuous Monitoring of Patients on Opioids.

Infusion Therapy Presentations	Boston • Oct. 15, 2015 • 85 participants

Infusion Therapy Safety

Mary Alexander, chief executive officer, Infusion Nurses Society

Infusion Pump Informatics

Rich Zink, managing director of operations at Regenstrief Center for Healthcare Engineering at Purdue University

Infusion Therapy Safety

Shannon Sims, director of pharmacy at Cartersville Medical Center in the TriStar Division of Hospital Corporation of America

Achieving Drug Library Compliance as a Gateway to Improved Patient Safety

Mary Kane, vice president and regional chief nursing informatics officer, Catholic Health Initiatives

Infusion Pumps: Using Data to Support Quality Improvement Initiatives

Dennis M. Killian, pharmacy director at Peninsula Regional Medical Center, and associate professor at the University of Maryland Eastern Shore School of Pharmacy

Are You Connected: Get Ready to Reduce Alarms, Avoid Alarm Fatigue, and Improve Patient Safety

Cathy Sullivan, associate director of sourcing at Mount Sinai Beth Israel Hospital

Infusion Therapy Safety Update: Massachusetts General Hospital

Nathaniel Sims, cardiac anesthesiologist and physician advisor to biomedical engineering at Massachusetts General Hospital, and associate professor of anesthesia at Harvard Medical School

Multiple Intravenous Infusions: Education Opportunities

Sonia Pinkney, manager of the electromedical group in medical engineering at the University Health Network; human factors engineer at HumanEra; adjunct lecturer at the Institute of Health Policy, Management, and Evaluation at the University of Toronto

Infusion Therapy Presentations — Chicago • Sept. 27–28, 2016 • 113 participants

End-User Compliance with IV Smart Pumps: A Descriptive Study

Karen Giuliano, nurse scientist at Hallmark Health and postdoctoral fellow at Yale University Graduate School of Nursing

Improving Compliance with the Drug Library: A Case Study from Western Maryland

Chrissy Ruhl, director of critical care services at Western Maryland Health System

Infusion Therapy Safety: The Allina Health Experience

Margaret Schmidt, coordinator of pharmacy services at Allina Health

Using Infusion Pump Benchmark Data to Improve Patient Safety and Quality

Rich Zink, managing director of operations at Regenstrief Center for Healthcare Engineering at Purdue University

Multiple Intravenous Infusions: Education Opportunities

Dennis M. Killian, pharmacy director at Peninsula Regional Medical Center, and associate professor at the University of Maryland Eastern Shore School of Pharmacy

Are You Connected: Get Ready to Reduce Alarms, Avoid Alarm Fatigue, and Improve Patient Safety

Cathy Sullivan, associate director of sourcing at Mount Sinai Beth Israel Hospital

Impact of Smart Pump Technology

Marla Husch, assistant vice president of digital innovation at Vassar Brothers Medical Center

Smart Pump Integration: A Triple Win: Safety, Quality, and Efficiency

Tina Seuss, manager of medication safety integration at Lancaster General Health

Infusion Therapy Presentations	San Diego • Nov. 18–19, 2017 • 95 participants

Don't Just "Go with the Flow": How Standards Promote Infusion Pump Safety

Mary Alexander, chief executive officer, Infusion Nurses Society

Making Smart Pumps Intelligent: Interoperability with the EHR

Deb Bonnes, nursing informatics specialist, and **Sondra May,** medical safety coordinator at UCHealth's University of Colorado Hospital

Maximizing Syringe Pump Safety, Minimizing Risk

Alison Bloomquist, pharmacist and clinical resource specialist at Smiths Medical

Pump Fiction: The Myths and Realities of Implementing Smart Pump Technology in a Large Health Care System

Centura Health's **Julie Prince,** clinical pharmacy manager, **Cynthia Parson,** interim system director of quality and patient safety, and **Rhonda Ward,** group chief nursing officer of the South Denver operating group, chief nursing officer of Littleton Adventist Hospital, and executive sponsor of smart pump implementation

Sheridan Memorial Hospital: Alarm Management, Infusion Management, Device Integration

Charlotte Mather, chief nursing officer and Robert Wood Johnson Foundation executive nurse fellow, and **Stephanie Eisenhauer,** informatics pharmacist at Sheridan Memorial Hospital

Multiple IV Infusions: Where's My Line? And Making the Invisible Visible

Sonia Pinkney, manager of the electromedical group in medical engineering at the University Health Network; human factors engineer at HumanEra; adjunct lecturer at the Institute of Health Policy, Management, and Evaluation at the University of Toronto

Using National Infusion Pump Benchmark Data to Improve Patient Safety and Qualty

Rich Zink, managing director of operations at Regenstrief Center for Healthcare Engineering at Purdue University

"Since the AAMI Foundation launched its first national coalitions, we've found that providing clinicians and their healthcare technology industry partners with the opportunity to meet face to face encourages knowledge sharing and communication in a way that online seminars can't."

