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Getting older can be a terrifying thing, particularly in Western culture, where the emphasis is very much on youth and appearance rather than accumulated knowledge and wisdom. However, much as we would like to deny it, we are all marching—or shuffling—off the mortal coil. And, according to the U.S. Food and Drug Administration (FDA) and the Census Bureau, the population is aging, with an estimated 72 million people in the U.S. over the age of 65 by 2030, increasing the incidence of chronic disease and disability.

I for one would like to avoid institutionalized care for as long as possible. When the moment comes, I hope to meet an untimely but thrilling end in what’s left of the Amazon forest. Should that fail, spending the remaining years at home in a comfortable armchair in front of the television, visited by the occasional relative or caregiver is a possibility.

For people of all ages, home healthcare and connected health are becoming increasingly common, because many more patients are being discharged from hospital to continue receiving medical care in their homes. Home healthcare is cheaper and more convenient than a long stay in the hospital and 12 million people (69% of whom are over 65) receive care in the home.

The move from the hospital to the home is being facilitated by high-tech developments in mobile healthcare and an explosion of home-care devices on the market, in addition to the migration of traditional clinical devices to the home. Many treatments that once used to be administered only at a hospital can now be received in nonclinical settings—at home, on the road, in an airplane, or on an aircraft carrier for that matter.

There are many benefits to this trend. However, there are also significant risks unique to the use of complex medical devices outside healthcare facilities, as evidenced by an increasing number of reported adverse events related to home use devices. In December 2012, the FDA issued a Draft Guidance for Industry and FDA Staff—Design Considerations for Devices Intended for Home Use, and in October 2013, AAMI and the FDA will hold a summit on healthcare technology in nonclinical settings to address some of these challenges.

In this issue of Horizons, experts in healthcare technology management, device design and manufacturing, and regulation came together for a spirited roundtable discussion on the impact of healthcare trends on home care. The issue also includes patient and caregiver perspectives, as well as articles on promoting safety, designing home-use devices, and supporting equipment in nonclinical environments.

With possible pitfalls in mind, we can move toward a world in which medical devices and care are seamlessly integrated into our lives and homes, ideally one in which we can receive state-of-the-art medical treatment while retaining our independence and dignity—whatever our age.

Erika Hatva, PhD
Managing Editor, Horizons

About This Issue

This issue of Horizons examines the latest practices and challenges in the field of home healthcare devices, as well as offering advice and practical tips from manufacturers, regulators, and home healthcare experts. This is the latest in a series of special-topic Horizons, published by the Association for the Advancement of Medical Instrumentation (AAMI).

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Horizons is a supplement to Biomedical Instrumentation & Technology (ISSN 0899-8205) and is published twice a year by the Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633; +1-703-525-4890. © 2013, Association for the Advancement of Medical Instrumentation. Publishing services provided by Allen Press Publishing Services, a division of Allen Press Inc.

Membership: AAMI members receive a complimentary subscription. Contact membership at AAMI at +1-800-322-2264, ext. 1214.


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POSTMASTER: Send address changes to BIRT, 810 E. 10th Street, P.O. Box 1897, Lawrence, KS 66044-8897. AAMI members send changes to AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633; +1-703-525-4890. Nonmembers send changes to Kansas address above.

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HOME HEALTHCARE NEWS & PRODUCTS

U.S., BRIC Countries Drive Home Healthcare Boom

A new report from Freedonia projects the world demand for home medical equipment will rise 7% annually to $28 billion by 2016, driven by patient needs in the U.S. and the “BRIC” nations: Brazil, Russia, India, and China. While the U.S. is expected to remain the biggest market, BRIC nations are experiencing greater prosperity, therefore, third-party and direct consumer payments for healthcare will grow, the report World Home Medical Equipment (January 2013) notes. Home therapeutic equipment sales will jump an estimated 7.5% annually to $17.3 billion in 2016 as increasing numbers of patients with chronic conditions, particularly cancer, respiratory disorders, and kidney failure, obtain care at home for longer periods of time, according to the report.

Sales of dialysis products, intravenous (IV) equipment, ventilators, portable oxygen concentrators for treating chronic obstructive pulmonary disease, and continuous positive airway products for sleep apnea are expected to rise. In addition, members of the aging Baby Boom Generation will need patient support equipment, including wheelchairs and walkers. The report’s authors anticipate that sales of this type of equipment will increase 5.5% annually to $5.7 billion.

Although per capita home medical equipment sales in Western Europe, Canada, Australia, Japan, and South Korea will remain comparatively high, overall growth will remain below the worldwide average as national health insurance plans impose tighter controls on coverage and reimbursement rates, according to the report.

With In-Home Health Monitoring Set to Soar, Challenges Remain

After being released from the hospital, patients suffering from a number of ailments—including congestive heart failure, hypertension, and mental health conditions—are being monitored remotely by their doctors to assess disease progression. As hospitals try to reduce the number of readmissions and cut costs, telehealth is becoming increasingly important. A new InMedica report, The World Market for Telehealth – An Analysis of Demand Dynamics – 2012, predicts the number of patients being monitored remotely will hit 1.8 million by 2017—up from 308,000 last year.

While telehealth has made major inroads in post-acute patients, progress is needed for those diagnosed at an ambulatory care facility but not yet hospitalized. In the U.S., an estimated 140,000 post-acute patients have been monitored by telehealth in the past year compared to 80,000 ambulatory patients, according to an InMedica prepared statement.

“A major challenge for telehealth is to reach the wider population of ambulatory care patients,” notes Theo Ahadome, senior analyst at InMedica, in the statement. “However, the clinical and economic outcomes for telehealth are more established for post-acute care patients. Indeed, even for post-acute care patients, telehealth is usually prescribed only in the most severe cases, and where patients have been hospitalized more than once in a year.”

Market for Remote Cardiac Monitoring to Take Off

Cardiovascular disease is the leading cause of death worldwide, taxing many healthcare systems that treat acute patients. However, the rapidly growing field of remote cardiac monitoring has the potential to cut down on these costs by helping physicians detect diseases before expensive acute care is required.

Because Medicare has started reimbursements for remote monitoring technology, an increasing number of healthcare providers in the United States are using these systems. In fact, the U.S. market for remote cardiac monitoring devices and services is expected to jump more than 25% between 2011 and 2016—from $686 million to $867 million, according to a new IHS InMedica report titled “World Market for Diagnostic Cardiology Devices and Remote Cardiac Monitoring Services – 2012.”

Medicare reimbursements are encouraging health service providers to use remote cardiac monitoring devices in the U.S. Elsewhere, the remote cardiac monitoring business is undeveloped, with only sporadic coverage, according to the report.

A number of big names already have entered the market, including Biotronik, Medtronic, Boston Scientific, and St. Jude Medical. Competition promises to be fierce, especially as doctors attempt to assess which patients require immediate treatment.
“With limited physician resources to cover the ever-increasing number of cardiac patients, remote monitoring enables patients to be observed away from the hospital over longer periods of time, providing a much needed cost-saving initiative,” explains Nicola Goatman, market analyst at IHS, in a prepared statement.

**SIDS Prevention**

A group of students from Brigham Young University (BYU) have developed a new device that they say will reduce the number of sudden infant death syndrome (SIDS) cases each year. Jacob Colvin and his team have fashioned a baby monitor that looks like a sock, dubbing it the Owlet. It straps to an infant’s foot and uses pulse oximetry to monitor heart rate and blood-oxygen levels. If the infant stops breathing or there is a marked change in heart rate, the monitor will warn the parents via smartphone.

The Owlet took top honors at BYU’s third annual Student Innovator of the Year competition, taking home a cash prize of $6,000. “The Owlet baby monitor has the potential to really benefit our society—and bring some peace of mind to new parents,” Justin Zsiros, faculty advisor to the completion, said in a BYU release.

**Skype, Web Apps for Infant Care**

Skype, a web application, is widely known as a way to video-chat in real time and keep in touch with friends and relatives via computer. But a Swedish study has found that it can also be useful in monitoring premature infants who have recently been released from the hospital.

The study evaluated the monitoring of premature infants by Skype and standardized nurse visits. It found that parents were enthusiastic about using Skype, as it helped reduce the need for home visits by nurses. In the study, 34 families were randomly assigned to three groups who received either standardized home care only; standardized care supplemented by a web-based eHealth system; or standardized care complemented by video conferencing via Skype.

The parents were very satisfied with the visits from neonatal nurses and also found the web app generally easy to use, allowing parents to answer questions about their child’s health and exchange messages with nursing staff. “The webpage was another possibility of contacting the home care nurse. It was easy to use, a complement to the home visits,” noted one respondent.

One frustration for the parents was the lack of response from some of the nurses. Four families indicated they had received no feedback about the information they had entered.

Skype technology itself proved quite popular with parents. When asked whether they liked videoconferencing versus ordinary phone calls, seven out of eight, or 87.5%, said yes. In addition, 75% indicated that the video calls reduced their need for home visits. “I think Skype could have replaced every other or every third visit,” one respondent said.

Even parents in the other two groups were enthusiastic about Skype: “If we had had Skype, we would have seen one another and you could show the child’s equipment and get instructions on how to use it,” explained one respondent. “It could have replaced visits where the nurse did not have to do anything, such as weigh the baby.”

Although the families were satisfied with the web application and video conferencing, the researchers noted some resistance from the nurses in the study, who tended to be older, with a median age of 50 versus 31 for the mothers. Of the six nurses, two were hopeful about the future use of web apps and Skype in home health, and three others had varying levels of enthusiasm. However, one nurse had a completely negative response, saying such technology threatened the personal relationship between the nurse and families.

The study findings were published Feb. 9 in *BMC Medical Informatics and Decision Making*.

**Cardinal Scoops Up AssuraMed for $2B**

Eying the growing home healthcare market, Ohio-based Cardinal Health paid $2.07 billion to buy privately held AssuraMed, which had annual sales of roughly $1 billion last year. The companies expect to wrap up the acquisition in early April, according to a prepared statement.

AssuraMed, which is based in Twinsburg, OH, has an at-home delivery service and a wholesale business and serves more than 1 million patients with its 30,000 products. The EdgePark home delivery service provides ostomy, diabetes, wound care, urological, incontinence, and respiratory products.

