AAMI
Advancing Safety in Medical Technology

A Vision for Anywhere, Everywhere Healthcare

Priority Issues from the 2013 AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings

Summit Conveners

AAMI

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a diverse alliance of nearly 7,000 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.

FDA

The U.S. Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. The 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.

About this Report

This publication covers the clarion themes, challenges, and priority actions developed by consensus at the summit. The report summarizes summit presentations and provides additional perspectives from experts. This publication is intended to be a helpful information resource, and reflects the expert advice and views of the summit experts. It is not to be construed as an interpretation of AAMI standards, nor does it constitute legal or regulatory advice.

A Special Note

Federal employees who had contributed to the summit planning were unable to attend due to the federal government shutdown; their perspectives are captured in this report from presentations prepared in advance.

More Summit Information on AAMI Website

The summit agenda, presentations, reference materials—including the AAMI spring 2013 *Horizons, Home Healthcare: Tackling the Challenge of Medical Technology in Nonclinical Settings*—and updates are posted on: www.aami.org/summit2013

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633
www.aami.org

A Vision for Anywhere, Everywhere Healthcare

PRIORITY ISSUES FROM THE 2013 AAMI/FDA SUMMIT ON HEALTHCARE TECHNOLOGY IN NONCLINICAL SETTINGS

Contents

A Call to Action

"Change is the law of life. And those who look only to the past or present are certain to miss the future."
—President John F. Kennedy

Dear Colleagues,

This year's AAMI/FDA summit, our fifth deep dive into a single, technology-related patient safety topic, will be remembered as the one that was held during the U.S. federal government shutdown, preventing government employees from actively participating in the two-day event.

An AAMI/FDA summit that is missing the U.S. Food and Drug Administration (FDA) may sound odd, but for staff of the agency's Center for Devices and Radiological Health (CDRH), who are passionate about the safety of medical technology in the home and other nonclinical settings, not being able to attend this summit was like missing their child's high school graduation.

In the end, more than 170 attendees from multiple disciplines and backgrounds incorporated the spirit of the FDA into the meeting, most notably via an emphasis on safe home care, evident in every discussion.

One strong, consistent drumbeat heard throughout the meeting was the call for policymakers, the Centers for Medicare & Medicaid Services (CMS), and other regulators to reassess whether the simplistic "wheelchair" model still works: A patient is discharged from a hospital, and a wheelchair magically appears at the patient's home upon arrival.

This model was designed in a very different era, for very different needs, and with very different technologies. However, it is now used to deliver complex, life-critical devices such as ventilators and infusion pumps to the home and other nonclinical settings. Manufacturers can design and produce perfect "home-ready" devices with the very best, intuitive instructions for use, and patients and their caregivers at home will still be at risk when using these devices if the rest of the system of care is not ready. A technology assessment of the home is crucial. As more technology used in patient care is driven outside the controlled hospital environment, we should heed President Kennedy's words of advice.

The desired outcomes of this summit were the following:

- To develop a list of issues about the use of healthcare technology outside controlled clinical settings that the healthcare community can commit to address.
- To agree on which issues are the highest priorities for follow-up.
- To identify which healthcare organizations can follow up on which issues.

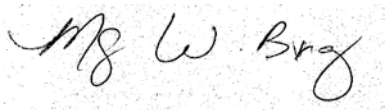
As before, this year's summit was a community event, and this publication belongs to the community. It does not present what either AAMI or the FDA thinks or believes. It presents what the community said. Please read, highlight, and share this publication with your colleagues. More importantly, please find the nuggets of information that call you and your organization to action!

We are grateful to the 16 supporting organizations that believed in the need for this event and agreed to support it: the Ambulatory Surgery Center Association; American College of Clinical Engineering; British Standards Institution (BSI); Center for Aging Services Technologies (CAST); Continua Health Alliance; ECRI Institute; eHealth Initiative; Healthcare Technology Foundation; Human Factors and Ergonomics Society; Infusion Nurses Society; The Joint Commission; Medical Device Innovation, Safety and Security Consortium; National Home Infusion Association; National Patient Safety Foundation; Underwriters Laboratories; and Wireless-Life Sciences Alliance.

We look forward to continuing the dialogue that was started at this defining event to promote the safety of patients who are using healthcare technology outside of controlled clinical environments. Whether you attended the summit or have found this publication via a different route, your feedback matters. We look forward to hearing about your suggestions, lessons learned, challenges, and successes.

Sincerely,

Mary Logan
President
Association for the Advancement of Medical Instrumentation



Mary Weick-Brady
Senior Policy Advisor
Office of the Center Director
Center for Devices and Radiologic Health
U.S. Food and Drug Administration

Executive Summary

"Vision is not enough. It must be combined with venture. It is not enough to stare up the steps, we must step up the stairs."
— Vaclav Havel, poet, playwright, and first president of the Czech Republic

A Vision for Anywhere, Everywhere Healthcare

The delivery of healthcare services and the use of medical technology outside clinical settings are increasing rapidly. The global population is aging and, with advances in healthcare, people are living longer—even with serious and often multiple medical conditions. People of all ages live, work, play, and travel with chronic health issues that can be managed outside hospitals and other clinical settings. People often prefer receiving care in the comfort of their homes or other settings, such as senior living or assisted care facilities, and many prefer the mobility afforded by portable devices as well. The enormous pressure on hospitals to cut costs is also driving the growth of healthcare outside traditional settings.

Advances in medical technology, pharmaceuticals, and other products have made this shift in healthcare to nonclinical settings possible. Whereas patients once had to visit doctors' offices, clinics, and hospitals for healthcare that required sophisticated medical technology, they (or their caregivers) now can use monitors, infusion devices, oxygen machines, ventilators, dialysis machines, telemonitoring systems, and much more without leaving their homes. People also are rapidly adopting "nonmedical" technologies—such as fitness sensors, vital signs monitors, and software applications on personal mobile devices—and grey-market[1] products to track and manage their health. This demand for medical equipment that does not necessarily meet regulatory requirements for products developed by traditional industry suppliers is projected to increase in the future. Advances in pain management and drugs to treat myriad medical conditions

The AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings drew a wide array of stakeholders. Here, Shashi Avadhani, CCE, a regional operations manager at Crothall Clinical Equipment Solutions, asks a question.

[1]The grey market refers to unofficial trade that circumvents manufacturers' authorized sales and distribution channels. Grey market products can be counterfeit, or less expensive than and inferior to products sold via authorized channels.

support the delivery of healthcare services in nonclinical settings as well.

At the highest levels of U.S. government, moving more healthcare services out of hospitals is of keen interest. The U.S. Department of Health and Human Services (HHS) has made home care a strategic priority; efforts at the Centers for Medicare & Medicaid Services (CMS), the U.S. Food and Drug Administration (FDA), the Veterans Administration (VA), and The Joint Commission (TJC), dovetail with this priority. Affordability is a factor, of course: Healthcare costs much more in a hospital than it does almost anywhere else. Notably, people often experience better health outcomes outside the hospital. The risk of infection is higher in hospitals than in nonclinical settings, for example, and hospital stays can be stressful for patients.

Healthcare delivered outside clinical settings already is helping millions of individuals with medical conditions live more normal and productive lives. There is the potential for benefits on a far greater scale: more independence and control by individuals, more portable and appealing healthcare technology, reduced costs, and better outcomes.

Today's Reality

The 2013 AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings illuminated many impediments to safe, effective healthcare outside hospitals. The full extent of the unprecedented challenges and unintended consequences is only now beginning to be understood.

Chief among the messages from the summit is this: It is increasingly difficult to keep up with all the changes in healthcare. In the absence of new processes, practices, and products, healthcare service and technology providers are retrofitting approaches developed—and used, in large measure, effectively—in traditional hospital ecosystems. Approaches that work well in robust hospital infrastructures, with well-trained professionals, fall short in highly variable nonclinical settings with patients and caregivers who are rarely healthcare experts. In fact, even individuals and caregivers who *do* have healthcare expertise can be confused by the different challenges they face when they are responsible for care in nonclinical settings, which lack a safety net of support.

In hospitals and other acute-care settings, healthcare professionals typically have clearly defined roles and responsibilities. They work together in a healthcare delivery organization or system to provide optimum care, ensure patient safety, and minimize risk. In nonclinical settings, healthcare service providers from multiple organizations function in loosely coupled ways, making it difficult to deliver coordinated services. Challenges are particularly evident during transitions in care—when patients are discharged from hospitals, their care migrates to different providers, there is a "handoff" from one service provider to another, or new or different healthcare technology or drugs are introduced into the mix of care.

Summit participants with experience in the field expressed the need for new models of care that synchronize all of the disjointed elements at play in nonclinical settings. They advocated a systems approach—encompassing people, workflows, therapies, technology, and payment—to redesign the full spectrum of healthcare.

At the 2012 AAMI/FDA Interoperability Summit, participants floated analogies to the "wild, wild West"—only to refute them. While challenges exist in many domains, it is a stretch to say that lawlessness and disorder dominate the regulatory environment, standards, or practices. However, when it comes to healthcare technology in nonclinical settings, many of this year's summit participants said they felt as though they *are* exploring uncharted territory. Regulations are inconsistent, unclear, or nonexistent—and it's not just FDA regulations that apply (or ought to apply). Standards that might make sense for healthcare technology used in hospitals don't necessarily translate well to nonclinical settings, nor do standards necessarily support the aggregation, integration, and effective use of data. The regulations, care processes, and payments for device use in the home are built on a very old model that never anticipated the kind of home care being provided today. These challenges, along with inadequate safety testing, make it difficult to ensure that medical devices used in nonclinical settings are safe.

Finally, summit participants asserted that too many medical devices deployed into nonclinical settings are not "home ready"—or ready to add value to patients' lives. Devices can be difficult to use for people with physical or cognitive limitations, and even for people without these limitations. User interfaces are highly variable and not always intuitive for patients and caregivers; instructions for use can be complex or unavailable. As a result, the same kinds of workarounds that clinicians come up with to manage healthcare technology in hospitals are also rife in nonclinical settings. Even worse, some people simply give up trying to use devices as they should. Summit participants called for manufacturers to "design with empathy" for intended users and apply human factors expertise throughout the design and development process.

Held Oct. 9–10, 2013, in Herndon, VA, the summit brought together patients, caregivers, clinicians, healthcare service providers, patient safety advocates, researchers, manufacturers, and healthcare technology management (HTM) professionals. Summit participants identified and prioritized issues they are encountering in the field. This report, with its clarion themes, challenges, and priority actions, reflects these discussions and presents a framework for moving forward.

Brian Rothman, MD, assistant professor of anesthesiology at Vanderbilt University Medical Center, spoke about telehealth considerations. Looking on are Neil Charness of Florida State University, and Bridget Moorman, of BMoorman Consulting, LLC.

The audience listens to a recording of Michele DeMeo, a former sterile processing manager who is terminally ill with ALS and cancer. She offered the perspective of both a healthcare professional and patient.

Summit Overview

"We need to raise the bar … to incrementally improve. When I heard about this summit, I was relieved. I might not get the benefit of it, but someone will."
— Michele DeMeo, a healthcare professional and an ALS and cancer patient in hospice care

One Patient's Call to Action

The AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings opened with a moving call to action from a woman who sees "both sides of the coin." As an expert in sterile processing, Michele DeMeo provided healthcare technology services and support throughout her career. For this event, though, she spoke as a patient advocate, drawing from her experiences as a terminally ill hospice patient with amyotrophic lateral sclerosis (ALS) and cancer, in a message she videotaped from her home.

She urged summit participants to come together around a well-rounded set of actions that will improve healthcare technology and patient care, not just from the manufacturer's or caregiver's perspective, but from the patient's perspective. "I urge you to consider training staff in broader ways, keeping in mind education levels, socioeconomic considerations, unknowns," DeMeo said. "As you approach the home and interact and build your business or service, or craft your new standard or regulation, remember that there are no two people alike, no two patients alike."

DeMeo personified the roughly 8.6 million to 12 million people who receive home care (The Joint Commission, 2011; National Association for Home Care & Hospice, 2010). "As someone who has been in the business over 22 years, and who has come to the point where I realize I am left in the hands of others, relinquishing some choices, relinquishing independence, and having to trust sets of hands I may never have met before," she said, "is challenging."

'True Patient Self-Care'

Summit keynote presenter Joseph Cafazzo is senior director of medical engineering and healthcare human factors with University Health Network at the University of Toronto, Canada. Cafazzo set the stage for identifying both challenges and opportunities for improving healthcare in nonclinical settings. Six chronic conditions—diabetes, lung disease, heart failure, high blood pressure, kidney disease, and mental health issues—consume 75% of healthcare spending, he said. Add cancer, and those seven conditions account for 85% of healthcare spending.

When these conditions can be managed in residential rather than acute-care settings, the cost of healthcare is reduced and patients' quality of life increases, said Cafazzo. "The big opportunity is true patient self-care in the home or otherwise," he said. There are barriers to overcome before this opportunity can be harnessed fully, beginning with

serious usability challenges with healthcare technology. "In some cases I think we've lost empathy with users. We're missing opportunities to create real innovations in healthcare products," he added.