—**Marilyn Neder Flack**, executive director emeritus of the AAMI Foundation

Patient Safety Seminars
2012–18

Beginning in 2012, the AAMI Foundation hosted a series of patient safety seminars (webinars) that showcased research, best practices, and case studies of initiatives in healthcare organizations to improve infusion therapy safety. The Foundation offered Certificates of Participation as a continuing education credit for each seminar. Slide presentations are included in this Anthology. Recordings are available on the AAMI Foundation website.

Multiple IV Infusion Safety • May 2012
Andrea Cassano-Piché, MASc, PEng,

Mark Fan, MHSc

Christine Koczmara, RN, BSc

Health Technology Safety Research Team, University Health Network, Toronto

Best Practice Recommendations for Infusion Pump–Information Network Integration • January 2013
Erin Sparnon, MEng, senior project engineer, Health Devices Group, ECRI Institute

Todd Cooper, executive director, Breakthrough Solutions Foundry

Raising the Bar on Infusion Therapy Safety: A Patient Safety Program at Catholic Health Initiatives • June 2016
Mary Kane, RN, MS, vice president and regional chief nursing information officer, Catholic Health Initiatives

Improving Patient Safety with Infusion Pumps: A Systematic Approach • July 2016
Molly A. Hicks, RN, MSN, director of patient safety

Jason Trahan, PharmD, pharmacy director–medical safety, Baylor Scott and White Health

Raising the Bar on Infusion Safety Seminar Series

Patient Safety Initiatives at Western Maryland Health System and Cameron Memorial Community Hospital • August 2016
Christine Ruhl, BSN. MBA, CCRN, director of critical care services, Western Maryland Health System

Scott Hirschy, RN, BS, IT applications manager, Western Maryland Health System

Andrew Aldred, PharmD, MBA, director of pharmacy and materials management, Cameron Memorial Community Hospital (IN)

Are You Connected? Get Ready to Reduce Alarms, Avoid Alarm Fatigue and Improve Patient Safety • October 2016
Cathy Sullivan, MSN, RN, FNP, CCRN, associate director of sourcing, Mount Sinai Beth Israel (NY)

Post Infusion Management Implementation: A Team Approach to Patient Care • November 2016
Angie Box, MSHI, BSN, RN, manager, Nursing Informatics

Karen Corrick, BSN, RN, Nursing Informatics

Managing Smart Pump Alarms: A Patient Safety Program at Palomar Health • February 2017

Diana Schultz, RPh, MHSA, Medication Safety, Palomar Health (CA)

Carol Suarez, Clinical Nurse Specialist, Pulmonary Progressive Care and Med-Surg Telemetry Acute Care, Palomar Health

LaQuoia Johnson, PharmD., BCPS, Pharmacy Supervisor, Forsyth Medical Center (NC)

Preparing for Integration of Your Electronic Health Record with Your Smart Infusion Pumps • March 2017

Tina M. Suess, MHA, BSN, RN-BC, CPHIMS, manager of medication safety integration, Lancaster General Health (PA)

A Case Study from Parallon: Improving Compliance with the Smart Pump Drug Library Across a Large Hospital System: Part 1 • June 2017

Lori Marsh, DPh, Tristar Division director of medication safety, Parallon Supply Chain Solutions

A Case Study from Parallon: Improving Compliance with the Smart Pump Drug Library Across a Large Hospital System: Part 2 • July 2017

Laura Monroe-Duprey, BS Pharm, PharmD, regional director of pharmacy, Inova Mount Vernon Hospital and Inova Alexandria Hospital (VA)

Infusion Pumps: A Structured Approach to Drug Library Optimization • August 2017

Dennis Killian, Pharm.D., Peninsula Regional Medical Center (MD)

Making the Invisible Visible • September 2017

Sonia Pinkney, PEng, MHSc, manager of the electromedical group in medical engineering at the University Health Network; human factors engineer at HumanEra; adjunct lecturer at the Institute of Health Policy, Management, and Evaluation at the University of Toronto

Multiple IV Infusion Safety: Where's My Line? • September 2017

Sonia Pinkney, PEng, MHSc, manager of the electromedical group in medical engineering at the University Health Network; human factors engineer at HumanEra; adjunct lecturer at the Institute of Health Policy, Management, and Evaluation at the University of Toronto

Andrea Cassano-Piché, M.A. Sc., PEng, human factors consultant, Human Factors North