During a conference call about the deal, George Barrett, Cardinal’s chairman and CEO, noted the acquisition will help his
company, particularly as more care is being delivered in the home—both for chronic and acute conditions.

Barrett noted during the call that AssuraMed is experiencing above-market growth, and pointed to the company’s broad product line and capacity to do complex billing.

“AssuraMed is a natural extension of the Cardinal Health businesses and of our mission to be essential to care. The acquisition of this industry leader allows us to serve the growing number of Americans treated in home settings—particularly those patients recovering from acute episodes and those suffering with chronic diseases. This is a platform opportunity for Cardinal Health products and services that will be increasingly important as the delivery of care migrates to more cost-effective settings,” Barrett said in a prepared statement.

Fitch Ratings affirmed Cardinal’s ratings in the wake of the deal at BBB+. Fitch noted the acquisition will give Cardinal “immediate and significant exposure” to the home healthcare industry, something the company currently does not have.

Patient Safety Pamphlets

ECRI Institute and the Healthcare Technology Foundation have collaborated on a series of patient safety pamphlets on home medical devices. They include Home Ventilation: A Safety Guide for Caregivers; Home Hemodialysis Safety: A Patient Guide; Fire Safety & Oxygen: A Patient Guide; and Home Devices: Can I Bring My Own Medical Device with Me to the Hospital? The pamphlets are available in both English and Spanish as free downloads from the HTF website at http://thehtf.org/publications.asp and the ECRI Institute website at www.ecri.org/Patients/Pages/Patient_Resources.aspx. Limited numbers of printed copies are also available.

Virtual Visits

Sweden has made a strong commitment to providing elder care. Government officials have noted that patients are increasingly starting to monitor mild to moderate illnesses at home or interacting with their healthcare providers over the phone. The number of elderly will continue to rise, making up roughly 25% of the population by 2050, according to government release.

Giraff Technologies AB is already looking to help the elderly age in place with its robot Giraff. The remote monitoring system allows caregivers, family, and doctors to check in on elderly patients over the Internet. “Visitors” can move around the house freely by moving a mouse and interact with elderly residents as if they were actually there. The Giraff is part of two European projects that are testing the technology in patients’ homes to see how it can improve quality of life for those aging at home.
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Home healthcare is vital for a large percentage of the population. According to data from the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control (CDC), 7 million people in the United States receive home healthcare annually. The use of medical devices in the home and other nonclinical environments is increasing dramatically. By the year 2050, an estimated 27 million people will need continuing care in the home or in the community and not in a controlled clinical environment.¹

The FDA recently announced its Home Use Devices Initiative and issued the document, “Draft Guidance for Industry and FDA Staff—Design Considerations for Devices Intended for Home Use” on Dec. 12, 2012.² The Center for Devices and Radiological Health (CDRH) regulates medical devices, but that regulatory authority alone is not enough to ensure safe and effective use of devices in the home. To address these and other issues, AAMI and FDA will co-host a summit on healthcare technology in nonclinical settings Oct. 9–10, 2013.

Mary Logan From a technology perspective, what makes the home environment different from a clinical setting?

Mary Weick-Brady In a clinical setting, technology is used by a healthcare professional in a controlled environment. The home environment has many users: clinicians; home healthcare aides with differing degrees of training in medical device use; and caregivers, usually giving care to a loved one—so there are many emotional aspects to the care that may influence their learning behavior with technology.

Care recipients may also use technology that may or may not help them, because it may or may not have been designed for environments outside of a controlled clinical setting. The home environment is uncontrolled: You can’t control for pests or vermin, air quality, noise volume, electrical safety or cleanliness of the environment in which that device is being used. You also have to think about the characteristics of the specific user, such as physical, emotional, or cognitive limitations.

James Keller It is also difficult to assess what is being used in that home care environment. Hospitals have a hard time just keeping track of inventory used in their institution. In the home and nontraditional settings, it is even more difficult to track a device recall, do preventive maintenance, or determine the training needs of the caregiver using the device.

Also, I’m a biomedical engineer and have worked with technology for years, but when it came to a relative who was home on hospice with a patient controlled analgesia (PCA) pump, I was afraid to, for example, give too much medicine.

Lisa Winstel We all have heard about the now ubiquitous “sandwich generation” family caregiver, but consider a 48-year-old woman...
providing care to her parent, there are children, friends, family, and other social members of the community coming in and out of the home. There is a lot of traffic in a home environment that you are not going to see in a clinical environment—people who track germs or pet hair, or are curious about the equipment.

**Scott Thiel** In a clinical setting, you also don’t have as many potential other devices that could interfere with medical devices, whether it’s from too much of a load on the electrical system or wireless system. Most hospitals are also situated physically near a reliable electrical supply and good wireless coverage, but not all locales where the equipment will be used have the reliable infrastructure needed.

**Mary Weick-Brady** Older technology or legacy devices tend to stay in nonclinical environments much longer than in clinical ones, so you have to be thinking about 20- to 30-year-old devices that are out there.

**Denny Treu** We have to look at the home environment as a system, from prescription to training to the devices. Are there consumables associated with it, and how are those consumables disposed of? What service and maintenance are required?

**Vicki Lewis** A very good place to start is simply making sure that the device performs in a way that meets the user’s expectation. We certainly need to consider the entire environment, but it would be terrific just to know that all home healthcare devices go through usability testing before getting out there.

**A very good place to start is simply making sure that the device performs in a way that meets the user's expectation.**

**Mary Logan** What is the number one challenge we face today in home healthcare related to technology, and how can we overcome that challenge?

**Wendy Rogers** There is a lack of a fundamental human factors or “know thy user” approach to the design of these home healthcare systems.

**Lisa Winstel** There is such a wide range of backgrounds, education, needs, visual acuity, dexterity, levels of arthritis, ability to lift, and ability to interpret directions. Not grouping all family caregivers and users in home settings into one polyglot is very important.

**Scott Thiel** Good design and development do not prevent devices from being used in a manner that was never intended during their design: Legacy devices designed to be used by a clinician in a clinical environment are being used now, for example, by an uncle who is stopping over to help out with care during the day.

**Chuck Parker** The technological challenge is that devices are not “plug and play.” Devices that require a certain level of customization in order to be maintained typically require technical help to maintain a connection on the back end.

**Daryle Gardner-Bonneau** There needs to be a realization that things are different for home healthcare devices in terms of the entire environment and infrastructure of care. For devices in a clinical environment, there is support for things like maintenance, repair, and cleaning—a support structure that doesn’t exist in the same way in the home environment.

**Nancy Kramer** Equipment maintenance, repair and cleaning is a routine part of care for complex medical devices supplied to patients by home infusion pharmacies and durable medical equipment (DME) providers. It is important to distinguish between medical devices that a patient may purchase directly without any home instruction or service component, and those that require routine maintenance and servicing (such as infusion pumps or other types of electronic durable medical equipment).

**Mary Weick-Brady** One of the major problems is the inability to follow instructions or labeling in a consistent way: If it’s not usable to that person, it’s not useful and therefore it will not be used. Ideally, there would be no labeling or instructions for use whatsoever.

**Reginald Cyrus** The number one challenge is the varying level of in-home competence of
maintenance professionals: If you don’t have a certain level of knowledge, it is difficult to help the care recipient.

Mary Logan How can we facilitate interoperability between the hospital and home with respect to technology and clinically relevant information?

Chuck Parker Organizations that support those types of standards could emphasize that from a purchasing perspective, systems are certified to have “plug and play” capability: Continua and now Integrating the Healthcare Enterprise (IHE) have certification programs in the market space.

Scott Thiel Not only do we have to drive it from the purchasing side, but also from the regulatory and manufacturing side of things. Health authorities in the U.S. and abroad must recognize standards and accept testing associated with the compliance of those standards.

Many government agencies need to be involved when it comes to exchange of information across a wireless system or a wired system.

Mary Weick-Brady The Federal Communications Commission (FCC) plays an important role in interoperability. Many government agencies need to be involved when it comes to exchange of information across a wireless system or a wired system. The FDA is very interested in making sure that the data that is being transmitted is received, and that it is the same information as that transmitted; as well as cybersecurity. We need to make sure that everybody is speaking together and moving ahead together.

Denny Treu It is really important to keep safety and risk management in mind as we develop a system and then pass data between devices or into an electronic health record (EHR).

James Keller Having formal evidence of the value that interoperability brings, for example, through funded trials, will be a really big driver in pushing healthcare organizations to emphasize interoperability when purchasing, which will promote the continuum of verified products hitting the market, impacting insurance companies and Medicare coverage decisions.

Reginald Cyrus It is quite a challenge to work with a case manager at an insurance company and a physician’s office to gather required documentation supporting a patient’s need for a device in their home, in order to get it approved by their insurance company. It is insurance company reimbursements for home care devices that will determine which technologies go into the community, and therefore which devices manufacturers produce.

Mary Logan What are the most challenging aspects of the reimbursement system and how patients afford complex medical equipment in the home?

Nancy Kramer From a home infusion therapy perspective, the lack of a comprehensive Medicare benefit presents a number of financial challenges for aging patients who require daily infusion. For instance, a diabetic patient who needs several weeks of daily intravenous antibiotic infusions for the treatment of a severe infection must either pay out of pocket for the equipment, supplies and professional services needed to dispense and monitor their antibiotic therapy, or they must make daily visits to the doctor’s office or outpatient clinic to receive their infusion. The alternative is a prolonged hospitalization or long-term care stay, as many patients cannot afford to cover these costs out of pocket.

Reginald Cyrus In one of my recent documentation assist efforts, an elderly woman caring for her husband had difficulty operating a manual patient lift and she was told her husband did not qualify for an electric patient lift. In order to get a replacement electric lift, I had to supply his physician’s office with the exact wording—“two or more people are required to move patient from bed, and to not do so would render him bed ridden and health would suffer”—to put on the prescription required by the insurance company for authorization. Clearly, HTM professionals going into the home must have a high level of understanding of the complex reimbursement system.
Lisa Winstel One of the most challenging aspects of getting the equipment into the home is that the caregiver is required to be at the hospital with the patient managing discharge at the same time that equipment (requiring the caregiver’s signature) is being delivered to the home. An earlier delivery would not be covered by insurance.