Usability challenges contribute to perceptions by both healthcare providers and patients that patients are simply not capable of managing their own care. Cafazzo countered these perceptions by pointing to success stories and innovations in the works.

"The group that has made the biggest impression on me is patients on home hemodialysis," he said. People with chronic kidney disease who require dialysis typically endure three weekly visits to a clinic and spend four hours in every session tethered to a dialysis machine. This conventional regime compromises their quality of life and productivity. More than a decade ago, Christopher Chan, Cafazzo's colleague at the University of Toronto, and other researchers began investigating what would happen if dialysis moved into the home.

At the time, this was an audacious concept. Nephrology nurses spend two years in specialized training. The researchers proposed training patients for six weeks to self-administer their own dialysis. Patients thought that home hemodialysis would be a burden on their family members. They were afraid of a catastrophic event in the absence of nursing support. They didn't believe they could learn to use the equipment.

But they did learn. Patients on home hemodialysis had improved health outcomes, including normalization of blood pressure, restored heart function, and better peripheral circulation and sleep quality. They gained autonomy and reduced their healthcare costs. Young women with end-stage renal disease were able to conceive and bear children.

Ingenious patients can do even more. Cafazzo shared the story of Hu Songwen, a Chinese man who built his own dialysis machine from kitchen utensils and old medical instruments after he could no longer afford hospital bills. He has kept himself alive for 13 years (Bates, 2013). Not many patients will invent their own healthcare technology, of course, but this story illustrates how motivated patients can be.

"Now, what else can patients do?" Cafazzo asked. Plenty, if work at the Centre for Global eHealth Innovation is any indication. For example:

- Teenagers with diabetes—a population that tends not to comply with doctors' orders for regular glucose monitoring—are using mobile phones with a built-in glucose meter to more effectively manage this condition. Teenagers transfer glucose readings over Bluetooth to healthcare providers, interact with peers on private social media sites, and earn iTunes redemption points for every reading. After three months using this application, known as Bant, daily testing frequency increased almost 50%, according to Cafazzo. A full, randomized control clinical trial is in the works. Notably, this application is designed with teenagers in mind. "We're doubling down on the gamification aspects," Cafazzo said. "Kids can be very

Data Points on U.S. Home Healthcare

- **8.6 million to 12 million** people receive home healthcare (The Joint Commission, 2011; National Association for Home Care & Hospice, 2010).
- By 2050, **27 million** people are expected to receive home healthcare (Home Care & Hospice, 2012).
- **More than 1 million** home healthcare and hospital workers care for these patients (The Joint Commission, 2011).
- **65.7 million** informal and family caregivers (29% of the U.S. adult population) care for the ill, disabled, or aged (Family Caregiver Alliance, 2012).
- **43.5 million adult family caregivers care for someone 50+** (Family Caregiver Alliance, 2012).
- The aging population (65+) will more than double between 2000 and 2030, increasing from 35.1 million to **71.5 million** (Family Caregiver Alliance, 2012).
- Estimates of the size of the home healthcare market range from **$68 billion** (Kayyali et al., 2011) to **$74 billion** (IBISWorld, 2013) to **$85 billion** (Leiber, 2012).

competitive. With a leaderboard, they can track their progress with their peers."

- Adults with hypertension are using a Bluetooth-enabled blood pressure monitor with a different set of incentives for patient compliance: reminders to check their blood pressure and warnings of any adverse trends. Individuals who used this monitor experienced a 20% drop in their cardiovascular risk, with no extra medications or visits, compared with those using a conventional monitor, Cafazzo said.

Successes that result from designing advanced home devices with the needs of users in mind suggest missed opportunities to improve healthcare outcomes on a broader scale, such as:

- Improved patient adherence of self-monitoring of blood glucose
- Improved medication adherence
- Lower dependence on physician care
- Improved self-awareness

"The bottom line: With randomized control trials, we're getting improved health outcomes at reduced cost," Cafazzo said. "But we won't get there without empathy in design. Given the right technology and environment, we can do great things."

Leveraging the opportunities will require the healthcare community to come together around the clarion themes and address the challenges identified at the summit.

Clarion Themes

1. Deepen all stakeholders' understanding of use environments—and their remarkable variability.
Research, information exchanges, and assessments of nonclinical use environments and practices—in homes, schools, offices, and public venues, in transit, and beyond—will help the healthcare community improve patient outcomes.

2. Coordinate multiple and recurring transitions in care to improve patient safety.
Delivering seamless care and support services to patients (and caregivers) as they move between clinical and nonclinical settings, interact with service and equipment providers, and adapt to medical technology will all help instill a culture of safety.

3. Adopt a systems approach—encompassing people, workflows, therapies, technology, and payment—to redesign the full spectrum of healthcare in nonclinical settings.
Synchronizing the disjointed components of healthcare delivery in nonclinical settings will help improve the quality of patient care.

4. Standardize and simplify.
Creating consistency and clarity in regulations, data, information, and testing will support integrated products and services and instill confidence in the security and safety of medical equipment.

5. Design with empathy.
Attending to human factors in developing medical devices that are "home ready" and designed to add value from the patient's perspective will support innovation and safety in healthcare.

CLARION THEME 1

Deepen all stakeholders' understanding of use environments—and their remarkable variability.

"If you thought hospitals were complex, varying, and high consequence, try the real world."
— Lane Desborough, product strategist, Medtronic

Challenge	Priority Action	Accountable*
Lack of understanding of the scope, complexity, variability, and higher risks associated with nonclinical use environments and practices Lack of information about patient outcomes in nonclinical settings	Research and analyze the full range of use environments outside controlled clinical settings, and compare patient outcomes in clinical and nonclinical settings. Identify effective and ineffective practices. Complete a gap analysis that specifies needed improvements. Identify and promote best practices.	• **CMS** • **TJC** • **AHRQ** • **Home health delivery organizations** • CHAP • AHCA • User advisory organizations • Academic researchers • AAMI/HTSI • Patient safety organizations • Professional societies
Lack of information about patient and caregiver experiences with medical devices in nonclinical settings	Create a mechanism or forum to gather and share information from both patients and caregivers about challenges, adverse events, near misses, and hazards with healthcare technology in nonclinical settings.	• **FDA (Medwatch)** • TJC • **CMS** • Continua Health Alliance • AAMI/HTSI • Patient safety reporting organizations • Manufacturers' quality systems
Lack of coordination in the use of appropriate technology for a specific patient in a specific use environment	Assess the use environment for healthcare technology readiness. Assess patient and/or caregiver abilities to use medical equipment safely and appropriately.	• **CMS** • **Private payers** • **Healthcare delivery organizations** • **Home health delivery organizations** • Clinicians

*Key organizations are bold-faced.

Use Environments: 'Completely Uncontrolled' and Marked by 'Perversities'

Summit presentations indicated that home use environments are idiosyncratic, complex, and riskier than clinical settings for the use of complex clinical technology.

ECRI Institute cited "poor usability of home-use medical devices" in its Top 10 Health Technology Hazards for 2012. Summit presenter James Keller, vice president of health technology evaluation and safety with ECRI Institute, attributed that choice to the growth in home-use technology and the following:

- "A completely uncontrolled" use environment
- Lack of home-care focused design
- Failure to manage home-based technology

"People use tap water for device use and cleaning, even if distilled water is specified. They smoke around oxygen systems. They reuse disposable supplies, such as IV tubing, gloves, syringes, and needles, because disposables are costly or inconvenient to replace."

— Elliot Sloane, Center for Healthcare Information Research and Policy

"Home-care" technology is a bit of misnomer, given the many locations in which devices are used—not just homes, but cars, planes, parks, schools, stadiums, and more. Poor usability can have serious consequences.

Keller shared the story of a cousin whose home lost power for almost a week during Hurricane Sandy, forcing him to run a generator for his constant positive airway pressure (CPAP) monitor for obstructive sleep apnea. The cousin had to run the generator and try to sleep during the day, when the generator could be monitored, leaving him exhausted.

His experience exemplifies the risk during power outages for people on life-critical medical devices. First responders and emergency shelters might not be equipped to support the power supply needs of people who depend on these devices to survive.

Summit presenter Elliot Sloane, president of the Center for Healthcare Information Research and Policy, highlighted typical electrical risks in use environments, including inadequate wiring, circuit breakers, fuses, grounding, and location and function of ground fault devices. Unexpected risks also can result from environment "perversities," Sloane said. For example:

- Insect or vermin infestation, and household pets (and children), can ruin devices, render clean and sterile supplies unsafe, and harbor and spread infections.
- High humidity can destroy ventilators that depend on air compressors, especially when they are placed in a damp basement, humid garage, or outdoors.
- Dry climates can cause static shocks that can disable, damage, or reset settings or alarms.

Air quality and the communications infrastructure vary considerably in nonclinical settings. Unsanitary, cluttered, or noisy conditions, and lack of storage space, are additional environmental factors that impede the safe and effective use of medical equipment and supplies. "We have to have a pretty open and frank discussion about what these nonclinical settings are," Sloane said.

Patients and Caregivers Subject to Murphy's Law

Patients and caregivers vary as much as physical environments. They generally have no clinical or technical background. They are diverse in terms of age, skill, ability, education, and physical condition. Social, cultural, and economic backgrounds differ, as do family makeup and availability of support, according to summit presenter Tobey Clark, director of instrumentation and technical services at the University of Vermont.

Given this variability, "Murphy's Law is relentless," Sloane said. This creates risks. People use tap water for device use and cleaning, even if distilled water is specified. They smoke around oxygen systems. They reuse disposable supplies, such as IV tubing, gloves, syringes, and needles, because disposables are costly or inconvenient to replace.

Even people whose backgrounds would seem to make them good candidates to use medical devices appropriately falter in nonclinical settings. That happened to Keller, a biomedical engineer who has worked in hospitals. When his mother-in-law was in hospice care dying of pancreatic cancer, she received

opioid pain medication via a patient-controlled analgesia (PCA) pump. "Honestly, I was scared to death to touch that thing, because I knew that the medicine my mother-in-law was receiving was morphine," he said. "I didn't have a good mindset, despite knowing the technology fairly well." People who are familiar with technology and know the risks might feel just as overwhelmed in nonclinical settings as people lacking such experience.

"Outside the hospital walls, I don't have a controlled environment," echoed summit presenter Kathy Puglise, vice president of infusion nursing for BioScrip, Inc. She spoke on behalf of the Infusion Nurses Society (INS), for which she is the presidential advisor. "I have no way to know what I will walk into, even though we screen patients. Nursing is never black and white. It is truly [many] shades of gray. We have to look at every patient."

Many people in home healthcare receive infusion therapy. Every patient is different. "Our patients are sicker and sicker and sicker," Puglise said. "The youngest patient I've ever had was one day old. The oldest was 106." Infusion nurses are trained to administer many types of infusion therapy according to INS standards of practice, in addition to the rules and regulations of state boards of nursing, and federal and state regulatory and accrediting agencies. Infusion nurses bring that expertise and training to home healthcare. "We make that environment controlled," she said. "We bring the supplies in, the technology in, we prepare everything, we do what we need to do to educate patients. Education is a huge part of what we do, day in and day out." That includes discussing with patients what to do in case of an emergency or power outage.

A Dearth of Information

Information about patient and caregiver experiences with healthcare technology in nonclinical settings is lacking. "There is a gap in what we know about ambulatory care," said summit presenter Tejal Gandhi, MD, president of the National Patient Safety Foundation (NPSF), and associate professor of Medicine at Harvard Medical School. "We know very little about the types of errors and what the right solutions are."

"We know very little about the types of errors and what the right solutions are."

— Tejal Gandhi, MD, president of the National Patient Safety Foundation (NPSF), and associate professor of Medicine at Harvard Medical School

The responsibility for reporting structures for sentinel events, adverse events, and near misses should be shared among manufacturers, medical device and equipment distributors, healthcare service providers, and payers, said summit presenter Margherita Labson, executive director for the Home Care Program at TJC. "Leaders in these organizations need to work together to identify and mitigate risks in use environments—and they need information to be able to do that," she said.

Too often, when an incident occurs, someone either "knew or suspected that risky behaviors existed," Labson said. "When they're asked why they didn't report it, they say that they didn't think anyone would do anything about it or that the technician would get in trouble. How often are direct-line staff involved in decisions about equipment used in the home? When a company commits to a technology, they have to make it work. They have to provide a feedback loop."

"Too often, when an incident occurs, someone either knew or suspected that risky behaviors existed. "

— Margherita Labson, executive director, Home Care Program, The Joint Commission

Summit presenter Reginald Cyrus, a certified biomedical equipment technician, prompted a Class II recall of an infusion device used in a patient home in 2006 by reporting a malfunction in the device. Cyrus, a retired U.S. Navy senior chief hospital corpsman, currently is a nuclear physics laboratory specialist at the Old Dominion University Research Foundation.

At the time, he was a durable medical equipment (DME) technician for a home healthcare company—an unusual staffing position in such companies then and now, Cyrus said. When he reported the problem with the infusion device, the manufacturer replaced it

with a new one, which had the same problem. After he complained again, he was told that his was the only complaint that had been received about this device. It turned out, however, that the manufacturer wasn't collecting data on reported incidents, he said.