Smart Pump Interoperability: A Multi-System Safety Journey • February 2018

Deb Bonnes, RN, MS, nursing informatics specialist, at UCHealth in Aurora, CO

Jennifer Biltoft, PharmD, BCPS, system clinical pharmacy manager, SCL Health (CO)

Transforming Healthcare: Implementation of Smart Pump/EMR Interoperability to Improve IV Medication Safety, Quality, and Cost • May 2018

Nilesh Desai, BS, RPh, MBA, administrator of pharmacy and clinical operations at Hackensack University Medical Center (NJ)

Going Deeper

Articles and Case Studies from AAMI and the AAMI Foundation

2010–18

BI&T (Biomedical Instrumentation & Technology), AAMI's peer-reviewed journal

Help Us Make Infusion Systems Safer
Baird, P. (September/October 2010)

First, Do No Harm: Making Infusion Pumps Safer
Brady, J.L. (September/October 2010)

Dangerous Connections: Healthcare Community Tackles Tubing Risks
Vockley, M. (November/December 2011)

What's the Prognosis? Making Infusion Systems Safer
Vockley, M. (September/October 2012)

Worth the Effort? Closed-Loop Infusion Pump Integration with the EMR
Pettus, D.C., & Vanderveen, T. (November/December 2013)

The Fundamentals of … Intravenous Pumps
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Pham, J.C., Carson, K.A., Benson, K., Doyle, P.A., Ijagbemi, M., Ravitz, A., Wyskiel, R., & Tran, G. (July/August 2016)

Reflections on the Current State of Infusion Therapy
Weinger, M.B., & Kline, A. (July/August 2016)

Case Study: Enhancing Use of Drug Libraries Across a Large Healthcare System
Miller, P.J. (September/October 2016)

Passion for Safety Underpins Healthcare System's Infusion Pump Upgrade
Vockley, M. (January/February 2017)

Reliable and Scalable Infusion System Integration with the Electronic Medical Record
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Case Study: Collaboration Fuels Success of Infusion Management Interoperability Initiative
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Next-Era Infusion Management Systems: Inherently Intelligent From the Start
Gray, G. (March/April 2018)

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Frequency and Duration of Infusion Pump Alarms: Establishing National Benchmarks
Vitoux, R.R., Schuster, C., Glover, K.R., & Dekker, M. (November/December 2018)

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Do Smart Pumps Actually Reduce Medication Errors?
Pinkney, S., Trbovich, P., Fan, M., Rothwell, S., Cafazzo, J.A., & Easty, A. (Fall 2010)

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'Where IT Meets IV': Integrating Infusion Devices with Hospital Information Systems
Pettus, D.C., & Vanderveen, T.W. (Fall 2011)

Using Informatics to Improved Medical Device Safety and Systems Thinking
Witz, S., Buening, N.R., Catlin, A.C., & Malloy, W. (Fall 2014)

Ensuring Secure and Safe Infusion Delivery in a Connected World
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Hardening Infusion Pump Communication Software for Medical Device Cybersecurity
Smigielski, R. (Fall 2017)

IV Smart Pumps and Error-Prone Programming Tasks: Comparison of Four Devices
Giuliano, K.K. (Summer 2018)

AAMI Blog Posts

James Rudolph: Understanding the Infusion Pump Crisis (April 10, 2012)

Mary Logan: Making Infusion Pumps More User-Centric (Jan. 17, 2013)

Tim Vanderveen: Moving the Ball Forward with Infusion Pump Safety (Jan. 7, 2014)

Tim Vanderveen: Don't Approach the Challenges of Pump Alarms with a Broad Brush (May 28, 2014)

Matthew B. Weinger: Why Are Our Infusion Pumps Not Smarter or Safer? (Jan. 28, 2015)

Tim Vanderveen: Imagine the Possibilities (Sept. 2, 2015)

Alison Bloomquist: A Simple Solution to Improve Syringe Pump Safety (Oct. 21, 2015)

Karen K. Giuliano: Addressing Technology Deficits to Make IV Smart Pumps Safer, Smarter (Nov. 19, 2015)

Salim Kai: Be A Partner in Patient Safety (May 31, 2017)

AAMI Podcast

Episode 15: Infusion System Safety (Nov. 23, 2015)

Infusion System Safety: Are We on the Right Path?
(Fall 2015)

AAMI dedicated the Fall 2015 ***Horizons*** to infusion therapy safety. The issue features perspectives on how simplified user interfaces for pumps can improve programming times and reduce use errors. Other research describes how improved smart pump drug library use can help eliminate clinical workarounds. The issue also features case studies, including the challenges and rewards of one group's smart pump implementation efforts, in which it leveraged quality data to improve pump safety and usefulness. Select articles:

The Big Picture

A Roundtable Discussion: Working Toward Safer, Easier-to-Use Infusion Systems

Perspectives

Reducing Intermittent Infusions Syringe Pump Errors via Weight-Based Safety Parameters

Bloomquist, A., & Seiberlich, L.