Chuck Parker With respect to reimbursement, under the current service-fee system, the healthcare system benefits from keeping the patient either in long-term care or the hospital longer. As we see a switch to more risk-based contracting, the emphasis will be on early release from the hospital and keeping the individual at home.

Mary Weick-Brady Accrediting bodies for home healthcare are another important aspect to reimbursement. How do their standards for accrediting home healthcare agencies impact equipment going into the home and what is reimbursed?

Many people get some device training before they leave the hospital, but it is typically on equipment familiar to the hospital and not necessarily what they will use in the home.

Mary Logan How can industry, the manufacturers and medical device companies address home healthcare requirements and needs, as well as the physical, emotional, and cognitive user characteristics?

Wendy Rogers The first priority is to involve representatives of the target user group very early in the design process. The second is that to make a device as usable as possible without having to consult outside information, one should consider “feed-forward” (what the user is supposed to do next) and feedback as to whether what they’ve done is correct. Manufacturers should also be aware that some instructions may be necessary, even if the device is designed to be intuitive.

Scott Thiel I think there is a correct way of making labeling as intuitive as the devices themselves. So it shouldn't just be a little tag beside the device. It needs to be right there with it.

Vicki Lewis Early usability testing is important—with a variety of home users. Some medical device manufacturers are not aware of what human factors involves or feel that it slows down product development. But the truth is that the earlier you consider human factors, the cheaper it will be. Early mockups need not be elaborate or expensive.

Denny Treu Device manufacturers need to switch gears and design home-based systems for usability and human factors from the very beginning, not when the early testing starts. The beginning of the design stage is the best time to understand users and their environment, and think up ‘out-of-the-box’, innovative, systemwide solutions that can make a big difference in simplifying the product and its delivery or use.
Daryle Gardner-Bonneau Designers and manufacturers need to recognize that most people do not want their lives to revolve around their healthcare and medical devices. If the burden of operating and maintaining devices is too heavy, users will abandon the devices. So device simplification is key.

Nancy Kramer It is important to balance the development and testing of a pump or a device that takes into account all possible scenarios, with the need to get improved technology into patients’ and caregivers’ hands.

Mary Weick-Brady Some people like to have that extra information though, so think about who the end user is: The younger generation would love to have their glucose— their insulin pump do all sorts of things for them. Older adults would have different needs. Also, manufacturers should incorporate technology that’s already available outside of healthcare, because people are familiar with it.

Reginald Cyrus In hospitals we have manuals, the Internet, and experts all around us. In the home, when a piece of equipment fails there is often no labeling to help the user. There is so much focus on how to operate the equipment, but the real need is what to do when it stops working. Manufacturers also need to keep in mind that home medical equipment is often actually used outdoors or in the car, and needs to be able to withstand a wide range of temperatures and environments.

Mary Logan In an emergency such as a power outage or fire that could make technology either dangerous to use or unusable, how can the risk to the patient be minimized?

James Keller Battery limitations are key. Even home devices designed to preserve life, such as ventilators, have a woefully inadequate battery capacity. If you lose power for a day, such as during the 2012 East Coast storms, you’re dead in the water with a ventilator or some other critical device. So just making sure that the battery capacity is improved and making contingency plans for a long-term power outage or having a generator is vital in planning for that patient.

Reginald Cyrus For some critical equipment, such as ventilators, many home care companies send a Serious Medical Certification Form to the local electric power company. This adds the patient to its database of people with home life-sustaining equipment and alerts the emergency medical services (EMS) if needed. The service may need to be expanded to other home devices.

Mary Logan Ten years from now, how will home healthcare have changed the healthcare technology field?

Chuck Parker You’re going to see a significant increase in the data points and that will lead to a new association with medical technologies and outcomes.

Mary Weick-Brady I would like to think that there would also be more innovation. Industry might argue that FDA is inhibiting innovation, but the Department of Defense for example, has done impressive things out in the field with robotics, getting medical care to remote and sometimes inaccessible environments. I would like to see that happen with the home environment, and innovations to make home use devices much more accessible and usable.

Daryle Gardner-Bonneau Ideally, in the future we would see more integrated kinds of solutions. When patients have to use many different types of equipment, the burden gets very heavy.

Scott Thiel We will see a continued increase in pressure from consumers and manufacturers to use consumer electronic designs and features in medical devices. There will be more of a blurring between user interfaces and how those technologies function in the medical device environment.

Nancy Kramer Ideally, we will have a comprehensive Medicare benefit that will allow the same level of care in the home for aging patients that those with commercial insurance receive. When our rapidly expanding Medicare
population is able to receive a full range of infusion therapies in their own home, the use of remote monitoring technologies to assess their response to therapy and prevent hospital readmissions can be clinically and economically justified.

Lisa Winstel When the “silver tsunami” hits and baby boomers come into this first as caregivers and then as care recipients, they will shift our entire paradigm. A generation that has reinvented and found new solutions at every turn will demand that that home healthcare issues be solved differently. We are also going to see larger, more technically savvy populations receiving care at home and have to be prepared for more demand and more creative solutions.

References

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Patient and Caregiver

Q&A With Michele DeMeo
And Johann Becker

With a 20-year career as hospital manager, sterilization expert, and independent consultant, Michele DeMeo continues to be a tireless advocate for the healthcare technology management (HTM) community, despite living with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig’s disease. In this Q&A, she and her partner and primary caregiver, Johann Becker, who happens to be a home health and hospice nurse, share insights and discuss their experience with home healthcare from the patient and caregiver perspectives.

Tell us a little about your background.

Michele DeMeo I am a sterile processing expert and love the profession. I am also a consultant, product designer and developer, author, manager, motivational speaker, and educator. As for my introduction to home healthcare, I was diagnosed in 2010 with ALS and most recently given the news I have another terminal disease, melanoma to my bones, an abdominal mass, and distant metastases to my brain. So I am a hospice patient.

Johann Becker As fate would have it, I am a nurse with 25 years of home health and hospice experience. I currently work in administration, but have worn many hats throughout my career: certified registered nurse infusion (CRNI) while in the field; later a team leader, quality manager, and project manager; and currently, director of clinical operations for an integrated healthcare system in South Central Pennsylvania.

What’s the biggest challenge about home healthcare from the patient perspective?

Michele DeMeo I would have to say the gap between a clinical visit and when my partner comes home. It is difficult being so sick, and I am alone from about 7 a.m. until 7 or 8 p.m. Monday through Friday. My team comes for about an hour twice a week. In between visits, I do my best. Sometimes it is hard to have an active mind and a body that wants to run and kayak, but my body says “No, not today ... maybe tomorrow.”

What’s the biggest technical challenge from the caregiver perspective?

Johann Becker The biggest technical challenges we’ve encountered involve mobility and safety. Michele is a minimalist, and we had downsized to a 500-square-foot cottage. Once we had an adjustable bed, oxygen concentrator, back-up oxygen tanks, bilevel positive pressure ventilation (BiPAP) machine, rollator, wheelchair, nebulizer, chest percussion vest that shook the house, enteral feeding equipment, and Jevity nutrition formula by the case, we ran out of space. Michele navigated inside our tiny home with her power wheelchair just as many of us used roller skates as children. She would go in one direction ... and simply run into the wall to stop. While objectively it seemed that she was not safe at home alone, independence was not negotiable, and she chose to be left...
alone while I work despite known risks.

The doorways and square footage of that house did not allow for wheelchair access, and the property was situated in a manner that would not tolerate a ramp to allow access in and out of the house. When the steps to the house became unmanageable, we moved, leaving our little cottage for an apartment that offers an elevator, all hardwood floors, wide open spaces for her to navigate, a rooftop deck, downtown businesses, and public transportation for her to utilize when she’s feeling well.

The other more "tactical" challenge was navigating the whole home health, palliative care and hospice continuum at home, and being on the receiving end of messages I had personally delivered over the years. For example, despite the fact that leaving home required a monumental effort, we continued to do so to enrich our quality of life. Michele’s homebound status was never really questioned, but it seemed we were always waiting for someone: a nurse, an aide, a durable medical equipment (DME) provider, a social worker, a chaplain. It was a challenge to remember that we were in control of our lives and were receiving services at home, not that we had “surrendered” to being home health or hospice patients.

What are the advantages of home health-care from your perspective?

Michele DeMeo There are many, but as someone who loves information, I get a lot out of the information that is provided by my clinical team, from an answer to a burning question or what my vitals are compared to the last visit, to discussing the team’s idea of what my life trajectory will be in the near future, so that I can plan. It is also good to have someone to bounce ideas off of and someone to talk to when a new something starts to fail, like the loss and change of my eyesight and visual processing from the brain involvement.

Johann Becker The main advantages for a client and caregiver at home are independence and autonomy. Our quality of life is supported rather than sacrificed. Visiting caregivers have offered support for our goals, and provided instruction and interventions that have impacted our ability to continue to live, laugh, and enjoy each day to its fullest.

Most importantly, we’ve been comforted knowing that we can contact our caregivers for direction 24 hours a day. At four a.m. one morning, we had a crisis and needed help. With one call, Michele’s hospice nurse came to the home, helped us through the incident, accompanied us to the emergency room, ensured her comfort and my peace of mind, accompanied us home, and called later in the day to follow up. It was a humbling call, but the reassurance we received was immeasurable.

You have a unique perspective as you are also an HTM professional. What insight has this given you into the home health-care device field?

Michele DeMeo It is surprising that regardless of how much I know about the home healthcare devices—what they are, how they work, how to clean and use them—it is different when you must do it for yourself. As confident as I am to teach others about them, actually using them on myself makes it more real and has changed my approach to teaching, when I get the occasional student.

How does Michele’s specialized knowledge affect your day-to-day interaction, and how does this compare with your experience with other patients?

Johann Becker Michele’s level of expertise and awareness does impact our daily lives. While she tolerates that life in the real world might entail preparing a sandwich, washing one’s hands and wiping them on an apron, the hyper vigilance is always visible behind her big blue eyes. Inside there’s a voice saying “Do you know what’s on that apron? Did you wash your hands after you touched my feet? Do you know that E. Coli are aerosolized in the bathroom, and did you REALLY just put my toothbrush down on the counter?”

What experience have you had with specialized home healthcare equipment? What type of equipment do you currently use?

Michele DeMeo I have had extensive experience. Currently, I use a bilevel positive airway pressure (BPAP) machine, nebulizer, oxygen concentrator, oxygen tanks, and the vest for
chest percussion. I do have a peg tube, but not a feeding pump yet.