Summit presenter Ant Ozok, associate professor at the Department of Information Systems at the University of Maryland, Baltimore County, and a dual adjunct professor at the Department of Anesthesiology and Division of Health Sciences Informatics at Johns Hopkins University, identified three challenges in the management of technology in the home for which more research is needed:

- **Managing multiple technologies at home.** This encompasses training for users, including home nurses, patients, and family members; the usefulness of instructions; how different technologies work together; the potential of reminder systems to help with the use of technologies; and system feedback, consistency, and timeliness of technology use.
- **Interacting with technology developers.** What do customers want? What are developers willing and able to do? Is there a disconnect?
- **People skills for user–developer interactions.** What skills do caregivers, nurses, and others interacting with trainers, company representatives, and others need?

The Goal: The Right Technology For the Right Patient in the Right Environment

The complexities of use environments, patients, and caregivers, coupled with inadequate information about what is really happening in nonclinical settings, can make it difficult to match particular technologies to particular individuals in particular environments.

Summit participants advocated for home assessments before medical equipment is delivered to ensure that patients (or caregivers) can use it appropriately and that the use environment is adequate to support the technology.

What Should a Home Assessment Cover?

Home assessment checklists may cover these topics, with emphasis on those that are particularly relevant to the type of medical equipment being used:

- **Physical, cognitive, emotional, and functional competencies of the patient and/or caregiver**
- **Patient health, medication, and healthcare technology inventory**
- **Household infrastructure, safety, and hazardous conditions**
- **Disaster and emergency preparedness**
- **Storage space availability**

For further information on home assessment requirements, go to www.jointcommission.org for TJC's 2012 "Joint Comission International Accreditation Standards for Home Care."

CLARION THEME 2

Coordinate multiple and recurring transitions in care to improve patient safety.

"Durable medical equipment providers, care providers, and patients are being left at risk for potential adverse events to occur. The DME driver often becomes the patient educator."

—Johann Becker, director of clinical operations at Wellspan VNA Home Care and caregiver

Challenge	Priority Actions	Accountable*
Complex and often changing patient needs that complicate the delivery of safe, high-quality healthcare in nonclinical settings	Create improved home care delivery models for patients with continuum-of-care needs.	• **CMS** • **Private payers** • AdvaMed • CMMI • TJC • Professional societies
Limited coordination among many healthcare and medical equipment providers in the management of multiple aspects of patient care and technology Lack of a consistent culture of safety	Craft seamless transitions in care and continuity of services from clinicians, DME providers, trainers, caregivers, and users. Streamline handoffs of one piece of equipment and/or service provider to another. Create feedback loops that keep all stakeholders abreast of changes. Eliminate breakdowns in communication to improve patient outcomes.	• **CMS** • **Private payers** • TJC • **Home health delivery organizations** • Healthcare delivery organizations • Professional societies • Researchers • PCMH Community • **Med Group** • IHE Patient Care Domain
Inadequate training and knowledge among clinicians, trainers, caregivers, and patients	Create effective train-the-trainer programs, and address the challenge of staff turnover. Create programs to educate clinicians, caregivers, and patients. Encourage comprehensive industry adherence to AAMI TIR 49:2013, *Design of training and instructional materials for medical devices used in nonclinical environments.*	• **AAMI** • **FDA** • **Home health delivery organizations** • Professional societies • Patient safety organizations • Supplier organizations

*Key organizations are bold-faced.

"Never confuse motion with action."
— Benjamin Franklin

A Fractured Delivery Model

Transitions in care are a flashpoint in the delivery of healthcare in nonclinical settings. Failure by the full range of providers to adequately manage and coordinate transitions between clinical and nonclinical settings, handoffs from one service provider to another, and frequent changes in care compromise patient safety. Complex and often changing patient needs exacerbate this challenge. Summit presenters and participants urged the healthcare community to develop new models of delivery that support seamless communications and a culture of safety across the continuum of care.

"Durable medical equipment providers, care providers, and patients are being left at risk for potential adverse events to occur," wrote Johann Becker, director of clinical operations at Wellspan VNA Home Care in York, PA. Becker, who is Michele DeMeo's partner and caregiver, was unable to attend the summit because of DeMeo's condition. AAMI President Mary Logan delivered her prepared remarks.

"Targeted interventions in the discharge process and post-discharge period have the greatest potential."
—Tejal Gandhi, MD

The challenges begin before patients leave their doctors' offices or the hospital, said Tejal Gandhi, MD. After appointments with their primary care providers that last, on average, 12 minutes, 75% of patients leave with unanswered questions, she said. The status quo in ambulatory care results in the following:

- Adverse drug events, with 25% of primary care patients experiencing adverse drug events (Gandhi et al., 2003); adverse drug events are common in nursing homes
- Outpatient prescribing errors
- Nonadherence to prescription medications
- Missed and delayed diagnosis
  - Inadequate follow-up on test results, with breakdowns in follow-up due to unclear definitions of adequate follow-up, lack of standard communication strategies, lack of failsafe mechanisms, and diffused responsibilities—especially when multiple providers are involved
  - Inadequate management of referrals, including lack of timeliness and clarity in communications
- Risky handoffs and transitions in care

"The 30 days post-discharge are a high-risk time," Gandhi said. She added that many errors are related to medication. "It's important to know what a patient is taking at every stage of transition—what they're taking at home, what they're taking in the hospital, what they'll be taking when they are discharged. One study found that half of all medication errors occurred at interfaces of care."

Solutions exist, and are emerging, to address many of these challenges. "Targeted interventions in the discharge process and post-discharge period have the greatest potential," Gandhi said. She recommended "warm handoffs," with nurse-to-nurse communications, person-to-person phone calls, using standard lists of key issues to coordinate care. Other solutions include:

- **Advanced e-prescribing** with decision support, and medication reconciliation, could prevent potential medication errors and adverse drug events.
- Ordering physicians and hospitals could put into place **more effective protocols and systems** for keeping track of and notifying patients about test results and follow-up orders—including referrals, procedures, and tests—with escalation strategies for patients who do not respond.
- **E-referral communication tools** could facilitate the flow of information between primary care physicians and specialists.
- **Improved patient education** about medications, and follow-up calls to patients three to five days after a hospital discharge, could improve their adherence to medication orders.
- Healthcare providers could **develop more useful discharge orders and standard templates for transitions in care** and better patient and caregiver instructions.
- **Online patient portals** could be used for two-way communications with patients about appointments, medications, test results, discharge orders, and health maintenance reminders.

Similar applications could help with transitions of care that pertain to appropriate use of healthcare technology. Indeed, similar challenges are common with healthcare technology during transitions of care. Patients needing medical devices who are discharged from acute- or long-term care

settings, or even coming home from a physician's office, often have multiple disease processes, which contribute to confusion, lack of attention, or dementia, Becker said. Caregivers often are not present when care and use of devices are explained.

In addition, "the technology or device is often delivered before the patient arrives home, especially for hospice patients—our sickest and most vulnerable population of users," Becker said. Even when patients are home, "the time of delivery often occurs at a time of saturation, stress, and fatigue for the patient and caregiver," she said. "The new equipment can be visually overwhelming—distracting at a minimum."

Inadequate Education and Training

The fractured delivery model extends to inadequate education and training of patients, caregivers, healthcare services personnel, and technology providers.

"Often the DME provider is the sole source of support for the patient, and unless educational needs are identified and conveyed to other providers, needs may be left unmet," Becker says. Training by proxy is a particular sore spot. The person who transports the equipment "often becomes the patient educator."

The training complexity is compounded by multiple pieces of equipment. DeMeo, for example, uses a bilevel positive airway pressure (BiPAP) machine, oxygen concentrator, feeding tubes, wheelchair, electric wheelchair, rolling walker, hospital bed, nebulizer, and "associated other gear that we were never taught how to safely use," Becker says.

Summit participants offered these training recommendations for manufacturers:

- Design training instructions in concert with device design for lay users. Consider worst-case scenarios.
- Gather input on training design from a diverse group of home users.
- Test training with users prior to release.
- Use hands-on training not only in device use, but also in maintenance, accessories, and consumables.
- Focus on emergent situations, including emergency contacts; the meaning of, response to, and audibility of alarms; and preparation for utility failures with batteries or generators.
- Take a multimedia approach to learning, using paper, Internet, video, personal mobile devices, and interactive voice response systems. Keep it contemporary, but cater to intended users.
- Respect cultural, social, economic, and environmental differences.
- Include an 800 number for questions.

"It is best to have knowledge in, on, or around the device—at the point of care," Clark said. Patient training before discharge is important, but not as effective as synchronizing training at the time of delivery, with follow-up support.

Summit presenter Suzanne Steidl, founder of Your Daughter's in Town: Health Advocacy for Elders, pointed out that not all patients and caregivers can read training materials. "At the Children's Home of Pittsburgh, a specialty pediatric hospital, staff develop their own series of pictures to help illiterate parents operate the machinery that their technology-dependent children require at home," she said. "Illiterate. The need is greater than you'd think."

That need extends to home healthcare providers. Steidl shared a story in which a child was discharged after a five-month hospital stay with nursing support, but no one, including the nurse, had appropriate equipment training. "Within a week, serious problems arose because no one knew how to troubleshoot the gastrostomy tube pump," she said. "That child was readmitted to the hospital."

Expert Advice

Johann Becker of Wellspan VNA Home Care urged consideration of a change in common practices or requirements for a second visit to homes (or other nonclinical settings) within 48 hours of equipment delivery. This visit would give patients or caregivers the opportunity to "teach back" to providers how to care and use their equipment. For people who are struggling, referrals for additional resources and support would be appropriate.

YES, THIS HAPPENED

"An HVAC technician came to our apartment. I just happened to be home at the time. He was working in a closet replacing coils on our air conditioning unit. There was banging and grunting ... in the door ... out the door ... to the truck ... and so it went on in the background for some time. Finally, I heard what sounded like a hot air balloon passing overhead and got up to investigate. The HVAC technician was using a huge blowtorch next to Michele's oxygen tanks and concentrator. I had him stop, turned her concentrator off, and moved the tanks. The repairman didn't recognize the concentrator and—drumroll here—we weren't supplied with a big red "O" sign to designate oxygen in use.

"I arrived at a home care client's home many years ago to find a Hoyer lift precariously tilted on its side. One of the upper support bars for the sling had broken a second floor window and the patient was loosely suspended partially inside and partially outside. The legs of the Hoyer were together and not spread wide."

—Johann Becker

A Caregiver's Perspective

Suzanne Steidl

Founder of Your Daughter's in Town: Health Advocacy for Elders and caregiver to her 89-year-old mother, who has been in hospice care with end-stage Parkinson's disease for nearly six years

"I'll tell you about my recent experiences. A hospital bed was delivered to our house with hasty verbal instructions by the driver on how to raise it, lower it, operate the brake and the side bars. Later I awoke to find my mother climbing over the rail. I've also found her trying to squeeze through them. Two weeks ago, my PhD brother and I struggled to figure out how to get the footrests on a wheelchair with the surface of the footrest facing in the right direction. It should have been easy but it wasn't. And neither of us had the hand strength to squeeze those buttons that allow height adjustment. He finally figured it out and taped instructions to the chair.

"An oxygen concentrator was delivered to the house. I didn't know what the flow rate should be (no one told me). The driver who delivered it told me how to turn it off and turn it on and where to keep the water level. That was pretty much it. I used tap water; I didn't know about cleaning the filter. The alarm went off the first night we used it, and I still have no idea why. I was astonished to discover how much heat those things create, and I've since learned there are very specific warnings related to that heat.

"Here's what really makes me feel stupid and incompetent: I did not know that clear instructions and warnings should have been provided and I assumed that since they weren't, the devices were easy to use and were safe. I signed the delivery slips without reading them—he's always in a rush—but my signature certified that I was given detailed instructions and that I understood them."

STAKEHOLDER PROFILE

Pediatric Home Service

Susan Wingert saw an opportunity to help medically complex children in their homes more than 20 years ago, and founded Pediatric Home Service in Minnesota. The business expanded to provide many services and support to families, including infusion and respiratory therapy, private-duty nursing, specialized nutrition and medical social work services, an infusion pharmacy and a staff medical director, in addition to biomedical specialties, technological research, and clinical support. Education and training for nurses, patients, and other caregivers are also provided.

Wingert saw the need for a comprehensive home care delivery model addressing many of the challenges identified at the summit, and particularly the need for qualified professionals to provide assistance at every step. Elements of that model include:

- **Discharge planners** working closely in hospitals with physicians, nurses, and other staff to plan patient transitions to home environments.
- **Care coordinators** visiting patient homes to conduct home assessments and planning medical equipment locations. If necessary, they make sure that the electrical infrastructure is upgraded to handle the load from equipment.
- **Clinical educators and technical support staff** training parents and other caregivers to care for their children and use equipment safely and effectively. These staff translate manufacturers' instructions for use into user-friendly language and images for parents and caregivers. Translations into languages other than English are available for common devices as well. Instructions are laminated for durability.
- **Healthcare technology professionals** on staff performing and keeping track of preventive maintenance and repairs.
- **Regulatory professionals,** who notify manufacturers of any equipment problems. Any potentially life-threatening problems are reported to MedWatch.
- **Clinical and biomedical support** that is available 24/7.