IV Smart Pumps: The Impact of a Simplified User Interface on Clinical Use

Giuliano, K.K.

Eliminating Clinical Workarounds through Improved Smart Pump Drug Library Use

Vitoux, R.R., Lehr, J., & Chang, H.

Case Studies

Implementing Smart Infusion Pumps at Kaiser Permanente

Harrison, L.T., & Peacock, J.

Ensuring Optimal Smart Pump Use Through Augmented User Interface

Hoh, T., Beer, I., & Krueger, P.

Conclusion

When AAMI and the AAMI Foundation set out to convene a summit, form volunteer committees, and launch a National Coalition for Infusion Therapy Safety, there was no way of knowing where any of this would lead. This was the first time in our organizational histories that such an ambitious patient safety initiative had been launched.

"I was in industry and found AAMI to be one of those beacons of safety in particular and practice at large. In this space, we relied heavily on the guidance direction from AAMI. As part of product development efforts, educating the company on the standards became guidance for roadmap planning, budgeting, and so on. It is critical to have organizations like AAMI to help the industry stay on course."

—**Chris Buckley**, chief commercial officer at Cuida Health in San DiegoUniversity of Massachusetts at Amherst's Institute of Applied Life Sciences and College of Nursing

A high level of interest and sustained engagement by hundreds of volunteers and almost three dozen professional organizations and corporate partners led to an ambitious scope of work to promote the safe and effective use of infusion systems.

The lasting result is a robust collection of knowledge about infusion therapy safety that can inform research, practice, and innovation to benefit the most important healthcare stakeholder: patients. Even as infusion technology continues to change, this body of work—which covers the entire sociotechnical ecosystem of people, technology, organizations, and processes—remains relevant, accessible, and useful to the field.

From Quick Guides to professional development in patient safety seminars to research and case studies, there is something for everyone, including:

- Healthcare executives, medical professionals, pharmacists, and risk managers.
- Researchers and educators.
- Device manufacturers, systems integrators, and innovators.
- Standards developers and regulators.

AAMI and the AAMI Foundation thank everyone who participated in promoting the safe and effective use of infusion systems. We invite you to share this Anthology with your colleagues and peers.

National Coalition for Infusion Therapy Safety

2015–18

Participating Organizations

- American Association of Critical-Care Nurses (AACN)
- American College of Clinical Engineering (ACCE)
- American Nurses Association
- American Society for Healthcare Risk Management
- American Society of Health System Pharmacists (ASHSP)
- California Hospital Patient Safety Organization
- ECRI Institute
- Healthcare Technology Foundation (HTF)
- Hospital Quality Institute (HQI)
- Infusion Nurses Society (INS)
- Institute for Safe Medication Practices (ISMP)
- National Patient Safety Foundation (NPSF)
- National Association of Clinical Nurse Specialists (NACNS)
- Premier Safety Institute
- Regenstrief Center for Healthcare Engineering
- The Joint Commission

Corporate Partners

Diamond Level

- BD
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- B. Braun Medical Inc.
- Ivenix
- Smiths Medical

Gold Level

- Cerner

Bronze Level

- Fresenius Kabi
- Safen Medical Products
- Zyno Medical

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Acknowledgments

AAMI and the AAMI Foundation are incredibly grateful to all who participated in this Coalition. We recognize that so much of the work of the infusion therapy initiative was taken on by volunteers who devoted their time, expertise, and passion for enhancing patient safety. Without their commitment, we would not have been able to produce such high-quality research, practical resources, and patient safety seminars to support healthcare organizations and clinicians who use infusion technology in the care of patients.

We would like to extend our sincere thanks to several individuals who helped support this Coalition and craft this anthology:

- Mary Logan, president and CEO emeritus of AAMI, who had the vision to create the coalition and expand the role of the Foundation
- Marilyn Neder Flack, executive director emeritus of the AAMI Foundation, whose energy and passion are unparalleled, for her ability to encourage others to share their wiser practices for the greater good
- Sarah Lombardi, former project manager of the AAMI Foundation, who provided incredible organizational support to the coalition
- Deborah Hille, education operations manager at AAMI, who helped with webinars and meetings and provided database support, and Barbara Saxton, website director at AAMI, who is a talented editor and who also supported our website.
- Martha Vockley and Jude Lang, principals at Vockley•Lang, for their ability to distill all of the information and deliverables created by our coalition teams into a wonderful resource
- The AAMI marketing and communications team and other AAMI staff who supported the activities of the coalition