**Johann Becker** Most of the equipment that we’ve utilized at home has been familiar to me. It’s most often delivered when I’m at work, so I haven’t been included in any education from the DME provider. The vest was the piece with which I was the least familiar. Although it didn’t end up being beneficial for her, I was enchanted. I kept wondering where this contraption was in the late 1980s when we were doing home visits for chest percussion and postural drainage routinely. Those visits were like aerobics!

**How does home healthcare compare with your experience as a patient in a hospital?**

**Michele DeMeo** That is a difficult question for me answer, because when I am in the hospital it is because it is an acute event and the multiple interactions and care given all day long are not only appreciated, but needed. However, with that said, I am chronically ill now and slowly dying, and so having the freedom to just “be” at home is a gift.

**Have you also worked in a clinical setting Johann? If so, how do your experiences in the two environments compare?**

**Johann Becker** Yes, I worked for about a year in a tertiary care hospital after college, then went straight to home care. The settings are as different as night and day. The locus of control is closer in a hospital, but the intimacy and ability to quickly establish a therapeutic relationship on the client’s own turf is magic. As a practitioner, the independence and autonomy home healthcare offers are unmatched. From a home caregiver perspective, the level of investment from clinicians has been terrific at home, although we’ve received some exemplary care from inpatient caregivers in a variety of settings as well. Overall, nurses rock!

**Have added responsibilities such as device maintenance, recalls, repair costs, and software updates been an issue?**

**Michele DeMeo** A bit. I have had different providers for different reasons and each covers different items and some are better than others for some needs. It is hard for me to call, or even remember to ask for more oxygen tanks and personally clean the filter in the concentrator, for example, when I can hardly get around well, let alone bend, remove the filter, clean, and return it. I get exhausted very easily.

**How do you find quality of care is impacted when Michele moves between the hospital and home? Is safety a concern?**

**Johann Becker** Transitions of care remain a challenge for all parties involved. From a patient and caregiver perspective, we have experienced the similar vacuum that home health practitioners encounter between hospital discharge and a follow-up visit with the primary care physician or specialist. After a stay in a tertiary care hospital, it’s often difficult to know which specialty to follow up with when complications arise.

**What recommendations would you have for fellow patients in the home healthcare setting?**

**Michele DeMeo** The best advice I can offer is not to be afraid to ask questions—that is the care team’s role and expertise. This is especially important, because you are more likely to be out of their sight than in their immediate view. Your body is changing or recovering and questions and concerns do present themselves—it’s natural. Nothing is more unsettling than to notice something new and not have an answer.

**How can the HTM field best serve patients in a home healthcare setting?**

**Michele DeMeo** Stay connected. Call and check up on your patients. Ask if there is anything you can do before leaving. Be present and in the moment, even though you may have five more patients to see after me. In the moment of the home visit, it is a person that is in front of you: I am more than a patient; I am Michele DeMeo.
Accessibility is becoming an increasingly important consideration in home healthcare due to changing user demographics, an emphasis on baby boomers, and the greater number and complexity of devices being used outside clinical environments. Medical device accessibility is defined as the degree of “ability to access” or benefit from the intended uses of devices within environments. Accessibility includes consideration of diverse users with functional limitations and analysis of barriers to use.\(^1,2\) Medical device accessibility can address diverse user needs related to receiving and providing safe and effective home healthcare.

The number of home healthcare recipients will likely continue to increase as the U.S. population ages, which also means more devices will be used outside of clinical settings.\(^1\) In 2010, about 12 million individuals received home healthcare, and this number will increase to 27 million by 2050.\(^4\) Along with professional caregivers, about 52 million informal and family caregivers provide care for others. Unpaid family caregivers likely will remain the largest long-term care provider group, reaching about 37 million caregivers by 2050.\(^3\)

Unpaid family caregivers likely will remain the largest long-term care provider group, reaching about 37 million caregivers by 2050.

Home healthcare will continue to grow as we are “sending people home sicker and quicker” to manage their health conditions, while “devices [are becoming] a frequent sight in the home” according to Mary Weick-Brady, U.S. Food and Drug Administration (FDA) senior policy advisor. Lay users are increasingly using devices that were not designed for use in nonclinical environments, and home-based medical procedures are becoming more complex, including dialysis and intravenous therapies.

Therefore, increased emphasis on development of safe and effective medical devices by applying accessibility and human factors considerations for a broad spectrum of users and environments is necessary to improve the overall quality and safety of home healthcare. Overall, observing FDA draft guidance for applying the human factors process to medical device and product design is a good starting point for creating safer and more effective devices for end users.\(^6,28\) There are numerous human factors methods, publications, and findings that also relate to the safe and effective design of home healthcare devices, however discussion of these resources is beyond the scope of this paper so they are not discussed here.

In recent years, more than 19,000 adverse events in home healthcare were reported to the FDA, which were attributed to challenges such as environmental hazards (e.g., power overload or failure), poor usability, and unsafe devices (e.g., insufficient labeling, complex displays, lack of easy-to-understand troubleshooting guidance).\(^9\)
With respect to accessibility, Molly Follette Story, FDA human factors and accessible medical technology specialist says, “FDA wants to know who’s using the device; and for human factors, we want to make sure that the people who are identified as being users can use the device safely and effectively. It relates to the match between the capabilities of the user, the knowledge of the user, and the demands of the device. As an agency, we can help make people aware of different user populations and the types of interface attributes that cause problems, ways to address those, and features that make interfaces easier and safer to use, and more accessible for more people. I really think if industry knew how simple this can be in some cases, they would do more to accommodate broader user populations.”

**Who Benefits From Accessibility?**

Accessibility is typically considered for people with diagnosed disabilities from conditions such as spinal cord injury or blindness. Older adults also benefit from accessible designs. However, when considering home healthcare devices and lay users, “disabilities” can exist due to environmental factors or other nonconventional user limitations.

Figure 1 compares two conceptual models for thinking about accessibility applied to home healthcare devices. Figure 1A represents more common thinking about users with diagnosed disabilities, such as older adults or users who are blind, being a minority user population for whom accessible design needs exist. Common thinking relegates people with disabilities to the lower end of the skewed normal distribution, and the majority of device users are nondisabled. Classic thinking suggests that accessible design is helpful for a limited number of users.

Figure 1B represents more realistic thinking about users with “disabilities” or functional limitations that can be caused by user or environmental limitations in home healthcare. Here, the normal distribution is shifted towards lower functional abilities. By considering nontraditional users and environmental limitations that emerge in home healthcare, it can be seen that a majority of users can benefit from accessible design in home healthcare. Examples of lay user abilities, disability diagnoses, and potential disabling factors in home healthcare that can present as functional

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**Table 1.** Examples of commonly diagnosed disabilities and nonconventional disabling factors experienced by lay users in home healthcare.

<table>
<thead>
<tr>
<th>Lay Users</th>
<th>Human Element</th>
<th>Examples of Disability Diagnosis</th>
<th>Examples of Nonconventional Disabling Factors</th>
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<tr>
<td>Perception: Hearing</td>
<td>Hard of hearing, Deafness</td>
<td>Television, HVAC systems, Construction, Children</td>
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<tr>
<td>Perception: Seeing</td>
<td>Cataracts, Glaucoma, Retinopathy</td>
<td>Dark room, Bright sunlight, No glasses (e.g., at night)</td>
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<tr>
<td>Cognition</td>
<td>Learning disabilities, Autism, Down Syndrome</td>
<td>Stress, Fatigue, Divided attention, Lack of medical education</td>
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<tr>
<td>Action: Manipulation</td>
<td>Neuropathy, Spinal cord injury, Arthritis</td>
<td>One handed use, Extended reach ranges, Tight spaces</td>
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Home healthcare users are diverse in age, backgrounds, and abilities, with 69% of the 12 million lay caregivers being 65 or older and likely experiencing their own functional limitations due to aging (e.g., decreased strength, vision and hearing loss). Many caregivers face non-healthcare-related life demands, such as being employed in addition to their caregiving roles. Lay caregivers are at increased risk for physical and mental health issues, especially with potential emotional impacts from learning about a diagnosis, navigating a care plan, and providing unsupervised healthcare with complex medical devices.

Some common emotional reactions include difficulty concentrating, memory loss, and decreased processing and problem-solving capabilities. Therefore, although users with severe functional limitations may not initially be intended to use devices independently, it is important to consider human factors that could cause physical, sensory, and cognitive limitations for users in home healthcare.

Some of the unique factors of home healthcare environments, such as diverse noise and lighting conditions of the outdoors or workplaces, can also cause users to experience “disabilities.” Weick-Brady explains that home healthcare devices include “devices in a nonclinical environment being used by someone who is not a healthcare professional.” Home healthcare environments are unpredictable compared to clinical settings, and lay users might not understand environmental risk factors, such as lighting, noise, or sterility and their potential negative impacts.

According to Story, “Environmental issues are something that manufacturers often don’t take into consideration as much as they should.” Therefore, it is important for manufacturers, healthcare providers, and patients to work together to better understand the risks and improve designs for home healthcare.

### Accessibility Resources

Accessibility literature relevant to medical device design can be referenced from different disciplines such as engineering, rehabilitation, and occupational therapy. Specific minimum accessibility guidelines and standards also exist, including a few targeted to medical device design and home healthcare. Forthcoming guidance is also likely due to FDA’s Home Healthcare Initiative, as well as the development of AAMI’s TIR49, *Design of training and instructional materials for medical devices used in non-clinical environments*. Some accessibility guidance relevant to home healthcare is provided in Table 2.

### General Considerations for Accessibility

Beyond applying human factors and accessibility methods to the design process, the following general accessibility considerations for home healthcare devices and lay users can help create safer and more accessible devices.

1. **Conduct evaluations with people with functional limitations**

Home healthcare devices are used by a diversity of users operating within highly variable environments. Therefore testing devices early and often with users with disabilities is beneficial for understanding potential lay user risk profiles. Because many user-environment-task interactions in home healthcare can closely mimic performance characteristics of people with disabilities, evaluating devices with these users helps drive design decisions to improve safety and use.