In addition, the company provides backup devices for all children on life-critical devices, such as ventilators; and works with payers to ensure not only that the full range of services are covered, but that outcomes of care and services are tracked.

"These are all value-added services," said Roy Maynard, MD, medical director of Pediatric Home Service. "The model of coordinated services under one umbrella works very well for our community. We're all on the same team."

This delivery model is unique in its breadth and focus on specialized pediatric care. However, this example from just one stakeholder shows the potential for a comprehensive CMS model for adult home care. Maynard suggested that the model could work for home healthcare delivery organizations that specialize in specific diseases or conditions, such as diabetes or renal failure.

CLARION THEME 3

Adopt a systems approach—encompassing people, workflows, therapies, technology, and payment—to redesign the full spectrum of healthcare in nonclinical settings.

Challenge	Priority Actions	Accountable*
An outdated workflow system for patient care in nonclinical settings Uneven alignment between healthcare payments and patient safety	Conduct systems analyses to redesign workflow models. Build regulations around new models. Align financial coverage (reimbursement) of clinical care, medical technology, and training in nonclinical settings to drive change.	• **CMS** • **Private payers** • Professional societies
Lack of focus on connecting technologies and people	Incorporate point-to-point interoperability in infrastructure across the full spectrum of care, focusing not only on technology, but also on people: clinicians, caregivers, and patients. Develop compatible systems within homes and other nonclinical settings. Ensure that all biological sensors communicate seamlessly.	• AAMI/UL • Continua • IEEE • HIMSS • HL7 • SNOMED CT • ONC • IHE
Difficulty managing the flow of clinical and device information	Develop consistent ways to upload data and make it easily accessible and valuable to providers and caregivers.	• AAMI/UL • IEEE • Continua • HIMSS • HL7 • SNOMED CT • ONC • IHE
Inadequate consideration of how technology fits into the workflow	Integrate medical equipment into the workflow, and recognize and manage associated changes in clinicians' tasks. Make technology a central consideration in care processes, rather than an afterthought.	• **CMS** • **Private payers** • **Home health delivery organizations** • IHE • IHI • Professional societies
An absence of checks and balances for preventive maintenance, repair, and management for home care devices	Create a medical equipment management plan and standards that cover all aspects of supportability, including device recalls.	• **CMS** • **AAMI** • ACCE • ECRI Institute • TJC • **DMEs**
Limited provider and caregiver ability to track and support devices patients acquire on their own	Determine how to safely manage medical equipment purchased by patients or obtained through nontraditional means (e.g., consumer or legacy devices, "hand-me-downs," and grey-market (unofficially traded) products.	• Consumers Union • **Consumer Product Safety Commission** • FTC

*Key organizations are bold-faced.

All Systems Are *Not* a Go

The many challenges in healthcare services and technology in nonclinical settings require systems thinking to address, according to summit presenters and participants. Systems encompass people, workflows, therapies, technology, and payment, all of which should be connected seamlessly. Right now, though, systems are disjointed.

There are new ways to treat, engage, and interact with patients and caregivers. But processes, practices, and products are not integrated into that workflow in ways that serve patients well. Technology is an afterthought—and it should be a central consideration. Reimbursement is not well aligned, either, with the realities and needs of healthcare delivery in nonclinical settings.

Summit presenter Nancy Kramer, vice president of clinical affairs at the National Home Infusion Association, spoke about one type of device: home infusion pumps. Infusion pumps range dramatically and their use involves not just the pump, but drugs, supplies, clinical pharmacy and delivery, and nursing care. "All can be reimbursable, separately or bundled in various ways" by commercial or government payers, she said.

Commercial payers typically set a per diem rate for infusion nursing support, which is intended to cover all costs. The per diem rate generally varies depending on the complexity of the technology. "Nursing care is often limited to what the 'average' patient needs—even though 20% of patients need more time to learn to self-administer infusions," Kramer said. "Medicare does not cover the full range of infusion therapy in the home." Not all patients are eligible for skilled nursing, which means that home infusion nurses teach patients how to use pumps, but they are not able to bill for this service.

Changes under consideration in Medicare Part B, meanwhile, might separate payments for pump suppliers, pump supplies, and drugs. If this happens, Kramer asked, "Who will choose the pump? Who will program the pump? Who will double-check the process? Who will teach the patients? What if the pump has a malfunction? Who will the patients call for help?" The greatest concern, Kramer said, is planned competitive bidding related to infusion pumps. Currently, home infusion therapy is managed by pharmacies contracted to provide the prescribed IV therapy drug, the infusion pump, and the nurses to train the patient in using the pump at home. These pharmacists do initial programming of the pump and the nurses are familiar with the specific pumps used by that pharmacy. Competitive bidding may reduce the cost of home infusion therapy, but may make an already complex system of care more difficult and prone to errors—for example, if two companies provide different parts of the infusion system (e.g., one the pump and the other the drug) to the patient, the home nurses assigned may not be familiar with the type of pumps provided (Counce and Noyes, 2013). Summit participants advocated for a broad reassessment of reimbursement for healthcare technology used in nonclinical settings.

Another wrinkle in seamless delivery: What if the patient bought the pump, or any other medical device, on his or her own? People increasingly are purchasing or acquiring new or used devices, and grey-market products from unofficial sources. They are also using "crossover devices," in Elliot Sloane's words, such as smartphones and tablets with software apps from the consumer market. Such devices and apps may not be safe, reliable, or accurate.

All of this technology produces data that could be valuable. However, it is difficult to connect technology and get information to the people who need it across the full spectrum of care. A single individual might use multiple devices, but consolidating the data from all of these devices into a comprehensive report on that person's condition and delivering it to care providers who need it is typically impossible. Clinical information that does make its way to clinicians, patients, and caregivers is not in a consistent or useful format. As in hospital settings, data overload without actionable information is problematic.

Additionally, the rigor with which healthcare technology professionals manage the full life cycle of medical equipment in hospitals is not always applied to devices in nonclinical settings. "Home healthcare companies don't have the money to pay a good biomed," and few have biomedical technology expertise on staff, said Cyrus. "Durable medical equipment technicians have no ownership" of the issues they encounter.

"From my point of view, organizations responsible for distributing technology in home environments haven't necessarily managed that technology very well."
—James Keller, ECRI Institute

"Who will choose the pump? Who will program the pump? Who will double-check the process? Who will teach the patients?"
— Nancy Kramer, NHIA

Rental items are moved from place to place without critical cleaning of filters, battery checks, or safety testing, Sloane said. In addition, the devices that patients acquire on their own are difficult to track or support. All of these challenges lead to gaps in preventive maintenance and repairs.

Systems Solutions

Summit presenter Vicki Lewis, associate director and usability division chief at the National Center for Human Factors Engineering in Healthcare, offered a sociotechnical systems model. It defined "home-ready" healthcare technology by taking into account the types of challenges that are evident, as shown in Figure 1.

"We need a systems approach—and this goes beyond the device," Lewis said. "If all we're thinking about is the technology, we're completely missing the boat. How the technology is going to function depends on the organization and resources, the physical environment, the technical infrastructure, the people who cut across every socioeconomic line, and the external environment—insurance policies for covering the price of the equipment and support of the equipment." This is not an exhaustive list, she said. Manufacturers, as well as those companies that provide healthcare technology equipment and related services, need to perform a scan of the system to identify all of the elements that need to be addressed.

"Fallibility is part of the human condition. We cannot change the human condition. But we can change the conditions under which people work."
—James Reason, University of Manchester

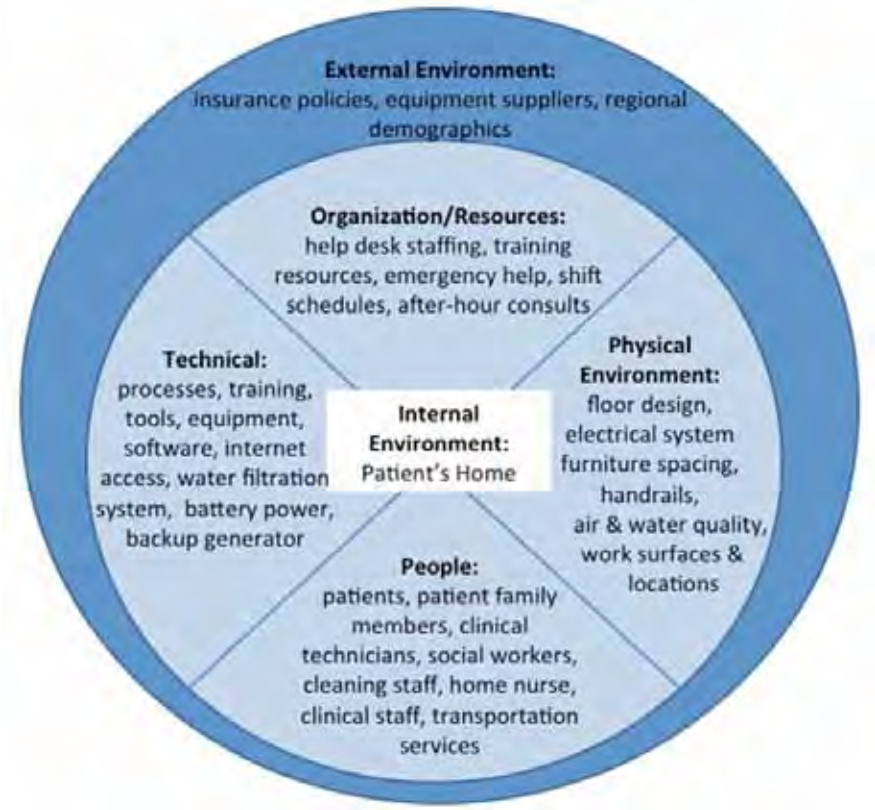


Figure 1. Sociotechnical Systems Model
Source: Vicki Lewis, "A Systems Approach to Defining Home Ready," presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013. Adapted from Kleiner, 2007.

STAKEHOLDER PROFILE
Kaiser Permanente

Kaiser Permanente's Garfield Innovation Center in San Leandro, CA, provides a simulated environment for testing emerging ideas for healthcare practices and technologies. More and more, the center is a hotbed for engineers, architects, technologists, physicians, nurses, and even Kaiser Permanente members to explore ambulatory and home care, according to summit presenter Carol Davis-Smith, vice president of clinical technology with Kaiser Permanente.

"At the Garfield Innovation Center, we can bring a system-of-systems approach to the integration of devices, therapies, people, workflow, and protocols, all in one place," Davis-Smith said. "We've been really challenged over the past couple of years to think forward, think beyond the traditional two care sites—hospitals and clinics—to the home as well as the Internet. The focus is health 360, with some health IT-focused, some equipment-focused innovations. It's all about keeping people out of our hospitals."

Davis-Smith also pointed out that most innovation in healthcare does not require new technology, but rather new applications of existing technology. In that vein, Kaiser Permanente is exploring the use of the Xbox 360 gaming and entertainment system to support and track physical therapy in the home. The system could be used with motion detectors to track body movements as people do physical therapy exercises in their homes. This data could be sent to physicians and other healthcare providers to make sure patients are adhering to their physical therapy regimen and doing their exercises properly.

Expert Perspective

Melissa Harvey
Policy advisor with the Office of Emergency Management within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS)

Hurricanes, tornadoes, floods, sustained power outages, and other natural and manmade disasters can lead to life-or-death situations for individuals who are dependent on electrically powered durable medical equipment (DME), such as oxygen concentrators, ventilators, and intravenous infusion pumps. If they are unable to charge and operate their equipment at home, these individuals may go to shelters or emergency care facilities, which might be unprepared to handle them or not equipped to meet their power supply needs.

Multiple factors contribute to the problems of DME-dependent patients during emergencies:

- Unidentified DME populations
- Unknown location of individuals and devices
- No access to individual or device status
- No alternative power for devices
- Shelters not equipped to handle individuals with medical needs
- Lack of communication tools
- Lack of viable communication infrastructure

ASPR is taking a systems approach to these challenges, with the goal of building more resilient healthcare technology and a more responsive system. An integrated system encompassing individuals, public health, emergency management, communities, and industry would include:

- Development and adoption of smart DME with signaling and sensing capabilities
- Formal platforms to inform emergency responders of the location of people in need
- Communication networks, such as MBAN, Wi-Fi, cellular, amateur radio, and mesh networks
- Social media applications for individuals and communities for everyday and emergency use
- An emergency response infrastructure
- Device and information security and privacy
- Partnerships with power and utility companies
- Energy solutions for patients and communities

CLARION THEME 4
Standardize and simplify.

"We need to ensure that variation in medical devices is adding rather than subtracting value or they won't be valued. Simplify, simplify, simplify."