When recruiting participants, it is often acceptable to group people with similar functional limitations that might manifest from

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<tr>
<td>ANSI/AAMI HE75: Human factors engineering - Design of medical devices; Accessibility considerations &amp; Home healthcare sections</td>
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<td>ISO/IEC 29138-1, 29138-2, 29138-3: Accessibility considerations for people with disabilities</td>
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<td>IEC 60601-1-11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</td>
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*Table 2. Accessibility Guidance Document Examples*
different diagnoses, especially when trying to understand the diversity of potential risks that may exist for home healthcare devices. Disability experts can be useful for informing design teams about potential risks for people with disabilities, but should not replace the observation of people with disabilities interacting with devices.

Therefore, even if devices are not necessarily intended for users with disabilities, there is benefit in observing the alternative performance strategies of these users, talking to people with disabilities, and learning more about potential risks for users with impairments that could apply to other users, use scenarios, and environmental characteristics.

2. **Consider real users with comorbidities using assistive technologies**

Many lay users in home healthcare have coexisting functional limitations. For example, it is practical that someone who is aging with diabetes might have tremor, strength, and grasping difficulties from aging as well as retinopathy and neuropathy from diabetes. People with disabilities also frequently use assistive technologies to enhance their function such as eyeglasses, canes, and hearing aids, which should be considered as part of the lay user profile for home healthcare devices.

For example, devices intended to monitor people as they sleep could be tested in a darkened room while participants are not wearing glasses to better simulate a scenario of an alarm state occurring as a caregiver is awakened from sleep. Observing performance strategies developed by people with disabilities, such as assembling a device by someone with arthritis or tremor, can help manufacturers learn potential alternative task strategies utilized by users with functional limitations. This could ultimately lead to device designs with decreased task demands for all users. Testing scenarios and users with functional limitations can help manufacturers create safer designs for home healthcare.

3. **Consider the environment as disabling**

Homes and other informal healthcare settings represent incredibly diverse and complex environments. Lay users more often encounter devices well suited for professional users and inpatient settings, which become difficult to use outside of clinical settings. Ultimately, the unique nature and diversity of users and environments in home healthcare cause human factors challenges that need to be adequately addressed to improve patient and user safety.

For example, many home healthcare devices are used in relatively dark settings, especially in traditional homes as compared to clinical environments. In a formative analysis of a device with an LCD display used by emergency medical technician (EMT) workers under sunlight and spot lamp indoor lighting conditions, most participants commented that the display had poor readability and mentioned the importance of backlighting and high contrast for displays in the home. Understanding “worst case” environmental interactions in home healthcare can help improve product labeling, training, and device use to positively impact patient and user safety.

Testing scenarios and users with functional limitations can help manufacturers create safer designs for home healthcare.
characteristics. Therefore, designs that include adjustable features can benefit large proportions of home users and environments.

**Redundant formats for product labeling** are important for devices that depend on effective labeling, training, and practical troubleshooting tips. In home healthcare, product labeling could be the only mitigation available to end-users in times of need, for example when clinical facilities are closed or experienced device users are unavailable. Printed instructions for use could be supplemented with other labeling, such as web-based instructions for use or video-based troubleshooting tips. Redundant labeling formats help users with visual limitations who might not be able to read traditional printed text; users who cannot find printed documentation; users in different locations than their documentation; or users needing interactive guidance to understand device processes, such as calibration or repair.

**Performance-based user prompts** are important for home lay users who are often not medically trained. Therefore, informative user prompts can guide lay users through complex task sequences involving multiple steps. For example, accessible prompts on a display to help lay users discover and eliminate a line occlusion go beyond using readable fonts and simplified terminology, such as “blocked flow” instead of “line occlusion.”

More accessible designs need to provide meaningful alerts and performance-based prompting for action steps, such as “Check for blocked flow. Remove blockage and restart.” Otherwise, lay user confusion about seemingly common procedures could leave users unaware of critical steps required after an alert is acknowledged. Therefore, accessible alerts, alarms, and user prompts need to provide timely, detailed, understandable, and user performance-based information.

**Working Together**

According to Story, addressing home healthcare risks is “a shared responsibility among the agency, manufacturers and medical providers for the health and safety of the patient.” Weick-Brady explains that it includes “practitioners taking more responsibility for who their patient is, or demanding devices that are designed based on what their individual patients need. Patients need to be more demanding for products that are designed more for ease of use. And manufacturers need to be more attuned to whom they’re selling their devices to and knowing that their devices are probably going into the hands of somebody who is not a prescriber or not a healthcare professional.” Ultimately, accessible design can address the diversity of user and environmental characteristics that confound the complex risks associated with home healthcare devices, which will help to improve the health and safety of patients and lay users.

**Acknowledgements**

The authors thank Mary Weick-Brady, senior policy advisor at the Office of the Center Director, CDRH, FDA, and Molly Follette Story, human factors and accessible medical technology specialist, CDRH, FDA, for their Sept. 21, 2012 interview.

**References**


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SOURCE CODE: PB
As life expectancy increases and medical technologies become more advanced, medical devices are being used more often at home by lay users—individuals without formal medical training. Lay users might be patients or nonprofessional caregivers, such as relatives or friends, who operate a device on someone else’s behalf. When developing medical devices for lay users, it is important to evaluate users’ ability to interact with the device safely and effectively in the home environment.

Conducting home-based usability testing provides a unique opportunity to understand the home environment, and see firsthand how the environment affects lay users’ ability to use a device appropriately.

Conducting home-based usability testing provides a unique opportunity to achieve this goal, understand the home environment, and see firsthand how the environment affects the lay users’ ability to use a device appropriately. This article focuses on unique aspects of home-based testing rather than providing suggestions and input regarding conducting usability tests in general.

Home healthcare device usability tests can be conducted in various locations, including a usability lab, a conference room, a hotel suite, and of course, the patient’s home. Selecting the most appropriate test environment depends on the stage of device development and the test goals, as well as the importance of conducting testing in a controlled and consistent environment.

It is valuable to conduct formative (i.e., exploratory) testing in the home to gain as many insights as possible regarding the actual use environments and whether users are likely to comply with prescribed device use when at home. Home-based testing enables researchers to learn about a device’s portability and placement inside, and sometimes outside, of the home. For example, if testing a respiratory therapy system that must be used continuously, the moderator could ask the participant to demonstrate how s/he positions the system when commuting or grocery shopping. The moderator might also want to learn how the user positions and uses the system while sleeping.

However, it might be best to conduct a summative (i.e., validation) usability test—a test intended to validate device use-safety—in a more controlled environment, such as a usability lab or conference room set up to simulate the home environment. By testing in a controlled environment, the possibility of unexpected conditions and distractions that might arise in a home are removed, so tasks can be presented consistently and devices validated in a “cleaner” manner.

Notably, the controlled environment should still represent the home environment and consist of more than a table and two chairs in an otherwise empty room. The home can be simulated by introducing realistic distractions, setting up certain pieces of furniture (e.g., a refrigerator and kitchen table; or a bed, dresser, and nightstand), and setting lighting levels to simulate daytime and/or nocturnal use.

Conducting home-based usability testing provides a unique opportunity to understand the home environment, and see firsthand how the environment affects lay users’ ability to use a device appropriately.
It might seem antithetical to conduct a summative usability test in a controlled setting, given that the most realistic use environment for a home healthcare device is, after all, the home. However, because an effective (and successful) summative test is the capstone to any device development effort, the advantages and disadvantages of each potential test environment should be carefully considered prior to making a decision.

If the decision is made to conduct testing in the home, whether during device development or validation, consider these tips when planning the test, recruiting participants, and conducting the sessions.

**Planning the Usability Test**
When planning the usability test, decide first how long the usability test sessions should last, and whether participants will use the device during a single test session or over an extended period of time. Most usability tests involve a single test session that might last one to three hours. However, to understand longer-term device use, participants can be asked to use the device independently (i.e., without researchers present) for several days, making notes about particular device interactions in a paper- or web-based diary.

Extending testing over several days increases the likelihood that participants will interact with the device in different areas of their home and outside of the home. This extended usability test can be initiated by delivering the device to the participant’s home, introducing the device and research goals, and collecting the participant’s initial impressions of the device. After the participant uses the device independently as planned, the test can be concluded by having the participant perform specific tasks with the device and provide his/her summary impressions of the device (much as during a traditional usability test session).

Regardless of the usability test’s duration, it is safe to assume that participants will deviate from the test activities or tasks, or encounter unexpected distractions such as a phone call, a visitor, or children coming home from school. To account for the home environment’s unpredictability, allot considerably more time for home-based test sessions than would be needed for lab-based test sessions. Having additional time available will allow more flexibility without worrying that the unexpected distractions will hinder the ability to complete the planned activities within the allotted timeframe.

To help stay on track despite the distractions that might occur, develop a moderator’s guide with introductory scripts, task instructions, and interview questions. If the test involves children (defined by FDA as individuals age 12 and younger) and/or individuals with below-average literacy or education levels, take special care to develop simple and concise content that is easy to understand. You can design scripts and instructions for participants with the lowest expected literacy level, or create multiple versions of the scripts and instructions. Taking the latter approach, content could be tailored toward specific user groups’ literacy and education levels, recognizing that more literate and educated users might feel insulted by the use of over-simplified scripts and instructions.

Moreover, ensure the interview questions are appropriate for the selected participants. For example, during a summative usability test, it is typical to have participants rate the use-safety of each task, as well as the device overall. While most adults can think critically about the device’s safety and consider potential consequences of inappropriate or incorrect device use, children will be less capable of doing so. As such, it might be appropriate to leave judgments of device safety to adults.

**Recruiting Usability Test Participants**
In addition to identifying the test session duration and developing the moderator’s guide, test planning involves identifying appropriate test participant characteristics (e.g., age, education level, experience with similar devices, relevant impairments). Then comes recruiting—perhaps the most daunting aspect of conducting a home-based usability test. Thinking critically about how to access prospective participants is key.
Although posting online advertisements and printed flyers will facilitate recruitment of adolescents and adults, these strategies may be less effective when recruiting elderly individuals, who are often the target of fraudulent solicitation. Instead, consider recruiting elderly individuals by reaching out to trusted leaders, including directors of assisted and independent living centers and senior centers.

There are a few basic steps that can increase the likelihood that prospective participants are interested in, rather than intimidated by, the research opportunity:

- **Provide a one-page summary of the test session activities and research goals so individuals can discuss the opportunity with their families. Emphasize that the research is a product evaluation rather than a sales presentation or solicitation.**

- **Leave ample time for individuals to consider whether they want to participate in and host the usability test.**

- **Encourage individuals (and their relatives and/or caregivers) to call with any questions or concerns.**

When speaking with interested individuals, describe all planned activities in detail so the individuals understand and become comfortable with what you intend to do in their home. Explain how many people will attend the session, whether you will video record and/or take still photos, what activities you might ask the participant to perform, and where in the home you would like to conduct the session. Also, describe what materials or equipment, if any, you would like the participant to provide. For example, ask the participant to be prepared to show his/her blood sugar testing materials (e.g., glucose meter, test strips, sharps container). Providing this information in advance ensures participants don’t need to hunt for items of interest during the test session.

Although you might engage a third-party firm to recruit participants, the moderator or data recorder should call the participant a few days before the test session to introduce himself/herself and begin gaining the participant’s trust. When speaking with the participant, it’s best to refer to the research as a “product evaluation” or “interview.” The term “test,” although accurate, might intimidate the participant and increase his/her anxiety about the session.

**Conducting the Usability Test**

By the time you arrive at the participant’s home, you should be familiar with the usability test goals and activities and feel comfortable hosting the research. Even so, you should make the best effort to minimize the perception that you are intruding into the home. One way to accomplish this is to limit the number of people who attend the usability test session. For example, suggest that only one or two clients or stakeholders observe testing in real-time and join the researchers in the home.

Involving a two-person test team is ideal as it provides safety and security for the researchers and the participant, and enables the moderator...
to focus on leading the session while the data recorder documents observations and feedback.

Although you want to minimize the number of clients, stakeholders, and researchers present, you might invite the participant to have a relative or friend observe the test session, thereby providing an added degree of emotional support and reducing the likelihood that the participant feels vulnerable in the presence of strangers.

That said, it is good to clarify upfront that the goal is to understand the participant’s interactions with and opinions about the device. At the end of the session, invite the other person to share his/her perspectives and impressions of the device. Taking this approach ensures a focus on the participant while also respecting the participant’s relationship with the other person who might be present.

Some of the data collected during home-based usability testing will be identical to the data collected during lab-based usability testing. However, in addition to documenting the participant’s feedback and device interactions, you might want to document particular characteristics of the home environment, for example, take photos in areas of the home where the participant might use the device, and measure lighting and sound levels. Some homes will be cleaner, quieter, better lit, and more spacious than others (or, conversely, messier, noisier, darker, and more cramped).

Last but not least, as previously suggested, embrace unplanned distractions. Expect that participants might receive phone calls or visitors. Although you can ask participants to limit the duration of these events, it is valuable to see how a participant handles the device amid realistic distractions.

Conclusion
Conducting usability testing of home healthcare devices in lay users’ homes can yield special insights into users’ ability to interact with devices safely and effectively in the home. However, these insights might not come easily: You need to establish trust and rapport with test participants and put them at ease. It is also important to be flexible and “expect the unexpected.” Taking these steps and putting yourself in the right mindset will enable you to conduct effective home-based usability tests. The insights gained through formative testing will serve as important design inputs to help manufacturers develop safe and usable home healthcare devices. The data collected during summative testing will serve as strong evidence that the devices are safe and usable in the home, which, after all, is the ultimate goal.

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Visual Language Can Enhance Medical Device Labeling

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As many medical conditions that once required hospital care are now being managed in the home, the operation of complex medical devices is left to patients and caregivers who may not be medically trained. This situation is compounded by the fact that medical device labeling has traditionally been created with trained medical professionals as the intended audience.

As a result, in some instances, the instructions for use (IFU) and other labeling of a device are written at a higher health literacy level than that of the untrained users. The net result of this dynamic is that the labeling for any medical device that may be used outside of a clinical setting should be designed with due consideration for untrained users in the home healthcare environment.

One way of making medical device labeling more accessible and in step with the transition toward home healthcare is to incorporate visual language—a method to communicate information primarily using illustrations and graphics instead of words. It is a vocabulary comprised of thoroughly researched and meticulously created artwork that is meant to clearly represent an object, concept, or action. When effectively combined, these visual elements can communicate how to successfully complete a process, such as operate and maintain a home medical device.

Because visual language is text-independent, literacy levels and language barriers can be overcome. Integrating visual language into IFU and other labeling may also provide additional, significant benefits, such as an increase in user comprehension and a measurable reduction in confusion when instructions include visual language as opposed to text alone. Visual language also improves a user’s information retention level. It has been shown that “people identify the objects in visual communication line drawings as easily as the objects in photographs, and (further) that line drawings are superior to photographs in terms of making the information conveyed in the picture memorable.”*

Recently, the FDA has taken steps to utilize visual language in publications they are developing for the safe and effective use of specific medical devices. In the spring of 2012, the FDA executed a Cooperative Research and Development Agreement (CRADA) with a visual language publisher in Virginia to produce two or more visual language publications by mid-2014. The assertion behind the FDA-industry joint effort is clear: Visual language-based publications will allow the same guide to be accessible to a variety of users including healthcare professionals, home caregivers, patients, and the general public.

In summary, minimizing text and incorporating visual language into medical device labeling can make them operable by a broad spectrum of intended users. In addition, as the skill and training levels vary greatly among individuals using medical devices in the home, labeling with visual language provides great benefits to the less trained, in-home caregivers and medical device users. Finally, perhaps the most significant benefit of primarily utilizing visual language in medical device labeling is that it should reduce the number of adverse incidents and make medical devices safer for home use by all patients and caregivers.

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Guidance for Manufacturers

Designing Effective Home User Labeling

Patricia A. Patterson

The fastest growing segment in the medical device market is that of devices for the home or lay user—nonmedically trained professionals in nonclinical settings who want to exercise greater control over their home healthcare. However, their health and safety are at risk when device labeling, the step-by-step set of instructions that accompanies medical devices and combination products, is designed more for the professional or clinician than for the average home user.

Wording that may seem clear to the professional and the manufacturer, assuming that the latter has reviewed it in depth, may not be so easy for the end-user to understand—a point not lost on the U.S. Food and Drug Administration (FDA), which released in June 2011 the nonbinding draft guidance, “Applying Human Factors and Usability Engineering to Optimize Medical Device Design.”

This guidance provides recommendations to improve device usability to “reduce use error, injuries from medical devices and product recalls,” according to the agency,1 and is quite clear in its position that manufacturers must have “an accurate and complete understanding of how a device will be used.” In too many cases, however, manufacturers overlook the role of labeling and training for lay users, which may account for the increase of “adverse events” in device usage, which cannot just be laid at the feet of the lay user.

Such issues motivated the acceptance of human factors engineering (HFE) and its role in designing labeling. HFE may have been thought to apply only to the device, but it is just as essential to assessing effectiveness of the labeling in the hands of the lay user when interacting with the device or combination product. Manufacturers that fail to consider labeling testing because they assume user guides are adequate can be shocked when human factors validation studies determine their assumption is erroneous. It is an oversight likely to prove costly at many levels.

HE75 and Use Error

AAMI’s publication of the standard HE752 Human factors engineering—Design of medical devices, emphasizes the importance of HFE in applying best practices for medical devices. In the section on user documentation, the standard strongly recommends instructional and information design methods as well as testing to assure the lay user can read, understand, and most importantly, apply labeling information. In 2012, the FDA recognized HE75 and the increasing importance of HFE. The FDA considers labeling and training part of the user interface and is placing more emphasis on assessment of its effectiveness.

About the Author

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An important question to ask is whether device manufacturers understand how to apply human factors and instructional design methods in the design of labeling for the nonprofessional. “There are manufacturers that don’t put a priority on it and those who do,” says Mary Brady, chair of the AAMI Home Healthcare Initiative and a senior policy advisor with the FDA, “but for the most part, there seems to be minimal priority on home-user labeling comprehension and we’re finding that it is necessary as more devices move into the nonclinical environment.”

Brady adds that from her experience, the role of human factors, particularly from the physical and emotional perspective of the lay user, is generally overlooked: “How much can people remember if they are under emotional stress or are getting training just before leaving the hospital? They may not retain the information, and manufacturers do not take this under consideration because they are thinking about the clinical user.”

Brady notes that the home environment setting has to be prioritized as it differs significantly from clinical locations, where the only training probably takes place, which is why the FDA “is working on a guidance document for manufacturers to use to design and test devices pre-market for the home-use environment.”

Helping Manufacturers Design Effective Labeling

These issues continue despite the requirement for risk analysis and its application to labeling as a component of risk control. The FDA, which has been clear about the importance of risk mitigation, strongly recommends human factors testing in the labeling design process. The agency’s recognition of HE75 acknowledges that manufacturers cannot always claim that confusion rests with the perception of the home user and not with labeling.1

The FDA has occasionally raised issues on unclear labeling and its negative impact on the safe and effective use of devices. Labeling has to be validated as understood and must be effective prior to market introduction, which explains the need for testing the labeling. It is here that HFE moves to the forefront.

Daryle Gardner-Bonneau, a Michigan-based human factors specialist and president of the HFE consulting company Bonneau & Associ-
confused and ultimately lack the confidence or willingness to use the device because of inadequate training.

In another example, Brady notes that many devices contain an unusually large number of warnings that frighten elderly product users to the extent that they are wary of using the device. Citing one product with a user guide that listed 19 warnings, she notes that this excess “causes emotional turmoil; instead of asking how [they] can design this differently, they add another warning.”

“Designers must be aware of the sensory, cognitive and physical limitations of users of home care devices,” Gardner-Bonneau wrote recently. Her article evaluated a combined home vital signs monitoring and patient education software application through a human factors assessment, but her warning is equally applicable to all labeling design.

“You need to be designing training instructions in concert with the design of the device,” said the HFE specialist. “You may find that in the process of designing the instructions and training, you need to change the design of the device; if you don’t find that out until the device design is finished, it’s going to cost you a lot more to change it than it would if you found out early.”

The Importance of Process

Bridging the gap between device manufacturer and the home user falls on labeling designers. Because risk control is so critical to all parties, the process should include the following components:

• **Start with human factors engineering.** Good labeling starts with good HFE that focuses on usability and behavior. The FDA recognized its importance when Jeffrey Shuren, M.D., the agency’s director of the Center for Devices and Radiological Health (CDRH), announced the Home Use Initiative in 2010.