—Lane Desborough, product strategist, Medtronic

Challenge	Priority Actions	Accountable*
Inconsistent regulation of different stakeholder industries	Create a consistent and appropriate regulatory framework that integrates healthcare, medical device, information technology (IT), telecommunications, and transportation regulations.	• **CMS** • **TJC** • **FDA** • FCC • **ONC** • DoT • FAA
Inconsistent data formats for aggregation and exchange of information between different types of medical devices impedes data analysis, identification of patient care and equipment concerns, and clinical decisions	Standardize data sets. Aggregate data from the home and other nonclinical settings. Develop algorithms to apply data and identify patient care and equipment problems. Warn providers of potential problems.	• MD PnP (data transfer) • ICE (data transfer) • IHTSDO (terminology) • NQF (aggregation/analysis) • CMS (aggregation/analysis) • ONC (aggregation/analysis) • Clinician organizations with expertise in particular diseases or conditions
Lack of clarity on who "owns" clinical data	Clarify privacy, transparency, and ownership of patient information.	• **ONC** • **CMS** • AAMI
Limited ability to assure patients, caregivers, clinicians, service providers, suppliers, and regulators that medical devices are safe for use in nonclinical settings	Develop a rigorous certification process.† Use existing standards that address risk/safety. Require testing to be conducted by a test house.† Test for safety and not just interoperability.†	• FDA • CMS • Test houses (e.g., UL) • Manufacturers • AAMI

*Key organizations are bold-faced.

†These processes are required already and are being used in the field. IEC60601-1-11 and IEC 62366 guide the certification process. Manufacturers must state conformance and have devices tested by a test house for FDA clearance for nonclinical indications. Testing for safety is already required as part of risk management in IEC 62366 and IEC 60601-1. Summit participants questioned whether there is enough attention to these processes, particularly for devices developed by nontraditional suppliers and for devices used in nonclinical settings by particular users, and reiterated their importance.

A Muddy Regulatory Playing Field

The diversity of healthcare technology used in highly varied nonclinical settings makes it difficult for all stakeholders to know with certainty which regulations apply to them. Summit presenters and participants urged a broader range of regulatory organizations to come together to create a consistent and appropriate regulatory framework.

FDA regulations, guidance, and approval processes govern "traditional" healthcare technology used in clinical settings. But what about healthcare technology that integrates IT and telecommunications features, as so much medical equipment does these days? What if the healthcare technology is only an IT or telecommunications solution? What about consumer devices and applications that are marketed and used as medical devices in homes and other nonclinical settings? Different rules may apply, and that's fomenting confusion and a sense of an unfair playing field.

Summit presenters and participants also raised a concern that does not yet seem to be on the regulatory radar screen. People travel with all sorts of medical equipment and supplies. Also, providers ship this cargo on planes, trains, ships, and other modes of public and private transportation. Some of this equipment—think oxygen tanks—could be hazardous. Who is regulating this?

Data Conundrums

The inability to make effective use of data from medical devices in nonclinical settings, which relates to all of the clarion themes from this summit, reflects inconsistent data formats used in different types of devices and in different settings. Summit presenters and participants called for standards-setting organizations to collaborate to develop common, standard ways to format data from devices used in nonclinical settings to make is easier to exchange, aggregate, and use it.

Summit presenters and participants emphasized multiple ways in which standardized data sets could be—and should be—used as healthcare services and technology continue to migrate to nonclinical settings. Aggregated data sets from healthcare technology could be analyzed to track trends, challenges, and outcomes, both for

FDA Perspective

Mary Weick-Brady
Senior Policy Advisor, FDA, Center for Devices and Radiological Health

Several guidelines cover the complex nature of the home use environment, including the FDA's Home Use Medical Device Initiative (2010) and Quality System Regulation, *Design Controls and Risk Management (21 CFR 820).* Designers and manufacturers of home use devices also have *Draft Guidance for Industry and FDA Staff – Design Considerations for Devices Intended for Home Use,* which was being finalized in 2013. Home use devices should address the risks unique to the home, and the devices should be:

- Useful
- Usable
- Iterative
- Intentional
- Intuitive
- Integratable
- Informative

Factors Involved when Using Medical Devices and Technologies in Nonclinical Settings

- **Use Environment Factors:** location, contaminants, water supply, temperature, dampness and humidity, atmospheric pressure changes, airflow, travel and international use, fluid exposure, disposal, storage, and keeping devices dry between uses.
- **User Factors:** physical (size, mobility, dexterity, coordination, flexibility, strength); sensory/perceptual (vision/hearing abilities, tactile sensitivities, ambient light conditions, alarm visibility); cognitive (literacy level, cognitive impairment); and emotional (anxiety and fear).
- **Device Factors:** design solutions versus lock-out mechanisms, reasonably foreseeable misuse calibration, mechanical strength, electromagnetic compatibility (EMC), wireless technology, alarm systems, electrical issues (supply mains, internal electrical power source), and permanently installed devices (protective grounding, installation by qualified professional, outlets and adapters, power outages and battery life).
- **Human Factors:** validation studies; usability; user training and certification; responsibilities of care partner, caregiver, and care recipient.
- **Labeling Factors:** Simple, concise, easily understood labels; prescription and over-the-counter devices; narrative format and pictures; hazardous waste material disposal; hygienic maintenance; and how to access labeling when separated from the device.

In addition, there are postmarket considerations, such as customer service (technical assistance phone numbers, website, e-mail address) for life-sustaining devices; and reporting, selling, and purchasing used devices.

devices and for patients. Manufacturers, healthcare and technology service providers, and patients could be alerted to any equipment problems. This data also could support healthcare technology management, from preventive maintenance to life-cycle planning. Individual patient data could be sent to clinicians or other healthcare providers to monitor patient health and intervene, if necessary; patient data could be integrated into electronic medical records (EMRs) or electronic health records (EHRs) as well.

Summit presenter Bridget Moorman, a clinical engineer and consultant, is working on a United4Health (Universal Solutions in Telemedicine Deployment for European Healthcare) project to support congestive health failure patients with home devices and telemonitoring. Patients use different devices in their homes, depending on their needs. Figure 2 shows an example of system architecture for this project.

A sample service model works like this: A telehealth service provider, such as a regional healthcare center, provides patients with a home device kit, installation and/or patient training, and services the telemonitoring devices. Data from the devices are sent to the regional healthcare center, which monitors measured information 24/7; aggregates and filters this information; transfers and communicates pertinent information to the healthcare enterprise (the hospital or local health district), and/or primary care physician, emergency service, social worker, and/or family, as appropriate. The regional healthcare center could use this system to "push" educational information to patients.

The healthcare enterprise receives data into the EMR/EHR, which should specify data and messaging standards at interfaces (HL7, IHE/Continua, with underlying IEEE 11073 and/or SNOMED CT). The healthcare enterprise also trains clinicians on workflow and provides clinical protocol data requirements and filter parameters for data. Hospital clinicians could serve as liaisons to the regional healthcare center, with clinical responses to patients based on the healthcare enterprise's protocol.

Moorman outlined some of the data considerations for this service model:

- **Who owns and has access to patient data?** Patients own their data—although cloud vendors and hospitals want to claim some ownership.
- **Is this telecommunications path secure?** The mobile telecommunications infrastructure has some embedded encryption; other paths may require security mecha-

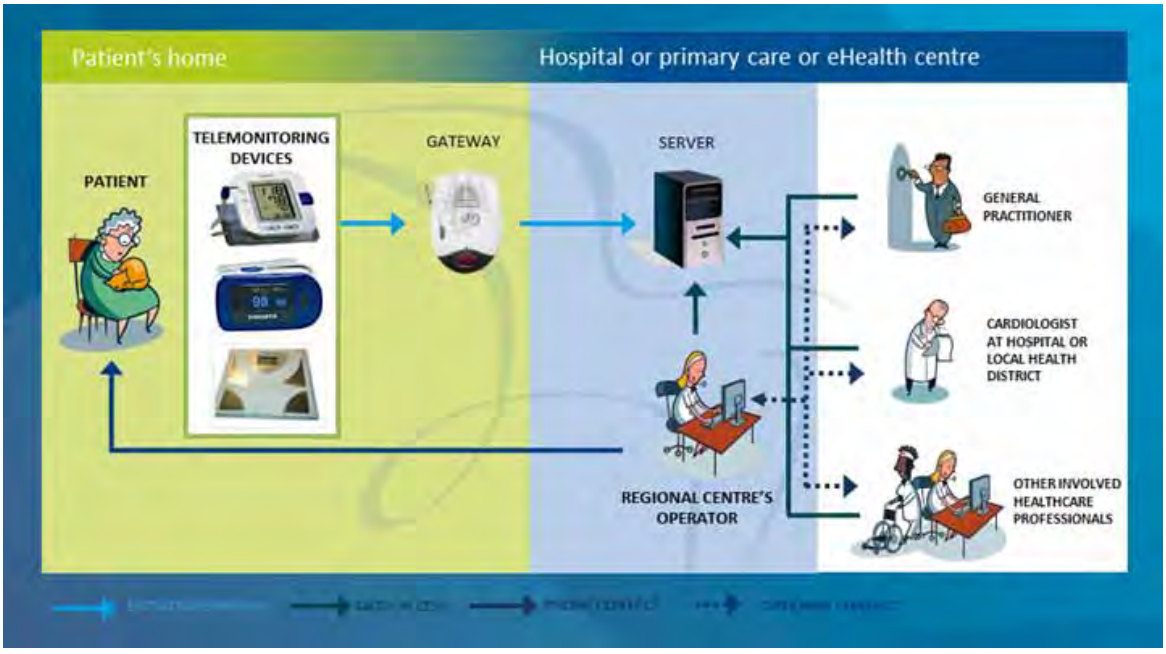


Figure 2. Sample System Architecture for United4Health Project, Europe

Source: Bridget Moorman and BMoorman Consulting, LLC. "Thoughts on Telehealth Systems." Presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

nisms. Devices that regulate physiological function require robust security for access to control mechanisms.

- **Who is actually sending the data?** Robust patient identification and validation mechanisms will help ensure that the patient or authorized caregiver, not the cat that steps on a scale, sends the data.
- **Is the data in usable format?** The healthcare enterprise might need to build interfaces into their IT systems to receive data—and train clinicians to use it. This training could cover media techniques, such as video teleconferencing, to consult with patients.

Testing for Safety

Summit presenters and participants called for a new paradigm for certifying healthcare technology intended for use in nonclinical settings, with a focus on ensuring device safety. Right now, some say, testing emphasizes the technical aspects of interoperability. This is important, but it does not go far enough.

"Every time you place a product on the market, there is a potential for risk," said summit presenter Anil Patel, vice president and chief marketing officer of the life and health business unit of UL (Underwriters Laboratories). There are business, product, and regulatory risks that executives must address, which are summarized in Figure 3.

Patel offered some food for thought for the regulation of home-use devices:

- How do patients and doctors recognize a home-use device?
- How do regulators regulate when the regulators' primary experience is with clinical use?
- Should there be a "home-use mark"?
  - Who owns it?
  - Will the regulators require it?
- Who is responsible for training—and how?
  - Manufacturer?
  - Distributor?
  - Retailer?
  - Renter?
  - Clinician?
- Has the training been assessed for usability?

Summit presenter Anthony Ciccarello, senior regulatory manager at Philips Home Healthcare Solutions, discussed his company's approach to the environmental, technical, and human factors considerations relevant to devices—such as sleep apnea devices, oxygen concentrators, and ventilators—in nonclinical settings. He said standards such as IEC 60601-1-11 address environmental conditions very well, including:

- Storage temperature and humidity between uses
- Operating temperature, humidity, and altitude

STAKEHOLDER PROFILE
Vanderbilt University Medical Center

Making effective use of data is more than a standards or technical challenge. Vanderbilt University Medical Center is exploring ways to use patient-centered data wisely. Vanderbilt has a "big picture" vision of what it wants to do—use data to engage clinicians and patients in managing healthcare, especially around chronic conditions, said summit presenter William Gregg, MD, assistant professor in the Departments of Biomedical Informatics and Medicine and program director, Population Health Informatics, at the university.

Vanderbilt is making widespread use of an online portal to capture patient-entered data, thereby making patients active participants in their healthcare. The university is using automated data capture on a limited basis, due to cost limitations and other factors. However, the university is launching a telephony pilot to collect blood pressure, pulse, and weight data for a limited patient population. Patients who are more passive about their healthcare, and less comfortable with the online portal, are candidates for this data collection method.

Vanderbilt also is working to integrate data into clinical care and workload, and enable decision support and data mining. Clinicians on the receiving end of the data don't get a data dump, but rather a visual summary on a dashboard. They have the option of digging deeper into the data details.

Lessons learned: "Don't limit yourself to one technology or channel of data capture," Gregg said. "Just because we can do something doesn't mean we should. Don't collect data unless there is a plan and a capability to use it. Avoid isolated focus on automation. Use pilot projects to test ideas."

Figure 3. Managing Risks in Nonclinical Settings

Source: Anil Patel. "Managing Risks in Nonclinical Settings." Presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

- Environmental shock that simulates rapid change in the environment
- Mechanical strength (shock, vibration, drop)

Likewise, manufacturers and testing organizations should be familiar with technical standards, which "may not be new for products designed for hospitals," Ciccarello said. In nonclinical settings, however, technical challenges abound, including:

- AC mains voltage variations
- Class II devices in settings with no protective or functional earth connection—essentially, no medical-grade power supply
- IPXX protection, which refers to the IP rating, plus a two-digit designation of that rating
- Uncontrolled electromagnetic compatibility (EMC) environment
  - Higher radiated immunity test levels
  - Higher electrostatic discharge (ESD) test levels
  - ESD sensitive symbol is prohibited

Human factors considerations do present challenges for Philips. The usability of documents that accompany devices, labeling, and instructions are the main challenges. "EMC disclosure information is too technical for the typical home user," Ciccarello said.