• **Develop a user profile and environment for use.** This is part and parcel of the FDA’s Home Use Initiative. The home environment is radically different from the controlled environment of a clinical facility where training with many devices usually occurs. Manufacturers need to recognize the influence of environment on device usage and develop user guides and their associated training accordingly.

• **Draft the labeling based on the HFE task and use error analysis.** The FDA emphasized the importance of the tasks and use error analysis in its 2011 draft human factors guidance. In essence, “analysts formally evaluate a device’s user interface against well-established interface design rules,” the document states. If the device user interface runs counter to one that is well established for similar devices, user guides should be revised accordingly and training should be required.

• **Assure the proficiency of those designing the labeling.** Historically, the responsibility for labeling rested with a marketing, systems engineering, or technical writer. While these three can certainly play an important role in producing effective labeling, they can lack the skills to describe human performance and translate that description into designing instructional materials intended to guide user performance.

• **Get lay users involved in the design and testing of the product early and often.** This may well be the best way to get the end user to clearly understand how to accurately and effectively use the medical device.

• **Test the effectiveness of labeling and training as a component of the user interface.** If labeling doesn’t support safe and accurate user performance, and risks associated with the device are significant, then it is not effective. “You need to test and it’s as simple as that,” Gardner-Bonneau says.

As is the case with the device, labeling and training have to focus on either eliminating or at least limiting risk to the user. Risk factors are likely to increase even if the barometer of validation is high scores in test groups. For example, if 80 percent of a group scores well in human factors testing, the FDA is still likely to frown on the results. Its concern will be focused on the remaining 20 percent, because it views them at a much greater risk due to insufficient clarity of labeling.

Better devices are designed with human factors in mind and the same should be true for labeling and training. Labeling cannot be placed on a back burner and relegated to those who have little or no understanding of instructional design or HFE and its role in analyzing user performance.
Labeling & Training

design, or HFE and its role in analyzing user performance. Effective labeling will never supersede the need for good device design. The goal in applying HFE to labeling design and testing is to increase and inspire confidence in lay users so that they are secure in their understanding of the proper and safe use of a device. This approach places the manufacturer on the same wavelength as the product user and is a vital step toward limiting risk to both.

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Caregiving is an inherently difficult role, replete with the emotional strains of watching a loved one deteriorate physically or mentally while trying to balance work and home responsibilities, and finding needed services with little or no guidance. These challenges are compounded by extreme stress, emotional overload, and a sense of isolation. Family caregiving is a lifespan issue, encompassing those with chronic conditions, disabilities, disease or the frailties of old age. Caregiving embraces a wide spectrum, ranging from the families of children with special needs to adult children caring for parents with Alzheimer’s disease.

Many family caregivers interact with medical devices in home settings.

Advances in medical technology have allowed care recipients to remain ambulatory and independent. Because care recipients expect to be able to stay independent, mobile or active, the term “home use” extends beyond the home to encompass all environments in which a person plans to use his or her medical device to continue or enhance the quality of daily life.1

For medical equipment designed for long-term use in the home, labeling will often not be with the device. In such cases, the home healthcare provider must develop his or her own basic instructions for use, maintenance, and cleaning. Through the MedWatch adverse event reporting system, the Food and Drug Administration (FDA) receives medical device reports of problems that stem from missing, absent or inadequate labeling, or misinterpretations of the information in labeling and instructions for use (IFU).

The FDA also receives anecdotal information from consumers, healthcare practitioners (HCPs), healthcare organizations and device manufacturers suggesting interest in enhancing medical device equipment labeling content and format. Consumers and HCPs are particularly interested in having a searchable website containing medical device labeling and instructions for products intended for home use.

This study was conducted to help the FDA better understand device labeling-related challenges that family caregivers face when care is provided in the home environment. Study respondents are members of the Caregiver Action Network (CAN), formerly the National Family Caregivers Association (NFCA), which educates, supports, empowers, and advocates for the more than 65 million Americans who care for loved ones with a chronic illness or disability or the frailties of old age,2 advocating for the needs of family caregivers, including their desires and need for instruction in the safe and effective use of medical devices in the home. These findings will assist in guiding the FDA’s future efforts to characterize information pertinent to medical device labeling and provide online access in order to facilitate safe medical device use at home.

The survey provided information on the content of medical device labels that respondents deemed important in devices used in the home, such as cleaning and troubleshooting information.
Methods
A web-based survey contained multiple choice questions with pre-coded responses offering CAN respondents the opportunity to provide free-text responses and comments. The questionnaires were developed collaboratively by CAN, FDA/CDRH, and contractor to the FDA Social and Scientific Systems (SSS). Questions for both methods were based around the following topics:
- Medical Conditions and Equipment Used
- Medical Equipment Training
- Information Provided in Instructions and Other Sources
- Instruction Use
- Instruction Preferences

The sensory, cognitive, and physical characteristics of each person will impact their understanding and use of a product.

The survey determined that the home medical equipment respondents most commonly used in the care of family members included wheelchairs, specialty hospital beds, blood glucose monitors, patient lifts, nebulizers, and assistive equipment, such as canes, walkers, and bathroom handrails.

Main Results

Demographics
One hundred twenty-seven respondents completed the web-based survey, a 22% response rate. Ninety-five percent of all respondents care for adult family members (over 21 years old). Forty-nine percent and 45% of these respondents care for a family member 65 years or over (n=63) or a family member between the ages 21-64 years (n=58), respectively.

Of these 127 respondents, 77% care for their family member in their own home (n=99) and 59% of all respondents have cared for their family member more than five years (n=76). Forty-four percent of all respondents care for their spouse/partner (n=56).

Medical Conditions and Equipment Used
The majority of respondents indicated that they have been using their medical equipment for two or more years for chronic conditions, including heart disease, lung disease, and diabetes, or conditions related to stroke and cancer. Free text responses also included conditions, such as dementia and Alzheimer’s disease.

The survey determined that the home medical equipment respondents most commonly used in the care of family members included wheelchairs, specialty hospital beds, blood glucose monitors, patient lifts, nebulizers, and assistive equipment, such as canes, walkers, and bathroom handrails. Survey questions allowed respondents to share their experiences using the aforementioned medical products, specifically their experiences with the labeling and instructions that accompany the products they use.
**Medical Equipment Training**

Respondents indicated that their medical equipment is most often delivered to their homes from the manufacturer or received from a pharmacy or drug store. From the free-text responses, respondents indicated that their equipment was handed down from friends or family after previous use. Respondents specified that it was ‘somewhat easy to very easy’ to learn how to use their medical equipment, and most received training prior to use. Equipment use training was most often provided from the medical supply company representative.

Other responses indicated that no training was received; or that training had been provided by the home health provider, rehabilitation staff, or hospital staff. Other methods besides training that helped respondents learn how to use their medical equipment included trial and error, following written (paper) instructions from the manufacturer, Internet instructions, verbal instruction, or observation and return demonstration.  

Respondents noted that the best time to receive written instructions was upon delivery of equipment at home and the worst time was at the hospital.

**Information Provided in Instructions and Other Sources**

When manufacturer instructions came with their medical equipment, respondents indicated that it was ‘somewhat easy’ to follow. Instructions were typically provided in a manual, booklet, or information sheet format. Respondents specify that the table of contents was most helpful in finding the information they need to use their equipment. When seeking information to troubleshoot their product, respondents believed they could ‘quickly and easily’ find the information in the manufacturer’s instructions.

In free-text responses, respondents indicated that they would make use of the 1-800 helpline, or ask a nurse or company representative when they need information about using their product in general or for information about troubleshooting. Free-text comments indicated that a DVD would be helpful for these purposes.

In addition to manufacturer’s instructions, respondents indicated that they obtained information from medical supply companies, home health agencies, and hospitals, in the same format as the manufacturer’s instructions.

Interestingly, even when manufacturer’s instructions are provided, information from additional sources is obtained in order to simplify and clarify the manufacturer’s instructions.

**Instruction Use**

Respondents did not always use the instructions, because they felt the training they received was enough. The survey results indicated that most respondents commonly used their instructions when they were first learning to use their equipment; until they felt comfortable using it; and for information about cleaning.

Respondents often referred back to their instructions when there was a problem, to find a phone number, or to refresh their memory and ensure they were using their equipment correctly. When respondents referred back to their instructions, they found what they needed to know. However, respondents specified that the information they needed was not always contained in the manufacturer’s instructions. Instead, this information could come from other sources, such as from friends.

Respondents who keep their instructions often file them with other medical information for as long as they own the equipment, which allows for easy access if needed. However, not all respondents have the instructions for their equipment. Whether this is because they never received it, or because they lost it requires further exploration.

Most instructions include pictures and diagrams; however, whether respondents find them helpful is unclear. Interestingly, free-text responses indicated that pictures, diagrams, and other visuals are indeed useful and suggest that these be included in the instructions.

Respondents report that the information they need to have to use their medical equipment, in the order of importance, includes the following:

- Cleaning information
- What the device is used for
- General operation and troubleshooting information
- Where to obtain replacement parts

*An educational technique in which someone demonstrates what he or she has just been taught, or had demonstrated to them.*
Storage information
• Emergency contact information
• Alarm information – what they mean
• Assembly information
• Battery information
• Calibration information
• Care and maintenance information

Instruction Preferences
Respondents indicate that they most prefer to find information via paper instructions, such as a manual, brochure, or quick-start guide affixed to the equipment itself. In addition, respondents will also seek information online and find it helpful to obtain instructional information by phone with a company representative or home health nurse. To that end, respondents commonly turn to these sources, in addition to seeking advice from friends or others with the same condition or equipment.

Respondents specify that a short version or quick-start guide would be helpful, especially if it includes the following:
• Basic information, such as set up and troubleshooting
• How-to instructions
• Cleaning instructions
• Do’s and Don’ts
• Step-by-step instructions
• Short descriptions
• Diagrams
• Laminated cards on equipment with basic information
• An 800-number helpline
• Checklists
• Large fonts

Sixty-five percent of all respondents are very comfortable with using computers (n=83), and 70% of respondents indicate they would welcome and make use of an FDA ‘searchable website that contained instructions for medical equipment used in the home’ (n=90). Respondents noted that if the FDA created a searchable website, it should include videos to supplement the written instructions, diagrams, and pictures, all of which should be easy to print, and parallel the instruction preferences discussed above.