STAKEHOLDER PROFILE
NxStage Medical, Inc.

Getting medical devices through the regulatory and certification process, and making sure they're safe for a nonclinical setting, "can be done, but it's really, really hard, especially if you are a startup company," said summit presenter Denny Treu, vice president of innovation and intellectual property, NxStage Medical, Inc.

The company, which makes both home and clinical dialysis machines, wanted to leverage designs for both the clinical and home markets. The cost to develop a new product is high, ranging from $20 million to $50 million, he said. At the same time, "shoe-horning" products into markets they weren't originally designed for is hard as well. Treu outlined the challenges in the certification process:

- Understanding the unique market requirements, including sometimes multiple therapies needed and their complexities.
- Designing specifically for the home, taking into account the environmental conditions of electrical supply, water quality, treatment areas, supplies, and locations. "There are a lot of water issues," Treu said. "How do you take water that a lot of us wouldn't drink and turn it into water that's fit for dialysis?"
- Interpreting many regulatory standards and guidelines from different standards-setting organizations and governments, suggesting the need for international harmonization.
- Understanding the test house certification process, including test house interpretation of risk-based standards.

"Overall system design is key," Treu said. "The system is really broad—everybody who is going to touch the device, including clinicians, biomeds, patients, and their families. We started with a clean sheet of paper" to plan the entire process. "I really believe that's the way to go."

NxStage Medical enlisted help from experts to carry out the plan, using a multidisciplinary approach to innovation and risk mitigation, applying existing and new technology. The team designed usability for the whole system, not just the user interface, including disposables, maintenance, education, and training. Finally, "the second person we hired was a test house expert," Treu said, so that planning for the certification process was an integral part of product development and design.

FDA Perspective

Jeffrey L. Silberberg, MSEE
Senior electronics engineer at the FDA/CDRH, and Secretary of IEC SC62A MT23, the working group responsible for maintaining IEC 60601-1-2

IEC 60601-1-2 draft Edition 4 of *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests,* which includes Immunity Test Levels for the Home Healthcare Environment.

Silberg submitted a presentation on immunity test levels specified for the home healthcare environment in draft Edition 4 of the IEC 60601-1-2 standard. Electromagnetic (EM) immunity is the ability of equipment to perform without degradation in its EM environment of intended use. The currently published third edition of the standard, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests,* specifies "general requirements and tests for [EM] compatibility of medical electrical equipment and medical electrical systems" that are appropriate for the general hospital environment.

MT23 has developed immunity test levels and other specifications for the home healthcare environment for Edition 4 of IEC 60601-1-2, which has been circulated as final draft International Standard in late Nov. 2013. Designing and testing to these levels and specifications will help ensure that medical electrical equipment and systems are home ready.

In this edition, the environment designations are harmonized with IEC 60601-1-11, Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Edition 4 specifies the environments of intended use to be the professional healthcare facility environment (e.g., hospitals and clinics), home healthcare environment (e.g., residences, modes of transportation, and areas accessible by walking), and special environments (e.g., close to active, high-frequency surgery equipment and in the controlled access area of MR equipment.)

Edition 4 differs from Edition 3 in that immunity test levels are specified for each electrical port of the equipment, as in the IEC 61000 series standards, and some immunity test levels are higher, based on reasonably foreseeable maximum environmental levels of the expected EM phenomena.

Draft immunity test levels applicable to the home healthcare environment are listed in Table 1 and Table 2.

As can be seen in Table 2, the draft standard specifies that immunity to radiofrequency (RF) communications equipment is tested at one or three frequencies in each band, depending on the width of the band. The specified immunity test level for a typical cellular phone band, for example, is 28 V/m.

An example of the difference between Editions 3 and 4 of the standard is that Edition 4 accommodates the fact that hospitals install carpeting in some patient areas and that carpeting is likely to be found in the home healthcare environment. A carpeted area is an example of an environment where the combination of synthetic materials and low humidity can result in voltages up to 15 kV.

The "conductive RF" method tests for immunity to radiated RF induced on the cables of the equipment. Conducted RF immunity test levels in the draft Edition 4 are higher (6 V) in the amateur radio and industrial, scientific, and medical (ISM) frequency bands because amateur radio and ISM equipment can cause field strengths to be higher in the home healthcare environment than would be expected from sources at other frequencies in the range, e.g., broadcast transmitters.

The fourth edition of the standard also covers intended uses such as in different types of transportation (e.g. land, sea, and air vehicles), in which applicable standards might include ISO 7637-2 or RTCA DO-160, and in other locations in the home healthcare environment accessible, for example, by walking (such as libraries and stores), where RF sources such as radio-frequency identification (RFID) readers and retail antitheft systems could be present. Edition 4 also updates the standard to accommodate the fact that the use of RF wireless communications equipment is integral to modern healthcare. An assumption was made that RF transmitters could be as close as approximately 30 cm (d) to a medical device, and the test levels for immunity (E) to this equipment were calculated from the 30-cm distance and from the maximum licensed RF output power (P) for the communications service:

$$E = \frac{6}{d}\sqrt{P} = \frac{6}{0.3}\sqrt{P} = 20\sqrt{P}$$

Equation 1 – Test level for immunity to a transmitter of maximum RF power P at a distance of d, and with d = 30 cm.

Designing and testing medical devices to the immunity test levels and specifications of the draft Edition 4 of IEC 60601-1-2 for the home healthcare environment will help ensure that medical electrical equipment and medical electrical systems are "home ready". Further work applicable to future amendments or editions of IEC 60601-1-2 includes IEC SC77B test methods on "proximity" radio frequency and magnetic field immunity and addressing items that were deferred from Edition 4.

Phenomenon and test method	Port	Immunity test level
ESD IEC 61000-4-2	Enclosure	Contact: ± 8 kV Air: ± 2, 4, 8, 15 kV
Radiated RF IEC 61000-4-3	Enclosure	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Power frequency magnetic field IEC 61000-4-8	Enclosure	30 A/m
Conducted RF IEC 61000-4-6	Input a.c. power	3 V, 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Table 1. Some immunity test levels are applicable to the home healthcare environment.

Test frequency (MHz)	Band (MHz)	Modulation	Maximum power (W)	Immunity test level (V/m)
385	380 – 390	Pulse, 18 Hz	1.8	27
450	430 – 4760	FM, 1 kHz	2	28
710, 745, 780	704 – 787	Pulse, 217 Hz	0.2	9
810, 870, 930	800 – 960	Pulse, 18 Hz	2	28
1720, 1845, 1970	1700 – 1990	Pulse, 217 Hz	2	28
2450	2400 – 2570	Pulse, 217 Hz	2	28
5170, 5450, 5730	5100 – 5800	Pulse, 217 Hz	0.2	9

Table 2. Test levels for immunity to RF wireless communications equipment for both the home healthcare envirolnment and the professional healthcare facility environment.

CLARION THEME 5

Design with empathy.

"With all this great work [human factors design and engineering] going on—cogent thinking that's well understood—why isn't it making its way to me and the people I know?"

—Suzanne Steidl, Your Daughter's in Town: Health Advocacy for Elders

Challenge	Priority Actions	Accountable*
Difficulty in developing devices that are "home ready" and add value from the patient's perspective	Conduct human factors assessments with intended users early in the design process. Consider human factors issues (e.g., device functionality, interfaces, power, labels, cleaning, storage, transport) for intended users throughout the design process. Encourage comprehensive industry adherence to ANSI/AAMI HE 75:2009, *Human factors engineering – Design of medical devices, and IEC 62366 – Application of usability engineering to medical devices*	• **FDA** • **Manufacturers** • **IT developers and vendors**
Variability in medical device interfaces is more problematic for caregivers and patients than it is for trained professionals.	Standardize device interfaces for use in nonclinical settings by incorporating common safety and use features. Standardize fail-safe modes.	• **FDA** • **Manufacturers** • **AAMI** • IHE
Complex, inadequate, or nonexistent instructions for device use by patients and caregivers	Standardize the format of instructions for use (IFUs), and use visual tools where possible. Design instructions for the user, not for the manufacturer. Encourage comprehensive industry adherence to AAMI TIR 49:2013, *Design of training and instructional materials for medical devices used in nonclinical environments.*	• **FDA** • **Manufacturers** • **AAMI**

* Key organizations are bold-faced.

The Elephant in the Room

Many of the challenges identified at the summit spring from inattention to the experiences of people who use healthcare technology in less than ideal nonclinical settings. Summit presenters and participants urged device designers and developers to bring decades of human factors research and expertise to the table, beginning early in the design process.

Summit presenter Melissa Griffin, a human factors analyst with HumanEra, at the University Health Network in Toronto, highlighted the research that team has documented in interviews with clients, caregivers, and family members, and with paid providers, and with home tours and photographs. She summarized four human factors issues in home care, as shown in the photographs.

Even when clients have access to assistive devices, they often aren't being used. The challenge: How can we make the benefit of using devices outweigh usability issues—and the stigma often associated with devices?

Figure 4. Unused Equipment—Even when patients have access to assistive devices, these devices are often not used: clothes stored on portable toilet*† (left) and disassembled wheelchair*‡ (right).

Source: Melissa Griffin and HumanEra UHN. "Usability, Accessibility and Workarounds in Home Care." Presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

Devices often do not fit well into home-care environments. The challenge: How can we ensure that devices will fit, have lower-profile storage requirements, and allow for realistic use in the context of the home?

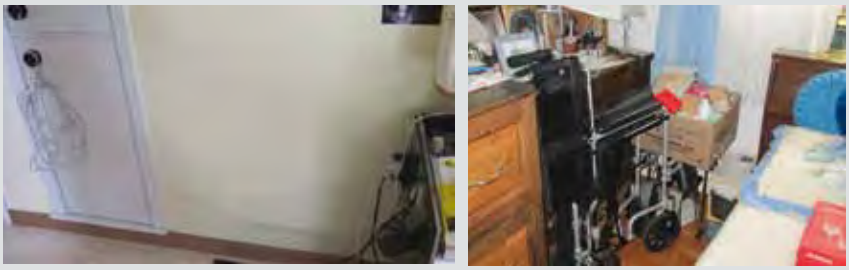


Figure 5. Awkward Storage—Oxygen tubing draped to prevent tripping*‡ (left) and storage in tight spaces*‡ (right).

Source: Melissa Griffin and HumanEra UHN. "Usability, Accessibility and Workarounds in Home Care." Presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

Summit presenter Ann Blandford, professor of human-computer interaction at University College London, discussed similar themes from her research. In interviews, observations, diary studies, and surveys, she has studied home hemodialysis and diabetes and medication management. "People are living their lives and finding ways to fit health management and device use into their lives," she said. "This can be an almost constant struggle. They're trading off the values of comfort and pleasure with safety."

Without human factors analysis, device designers and developers are making inappropriate assumptions about actual device use, resulting in workarounds and nonadherence by users, introducing vulnerabilities in care. Individuals manage their own technology glitches, from dead batteries, to patching up tubing, to troubleshooting problems and improvising solutions. "People don't want to criticize their device," she said. "It might appear that they're not competent—and they don't want to be disqualified from home hemodialysis."

Summit presenter Linda Harley, research scientist in the human systems integration division at the Georgia Tech Research Institute, addressed the particular challenges of designing home health technology for older adults. Device designers and developers must consider:

- Users' abilities
- Task demands
- The interaction between the context—the situation and the environment—and both the users' abilities and task demands

"Many older adults often don't only suffer from one thing," Harley said. "They have comorbidity. Someone with diabetes might lose their sight. They might have peripheral

* Marck PB et al. (2010). Safety in Home Care: A Research Protocol for Studying Medication Management. Available at: www.implementationscience.com/content/5/1/43. Accessed Dec. 3, 2013; Canadian Institutes for Health Research, Canadian Health Services Research Foundation, Canadian Patient Safety Institute, Ontario Ministry of Health and Long Term Care, Ministre de la Sante et des Services Sociaux (Quebec), and Nova Scotia Health Research Foundation.

† Lang A, Macdonald M, Marck PB (2009–2014). Safety in Home Care: A Focus on Medication Management; Canadian Institutes of Health Research, Canadian Health Services Research Foundation, Nova Scotia Health Research Foundation, Canadian Patient Safety Institute, Ontario Ministry of Health-Long Term Care & Ministere de la Sante et des Services Sociaux.

‡ Doran D, Blais R, Lang A, Macdonald M. (2010–2013). Safety at Home, A Pan-Canadian Home Care Safety Study; Canadian Patient Safety Institute, The Change Foundation, Canadian Foundation for Healthcare Improvement, Canadian Institutes of Health Research.

Individuals and caregivers need better devices to manage complex medication regiments. The challenge: How can we help people manage everyday challenges, such as added, discontinued, or titrated medications; over-the-counter vs. prescription medications; pill vs. liquid vs. syringe forms; and medication adherence?

Figure 6. Medication Challenges—Modified medication management tools*†‡ (left) and mixtures of pills in unlabeled containers*‡ (right).

Source: Melissa Griffin and HumanEra UHN. "Usability, Accessibility and Workarounds in Home Care." Presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

Patients come up with unique solutions to store, use, and manage medical equipment and supplies. However, valuable insights from users and caregivers are rarely incorporated into device design. The challenge: How can device designers and manufacturers integrate feedback and preferences of users so devices can better support user needs?

Figure 7. User Ingenuity—Oxygen tanks stored in a Pepsi palette*† (left) and linking tasks in with established routines*† (right): by moving the pink paper forward and sideways, the patient kept track of which arm to inject.

Source: Melissa Griffin and HumanEra UHN. "Usability, Accessibility and Workarounds in Home Care." Presented at the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

"People don't want to criticize their device. It might appear that they're not competent."
— Ann Blandford, professor of human-computer interaction at University College London

FDA Perspective

Molly Follette Story, PhD
Human factors and accessible medical technology specialist, FDA/CDRH and the Office of Device Evaluation (ODE)

Usability and Accessibility

Human Factors Considerations for Technology in the Home

Human factors in three key areas should be taken into account when designing medical devices or technologies: users, the use environment, and the user/device interface, as shown in Figure 8:

1. **Users.** As seen earlier, there is great variation in users: professional or nonprofessional, knowledge and experience levels, age and functional capabilities, as well as mental and emotional conditions.
2. **Use Environment.** The home environment is varied, including a house, mobile home, townhouse, apartment, community setting, or outdoors.
3. **User Interface.** Variables in the user interface include tasks (device setup, use, disconnection, and cleaning) and interactions (user input and device output).

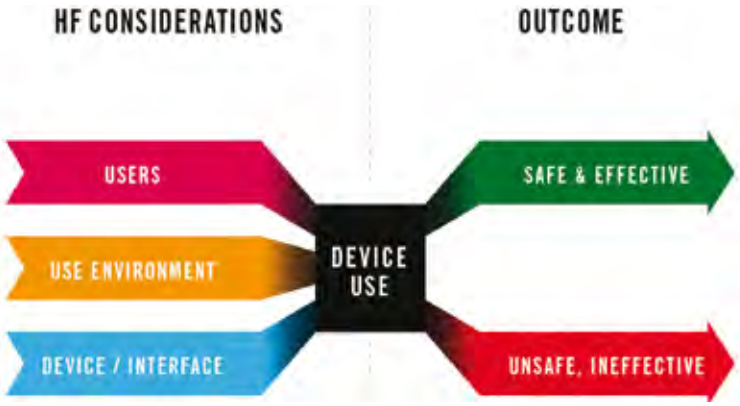


Figure 8. The Impact of Human Factors on the Outcome of Medical Device Use

Source: Molly Follette Story and the FDA "Medical Devices for Nonclinical Settings and the FDA." Prepared for the AAMI/FDA Summit on Healthcare Technology in Nonclinical Settings, Oct. 9–10, 2013.

Ideally, intended users can operate medical devices effectively and without making use errors that could result in serious harm to the patient or user. This can be achieved by following the standard ANSI/AAMI HE75:2009 *Human factors engineering process for risk management of medical devices;* conducting human factors validation studies using realistic tasks, use scenarios, environments, and conditions; and analyzing post-market data, for example from the FDA's MAUDE database. The FDA is dependent on users to report problems, and has a new consumer reporting form: 3500B.

neuropathy, so they can't use their little fingers. Look at the task demands of using a blood pressure monitor"—a 10-step process. "We need to match up the user's ability with the task you're asking them to accomplish." Harley terms the process of matching user ability, task demands, and their interactions in the use context human systems integration.

Summit presenter Neil Charness, director of the Institute for Successful Longevity, Florida State University, is helping to address connectivity challenges for remote monitoring in nonclinical settings and echoed this user ability–task demands–interactions framework for human factors analysis.

"Honor the user is the first commandment of human factors," said Charness. "A person may be highly motivated to interact with a system or not so motivated. The important thing is individual differences. The degree of fit determines the outcomes in terms of efficiency and safety. And please don't overlook comfort."

In Search of User-Friendly User Interfaces

Charness pointed out that many older people do not use the Internet, a platform for healthcare technology services, or smartphones, which can be models for devices or interfaces, or for built-in devices and applications. Only 56% of those 65 and older report using the Internet, and many do not use smartphones. "About 80% of home healthcare users are 65 and older," Charness said.

"If you are going to use smartphones or tablets, you are going to have to train them." For pumps or other devices designed to resemble the features and functionality of such consumer devices, "you're asking them to use a device for which they do not have a mental model," Harley said. Nor do they necessarily have the dexterity or vision to use such devices.

Shaky fingers and failing eyesight are among the human factors that device designers and developers should consider when they design user interfaces. User interfaces can be complex, and they are inconsistent from one device to another, thus imposing even more of a burden for the many people who use multiple devices. Summit participants advocated for standard, intuitive user inter-

faces with robust safety features that prevent unintended use. The display of information should be different for lay people and healthcare professionals, Charness said.

Applying Human Factors to Instructions for Use

Instructions for use of healthcare technology in nonclinical settings are a bone of contention. Too often, instructions for use are designed for experts, not for lay users, and produced by engineers, marketers, regulators, and lawyers, not instructional designers or professional writers. Users also complain that they were never provided with any instructions for use.

Summit presenter Pat Patterson, president of the Agilis Consulting Group, a human factors firm, explained why and how to use AAMI TIR49:2013, *Design of training and instructional materials for medical devices used in nonclinical environments*. A technical information report (TIR) differs from a standard or recommended practice, both of which are subject to a formal process of committee approval, public review, and resolution of all comments. A TIR is not subject to the same formal approval process, but it is approved for distribution by a technical committee and the AAMI Standards Board. A TIR may need further evaluation from the field, but releasing it is valuable because the industry and the professions have an immediate need for it.

The purpose of TIR49 is to support safe, accurate, and efficient user performance by providing guidance on the design of user instructions and training. TIR49 incorporates:

- **Research-based information and best practices** on how to influence user performance with instructional materials. Patterson emphasized that instructions must support user performance, not just understanding. "There are 50 years of data on how to design instructional data," she said. "Clinical studies data cannot substitute for human factors observational and probing data."
- A description of **a systematic and validated approach** to designing instructions and training. Instructions and training should be developed throughout the product development process, not as an after-

"I wish that clear, large-type, laminated instructions with concise, bulleted declarative sentences (narrative doesn't work for me) were attached to every piece of equipment for each function...cleaning, changing tubing, troubleshooting.
Bullet: Do this. Bullet: Do that. Bullet: Then do this."
— Suzanne Steidl

Expert Perspective

Lane Desborough
Product strategist, Medtronic

12 Device Design Facts

1. The vast majority (99.95%) of chronic disease management is performed outside the clinic.
2. Chronic diseases are context-sensitive, "lifestyle" diseases.
3. Disease management is a team sport—and the players are mobile, on a global playing field.
4. Coordination of stakeholders is key.
5. Nonclinical use conditions vary widely.
6. Sensors, smartphones, and the Internet are changing everything, quickly.
7. Once it's electronic, it can be anywhere.
8. Devices create new expectations and new possibilities for security, upgradability, dependability, simplicity, privacy, insights, variability, design, behaviors, and speed.
9. It takes a village—and there are different stakeholders with different perspectives.
10. The physical, financial, cognitive, and emotional burden of disease is already high; devices shouldn't add fear, embarrassment, and frustration to that burden.
11. Burden has huge implications, including misuse, disuse, and waste.
12. "Home ready" means ready to add value in the complex, multiagent, rapidly changing, heterogeneous world outside the clinic.

"Avoid the myth that 'writing' instructions—draft after draft after draft—is the same as designing this unique part of the user interface."
— Patricia Patterson, Agilis

thought. An instructional designer on the device design team "can provide an early warning sign" of design problems, and help determine what to include or leave out of instructions for use, and which media might be appropriate for communicating instructions for use.

Instructions for use should be assessed as well, beginning with early-stage formative evaluations during product development. Assessments of intended users and environments, and task-based scenarios, should be used to conduct human factors evaluations of the device and use error analysis. "Assess early and often and definitely before final evaluation," Patterson said. "Avoid the myth that 'writing' instructions—draft after draft after draft—is the same as designing this unique part of the user interface."

Patterson offered words of caution about low-literacy users, who are typically defined as reading at the sixth- or seventh-grade level. Some summit participants suggested that a fourth-grade reading level might be necessary for some instructions for use. It can be a challenge to write and evaluate instructions for use for people who read at low levels. The Agency for Healthcare Research and Quality has developed the Rapid Estimate of Adult Literacy in Medicine, a tool that can be used to measure an aspect of health literacy—individuals' reading comprehension in a medical context.

Finally, instructions for use can be a powerful training tool as well. Healthcare professionals should train people to use the instructions for use at the same time that they train them how to use the device, Patterson said.

"Honor the user is the first commandment of human factors."
— Neil Charness

FDA Perspective

Lisa K. Simone, PhD, MS, MOT
Biomedical and software engineer, FDA/CDRH

Five Important Device Design Considerations for Nonclinical Environments

1. **Expectations and Behavior**
   The user not only expects to interact with medical devices as with other electronic consumer devices, but also expects higher quality in the medical device. The reality is that functions we take for granted, such as key pressing and mouse clicking, may be quite different or even inaccurate in medical devices. Although some conventions are nearly universal, a firm cannot be required to comply with something that has no standard (like standard mouse-click behavior). However, the quality system requires that engineers are trained, know, and understand expected behaviors of devices.

2. **Configurability and User Qualifications**
   There is significant variation in user qualifications to operate a device. Some users and clinicians want to control settings, displays, and access; whereas others are novice users. Connectivity, configurability, and interoperability provide myriad permutations of possibilities of device operation. Therefore, while a manufacturer cannot vet all possible combinations for safety and effectiveness, users can be provided with a safe range of operating options.

3. **Reasonably Foreseeable Misuse**
   Technology and device misuse may be unintentional, due to tampering, or related to the design of the device. Multiple scenarios are possible, including reckless and malicious activities, such as hacking. To design a device that is home ready, hazardous possibilities have to be identified and mitigated, and risk-benefit analyses need to be conducted before that device can be released.

4. **Performance Requirements**
   Regulatory 510(k) submissions to the FDA often do not consider the environment of operation. In one example, a firm provided performance specifications for a ventilator covering temperature, humidity, shock, and vibration, but it did not specify requirements for the operating range of atmospheric pressure. When asked to provide these, the firm provided an unusable guaranteed operating range. Defining appropriate operating conditions is essential for patient safety.

5. **Root Cause Analysis**
   With the wider range of hazard situations and risks to patient safety, effective root cause analysis processes must be in place. Results of root cause analyses submitted to the FDA for adverse events and recalls are generally inadequate to determine the actual root cause(s), or trend(s) in cause types or across product types, or to assess if proposed Corrective and Preventive Actions (CAPA) are adequate. Identifying methods to gather useful information in the nonclinical environment will help manufacturers and the FDA address the causes of challenges and adverse events in the nonclinical environment.

Conclusion

"Thank you and the AAMI team for organizing such an important meeting and having it done well… Knowledge is power."
—Mei Zhang, Director of Engineering, Zyno Medical, LLC

The seamless delivery of healthcare and healthcare technology in nonclinical settings could pay tremendous dividends in the future. Improved health outcomes, better quality of life, and reduced costs would benefit individuals, the healthcare community, and the nation.

There are hurdles to be overcome to realize that Holy Grail of seamless healthcare in nonclinical settings, including:

- Complex and highly variable use environments
- A patchwork approach to multiple and recurring transitions in care
- Jury-rigged models and a disjointed system of care
- Inconsistent standards and regulations
- A lack of empathy in the design of healthcare technology for people, with all their frailties, who are its intended users

None of these challenges is insurmountable. Summit participants identified priority actions that key organizations could undertake, starting now, to address the challenges. Solutions and leading practices exist. Working together toward the vision of anytime, everywhere healthcare, with inspiration, innovations, and ideas from this AAMI/FDA summit, we can create a culture of safety and improved results in this emerging frontier of healthcare.

Multiple and complex use environments are just one of the challenges in providing seamless healthcare in nonclinical settings.

Key Definitions

These are the FDA's current operational definitions in its draft guidance document, *Draft Guidance for Industry and FDA Staff — Design Considerations for Devices Intended for Home Use,* 2012.

Home use device. A medical device intended for users in any environment outside of a professional healthcare facility or clinical laboratory. If the device is intended to be used in professional healthcare facilities and also outside those facilities, it is also a home use device.

Home. A dwelling or nonclinical environment excluding or other than a professional healthcare facility or clinical laboratory where a device may be used. This could include, but is not limited to, outdoor environments, office environments, schools, shelter-in-place environments, and in vehicles.

Professional healthcare facility. An environment where operators with medical training are continually available to use devices when patients are present. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities.

Clinical laboratory. A facility that (a) performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings; and (b) has been certified to perform such testing under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) in accordance with 42 CFR part 493, or has met equivalent requirements as determined by the Center for Medicare and Medicaid Services in accordance with those provisions.

Qualified healthcare professional. A licensed or non-licensed healthcare professional with sufficient skills and experience with the use of a device to aid or train someone to use and maintain the device.

User. A lay person such as a patient (care recipient), caregiver, or family member who directly operates or handles a device, or provides assistance to a patient in using the device.

— Mary Weick-Brady, FDA

GLOSSARY OF ACRONYMS

AAMI	Association for the Advancement of Medical Instrumentation
ACCE	American College of Clinical Engineering
AHIC	American Health Information Community
AHCA	Agency for Health Care Administration
AHRQ	Agency for Healthcare Research and Quality
ALS	Amyotrophic Lateral Sclerosis
ANSI	American National Standards Institute
ASPR	Assistant Secretary for Preparedness and Response
ATA	American Telemedicine Association
BiPAP	Bilevel Positive Airway Pressure
CAPA	Corrective and Protective Action
CDC	Centers for Disease Control
CDRH	Center for Devices and Radiological Health
CHAP	Community Health Accreditation Program
CMMI	Capability Maturity Model Integration
CMS	Centers for Medicare & Medicaid Services
CPAP	Constant Positive Airway Pressure
DOT	Department of Transportation
ECRI	Emergency Care Research Institute (formerly)
EHR	Electronic Health Record
EMC	Electromagnetic Compatibility
EM	Electromagnetic
EMR	Electronic Medical Record
ESD	Electrostatic Discharge
DME	Durable Medical Equipment
FAA	Federal Aviation Administration
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HHS	Department of Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven
HTM	Healthcare Technology Management
HTSI	Healthcare Technology Safety Institute
ICE	Integrated Clinical Environment
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IFU	Instructions for Use
IHE	Integrating the Healthcare Enterprise
IHI	Institute for Healthcare Improvement
IHTSDO	International Health Terminology Standards Development Organisation
ISM	Industrial, scientific and Medical Radio Bands
IT	Information Technology
MBAN	Medical Body Area Networks
MD PnP	Medical Device "Plug-and-Play" Interoperability Program
MedWatch	FDA Safety Information and Adverse Event Reporting Program
MT	Maintenance Team
NQF	National Quality Forum
NPSF	National Patient Safety Foundation
ONC	Office of the National Coordinator for Health Information Technology
PCMH	Patient-Centered Medical Home
SC	Subcommittee
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms
TIR	Technical Information Report
TJC	The Joint Commission
UL	Underwriters Laboratories
WI-FI	Wireless Fidelity

References

AAMI Horizons: Home Healthcare: Tackling the Challenge of Medical Technology in Nonclinical Settings. Spring 2013. Available at: www.aami.org/summit2013/AAMI/2013HomeHealthcareHorizons.pdf. Accessed Dec. 3, 2013.

AAMI TIR49:2013, *Design of training and instructional materials for medical devices used in non-clinical environments.* Association for the Advancement of Medical Instrumentation; 2013.

ANSI/AAMI HE75:2009, *Human factors engineering process for risk management of medical devices.* Association for the Advancement of Medical Instrumentation. 2009. Available at: www.aami.org/publications/standards/he75.html. Accessed Nov. 5, 2013.

ANSI/AAMI/IEC 60601-1-2, ed. 3, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.* 2007. http://webstore.iec.ch/webstore/webstore.nsf/artnum/037859!OpenDocument. Accessed Nov. 15, 2013.

ANSI/AAMI/IEC 62366:2007/(R)2013, *Medical devices - Application of usability engineering to medical devices.* Available at: http://my.aami.org/store/detail.aspx?id=62366. Accessed Dec. 3, 2013.

Bates, C. (2013) Chinese Man Keeps Himself Alive for 13 Years with Homemade Dialysis Machine. *The Daily Mail*. Available at: www.dailymail.co.uk/health/article-2266412/Chinese-man-kept-alive-13-years HOMEMADE-dialysis-machine.html. Accessed Nov. 10, 2013.

Beaulieu D. (2013) House calls may offer cost-effective, higher quality care for elderly. *Fierce Practice Management,* July 30, 2013. Available at: www.fiercepracticemanagement.com/story/house-calls-may-offer-cost-effective-higher-quality-care-elderly/2013-07-30. Accessed Nov. 15, 2013.

Becker S, **DeBartolo M**, **Freerks N**, **McGuireWoods.** (2013) 17 Healthcare Niches—Observations for 2013. *Becker's Hospital Review.* Available at: www.beckershospitalreview.com/hospital-management-administration/17-healthcare-niches-observations-for-2013.html. Accessed Dec. 3, 2013.

Centers for Disease Control and Prevention. Adoption and Use of Electronic Health Records and Mobile Technology by Home Health and Hospice Care Agencies. *National Health Statistics Reports.* Available at: www.cdc.gov/nchs/fastats/homehealthcare.htm. Accessed Dec. 3, 2013.

Centers for Disease Control and Prevention Home Health Care and Discharged Hospice Care Patients: United States, 2000 and 2007, *National Healthcare Statistics Reports*. Available at: www.cdc.gov/nchs/data/nhsr/nhsr038.pdf. Accessed Nov. 15, 2013.

Centers for Disease Control and Prevention National Home and Hospice Care Survey. Available at: www.cdc.gov/nchs/nhhcs.htm. Accessed Dec. 3, 2013.

Counce J, **Noyes B.** (2013) Medicare Competitive Bidding and External Infusion Pumps. Available at: http://onlinedigeditions.com/article/Medicare+Competitive+Bidding+and+External+Infusion+Pumps/1525708/0/article.html. Accessed Dec. 13, 2013.

ECRI Institute Top 10 Health Technology Hazards for 2012. Available at: www.ecri.org/Products/Pages/Top-10-Hazards-Resources.aspx. Accessed Dec. 3, 2013.

Family Caregiver Alliance, 2012. Fact Sheet: Selected Caregiver Statistics. Available at: www.caregiver.org/caregiver/jsp/content_node.jsp?nodeid=439. Accessed Dec. 3, 2013.

FDA. *Draft Guidance for Industry and FDA Staff – Design Considerations for Devices Intended for Home Use,* 2012. U.S. Food and Drug Administration. Available at: www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm331675.htm. Accessed Dec. 3, 2013.

FDA. Home Use Medical Device Initiative, 2010. U.S. Food and Drug Administration. Available at: www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/homehealthandconsumer/homeusedevices/ucm209056.pdf. Accessed Dec. 3, 2013.

FDA. MEDWATCH Consumer Voluntary Reporting: Form FDA 3500B. U.S. Food and Drug Administration. Available at: www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf. Accessed Dec. 3, 2013.

FDA. *Quality System Regulation - Design Controls and Risk Management (21 CFR 820),* 2013. U.S. Food and Drug Administration. Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=820&showfr=1. Accessed Dec. 3, 2013.

Gandhi TK, Weingart SN, Borus J et al. (2003). Adverse Drug Events in Ambulatory Care. *New England J of Med,* 348 (16): 1556-1564.

IBSWWorld. *Home Care Providers in the US: Market Research Report.* August 2013. Available at: www.ibisworld.com/industry/default.aspx?indid=1579. Accessed Dec. 3, 2013.

IEC 62366:2007, *Medical devices -- Application of usability engineering to medical devices.* International Organization for Standardization. Available at: www.iso.org/iso/catalogue_detail.htm?csnumber=38594. Accessed Dec. 3, 2013.

Kayyali B, Kimmel Z, van Kuiken S. (2011) Spurring the Market for High-tech Home Health Care. McKinsey & Company. Available at: www.mckinsey.com/insights/health_systems_and_services/spurring_the_market_for_high-tech_home_health_care. Accessed Dec. 3, 2013.

Kleiner BM. (2007). Sociotechnical system design in health care. In P. Carayon (Ed.), Handbook of Human Factors and Ergonomics in Health Care and Patient Safety. Mahwah: Lawrence Erlbaum Associates.

Leiber N. (2012) CareLinx's New Model for Home Health Care. *Bloomberg Businessweek*. Available at: www.businessweek.com/articles/2012-10-25/carelinxs-new-model-for-home-health-care. Accessed Dec. 3, 2013.

National Association for Home Care and Hospice Basic Statistics about Home Care, 2010. Available at: www.nahc.org/assets/1/7/10hc_Stats.pdf. Accessed Dec. 3, 2013.

Slabodkin S. (2013) Remote patient monitoring to save $36B globally by 2018, *Fierce Mobile Healthcare*. Available at: www.fiercemobilehealthcare.com/story/remote-patient-monitoring-save-36b-globally-2018/2013-07-17. Accessed Dec. 3, 2013.

The Joint Commission. Home—the Best Place for Health Care: A Positioning Statement from The Joint Commission on the State of the Home Care Industry. Available at: www.jointcommission.org/assets/1/18/Home_Care_position_paper_4_5_11.pdf. Accessed Dec. 3, 2013.

The Joint Commission. New Joint Commission Video Offers Advice on Medical Care at Home Sept. 10, 2013. Available at: http://finance.yahoo.com/news/joint-commission-video-offers-advice-173000224.html. Accessed Dec. 3, 2013.

ACKNOWLEDGMENTS

Supporting Organizations

Ambulatory Surgery Center Association
American College of Clinical Engineering
British Standards Institute
Center for Aging Services Technologies
Continua Health Alliance
ECRI Institute
eHealth Initiative
Healthcare Technology Foundation
Human Factors and Ergonomics Society
Infusion Nurses Society
The Joint Commission
Medical Device Innovation, Safety and Security Consortium
National Home Infusion Association
National Patient Safety Foundation
Underwriters Laboratories
Wireless-Life Sciences Alliance

Summit Presenters and Expert Commentators

Johann Becker
Wellspan VNA Home Care

Ann Blandford
University College London

Joseph Cafazzo
Centre for Global eHealth Innovation
University Health Network
University of Toronto

Neil Charness
Florida State University

Anthony Ciccarello
Philips Healthcare

Tobey Clark
University of Vermont

Reginald Cyrus
Old Dominion University

Carol Davis-Smith
Kaiser Permanente

Michele DeMeo

Lane Desborough
Medtronic Diabetes

Tejal Gandhi
National Patient Safety Foundation

William Gregg
Vanderbilt University Medical Center

Melissa Griffin
HumanEra

Linda Harley
Georgia Tech Research Institute

Melissa Harvey*
U.S. Department of Health and Human Services

Danielle Hoover*
VA National Center for Patient Safety

James Keller
ECRI Institute

Nancy Kramer
National Home Infusion Association

Margherita C. Labson
The Joint Commission

Vicki Lewis
MedStar Health's National Center for Human Factors Engineering in Healthcare

Roy Maynard
Pediatric Home Service

Susan Miller*
Centers for Medicare & Medicaid Services

Bridget Moorman
BMoorman Consulting, LLC

Ant Ozok
The Johns Hopkins University

Anil Patel
Underwriters Laboratories

Pat Patterson
Agilis Consulting Group, LLC

Kathy Puglise
BioScript, Inc.

Brian Rothman
Vanderbilt University Medical Center

Jeffery Silberberg*
U.S. Food and Drug Administration

Lisa Simone*
U.S. Food and Drug Administration

Elliot Sloane
Center for Healthcare Information Research & Policy

Suzanne Steidl
Your Daughter's in Town: Healthcare Advocacy for Elders

Molly Story*
U.S. Food and Drug Administration

Denny Treu
NxStage Medical, Inc.

Mary Weick-Brady*
U.S. Food and Drug Administration

Matthew Weinger
Vanderbilt University

Susan Wingert
Pediatric Home Service

Mei Zhang
Zyno Medical

Writing

Martha Vockley
VockleyLang

Erika Hatva, PhD
Managing Editor, AAMI

Layout and Artwork

Kristin Blair
Graphic Design, AAMI

* Invited speakers who were unable to attend due to the government shutdown

Thank You Sponsors

This publication was made possible by the financial support provided by these organizations.

Agilis Consulting Group, LLC
www.agilisconsulting.com

Patricia Patterson
ppatterson@agilisconsulting.com
480-614-0486

CareFusion
www.carefusion.com

Rachel Amparan
rachelamparan@carefusion.com
858-617-2230

Covidien
www.covidien.com

David J. Giarracco
david.giarracco@covidien.com
303-305-2361

Medical Specialities Distributors, LLC
www.msdonline.com

Alyssa Kelliher
akelliher@msdistributors.com
800-967-6400 ext. 6345

NxStage Medical, Inc.
www.nxstage.com

Daniel Call
dcall@nxstage.com
978-687-4700

UL
www.ul.com

Tara Kambeitz
tara.kambeitz@ul.com
360-263-6987

The sponsors listed on this page helped to pay for the production, printing, and mailing costs for this publication. The FDA was not involved in AAMI's securing of the sponsors. The sponsorships do not constitute any type of endorsement of the sponsors by AAMI or the FDA. AAMI expresses its gratitude to these companies for sponsoring this publication.

AAMI
Advancing Safety in Medical Technology

4301 N. Fairfax Drive, Suite 301 Arlington, VA 22203-1633 Phone: +1-703-525-4890 Web: www.aami.org