Discussion
Individuals likely to use medical products in the home setting may be elderly, chronically ill patients of any age, pregnant women, high-risk infants, and rehabilitation patients. These individuals vary significantly in their ability to operate and maintain devices. Complex instructions with multiple steps could confuse the user’s ability to understand or adequately operate the device. To that end, instructions and information written in simple language should accompany any home use device product. Photographs, diagrams or other graphical representations may be used to provide clarity, as evidenced by respondent preferences.

Survey results about medical equipment training portray an interesting situation: More complex devices used in the home environment are designed to be used by trained healthcare professionals in an acute care facility, rather than in a nonclinical setting. Furthermore, care recipients may not be able to choose the devices that they will ultimately use, as the device may be pre-selected by their insurance, for example.

For these reasons, care recipients may not receive devices that are optimal for their comprehension level or that of a family caregiver. Therefore, it is imperative that home care recipients are properly trained on how to use their device as well as provided with instructional information that is readily accessible, easily understood and in a format that meets the users’ needs.

Limitations
While this study generated important feedback on medical device labeling and use instructions, not all respondents (n=127) answered every question. Toward the end of the survey, there was attrition, evidenced by the dwindling number of responses to all remaining questions. This is likely due to the fact that respondents were requested to answer questions related to three pieces of medical equipment, which, in hindsight, is a large time commitment. While the free-text responses presented respondents with an opportunity to elaborate on their responses, many free-text reactions include ‘gripes’ about the specific equipment(s) they use. Future studies like this one should consider responses of this nature during survey question development.

Social desirability respondent bias was also present in this study. When comparing responses to questions with pre-coded selections with responses to questions that offered...
free text, there was a tendency for respondents to select favorable pre-coded responses to downplay the difficulties they experience, especially with regard to learning, following instructions, and using medical equipment. The pre-coded responses do not always match free-text feedback, which many times express frustration and confusion with regard to following medical device labeling and instructions. Furthermore, many free-text responses indicate that respondents do not recall receiving or did not receive instructions upon receipt of their medical equipment, which may also skew the results.

Many study respondents are comfortable using computers, and often refer to information sources online and using a website that contains instructions for medical equipment used in the home. This finding, however, cannot be generalized to the entire population. Clearly there is selection bias at play: Respondents taking a web-based survey are likely to be more comfortable with computers, which could impact their ability to accurately respond to these questions.

Another limitation to this study is that CAN respondent educational levels were not captured, nor were they included as part of the selection criteria eligibility. Authors suggest that in future studies of this nature, a question to obtain respondents’ educational levels be included to determine whether there are relationships between education and labeling comprehension ease.

References

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Communicating information about the use of medical products, including medical devices, has become increasingly important. One of the most critical means employed by the U.S. Food and Drug Administration (FDA) and the device industry is medical device labeling. However, there is currently insufficient empirical evidence on how practitioners utilize and view labeling.1 In order to understand how or if healthcare practitioners use medical device labeling and to assess provider preferences for the content and format of labeling, we conducted two studies: a series of focus groups and a survey of healthcare providers.

Focus Groups
In 2011, we conducted a series of nine focus groups in three cities with a variety of different healthcare practitioners (n=77). Participants were asked if they were aware of or referred to medical device labeling, which sections and what information they believed were the most important in device labeling, and their level of satisfaction with existing labeling. We also requested participant feedback about possible changes to device labeling.

Results suggested that several sections of labeling are crucial in drawing provider attention and satisfying their needs. The most important sections identified by practitioners were instructions for use, warnings, precautions, contraindications, troubleshooting, and manufacturer's contact information (e.g., phone number for 24-hour technical support), along with the device name, serial number, and expiration date. Providers expressed a need for concise, clear and less technical language accompanied by a clear graphical depiction of the device. Respondents also generally wanted to have access to both short and long versions of the labeling. Figure 1 illustrates an example of the labeling we generated in response to focus group results.

Practitioner Survey
In 2012, we conducted a web-based survey of healthcare practitioners, including doctors and other prescribers, nurses, therapists, and technicians. Participants (n=411) were randomly assigned to comment on one of three sample versions of abbreviated (shortened) device labeling and asked to assess their usefulness. Data collection continued through fall 2012; data collected through October 19, 2012, was used for the present analysis. All of the versions reflected design suggestions from formative research and differed only in format and section ordering.

Results confirmed that the iterative design process was successful, as most respondents viewed the proposed labeling favorably, regardless of which version of the labeling they viewed. Approximately 82% of participants (335 of 410), across all versions, found the headings in the labeling they viewed to be “very easy” to understand. Approximately 90% of respondents (368 of 411), across all versions, were “satisfied” with the order in which the information was presented. We also found no significant differences between job categories in perceived ease in understanding the labeling headers (p > .05 for an ANOVA comparing prescribers, RNs and LPNs, and technicians and therapists).

In summary, these results suggest that practitioners want concise and informative labeling. Example labeling developed through this study shows promise in improving efforts to educate users about device safety and use.
Using Formal Methods to Improve Home-Use Medical Device Safety

Ayan Banerjee, Yi Zhang, Paul Jones, and Sandeep Gupta

Advances in technology give rise to increasingly robust and versatile home-use medical devices. Many of these devices are designed to monitor and interact with patients and their physiological systems to help maintain a particular level of health while permitting the patient to be mobile. Unfortunately, there is no well-established physics for human physiological systems and their coupling with medical devices. As a consequence, device designers have to resort to gathering empirical data in laboratory or other controlled environments to develop algorithms for approximating physiological systems. This can be expensive, incomplete, and fraught with inherent risks.

Academic research on hybrid automata shows the potential for precisely modeling both the computing aspects of home-use medical devices and their interaction with physiological systems using unified mathematical representations. Formal analysis and in-silico simulation can be performed on such representations. This makes possible a more comprehensive and complete assessment on the safety of these devices than traditional approaches.

In this paper, we examine the feasibility and advantages of applying hybrid automata to home-use medical devices, by constructing a non-linear hybrid automaton for a simple artificial pancreas (i.e., closed-loop insulin pump) model. This automaton formalizes the control logic of our artificial pancreas model as a finite state machine and specifies its interaction with the human glycemic system as differential equations. Our study shows that simulation using this automaton can expose potential design flaws in an artificial pancreas system.

Introduction

Advances in technology have enabled the development of novel home-use medical devices to meet society’s ever-growing demands for quality healthcare. Many of these devices are designed to work closely with patients by monitoring their physiological conditions to control and deliver appropriate therapy. This type of design, known as closed-loop control, not only facilitates early detection of adverse medical conditions, but also enables autonomous decision making for appropriate therapy.

Designs of home-use devices, especially those with closed-loop control, should guarantee: 1) accurate and timely monitoring of patients’ physiological condition(s), 2) correct prediction of patients’ needs for therapy, and 3) correct delivery of the predicted therapy. Many of these devices can be quite complex and present varying degrees of risk. It is important that such devices are safe and effective.

Unfortunately, there is no well-established physics for human physiological systems and their coupling with medical devices.
Assessing the safety of closed-loop home-use devices presents unique challenges. For example, it requires a profound understanding of the physics of human physiology, which is still being discovered. Moreover, the design of home-use devices must account for the patient’s rapidly changing environments and varied physiological needs (e.g., change in energy needs from walking to running). Current assessment methods rely on experimentation and testing. This is not sufficient, because it only assesses the device under a limited set of scenarios and in controlled environments.

The theory of Hybrid Automata (HA) provides a mathematical means of describing both the continuous and discrete dynamics of complex (closed-loop) control systems, such as those found increasingly in home-use devices. Having such a mathematical representation provides a useful tool for assessing safety properties of these devices, because it allows characterizing these devices, including their functioning mechanisms, discrete control operations, and interaction with patients, into a unified (mathematical) framework.

This facilitates automatic analysis, including in-silico simulation, which can be performed on HA models to help manufacturers detect design flaws and other safety issues in their devices early in the design phase. More importantly, such analysis enables a more comprehensive assessment of these designs, as compared to current practices, by facilitating the exploration of a much broader set of behaviors from these designs.

In this paper, we demonstrate the usefulness of HA in home-use medical device design by applying it to a relatively simple, yet generic, artificial pancreas (AP), i.e., closed-loop insulin infusion pump, design. This study aims to assess the safety of the control strategy underlying this design. We construct a non-linear HA model that includes interaction with patients. Time-bounded simulations were performed on this model. Simulation results revealed that this design might cause hypo/hyperglycemia in diabetic patients.

Artificial Pancreas Systems

AP devices are a good example of home-use devices with closed-loop control. Several novel AP (control) systems have been proposed and many are under clinical study. Most AP devices utilize one or more Continuous Glucose Monitor (CGM) sensors to constantly measure the patient’s Blood Glucose (BG) level. This provides a basis for determining the amount of insulin (in the single hormone systems) or insulin and glucagon (in the bi-hormonal systems) to be delivered. Current AP devices use a variety of controllers, including proportional-integral-derivative (PID) controllers, fuzzy logic controllers, and model predictive controllers.

In this paper, we consider a simple yet representative AP design (Figure 1) comprising:

- **An insulin pump.** This provides continuous (or near continuous) delivery of insulin.
  - Insulin delivered throughout the day to meet the patient’s variable background metabolic need is referred to as the basal insulin.
  - Insulin delivered to address meals (carbohydrate intake) is referred to as the pre-prandial bolus insulin.
- **A CGM sensor.** This continuously monitors the patient’s interstitial glucose level and reports it to a remote receiver via wireless communication.

![Figure 1. Example of an Artificial Pancreas System](image)

* This model was first proposed by Kovatchev et al. in 2009. The sole reason for using the AP model in our study is to show the potential use of HA in home-used medical device design verification. For recent advances in AP technology, see for example Patek et al., 2012.
• A remote computer-based controller. For example, the system receives interstitial glucose values from the CGM sensor, and the controller processes these values through a simple Kalman filter to predict the patient’s blood glucose in the near future if the current insulin delivery rate remains unchanged. If the predicted level exceeds programmed bounds (lower and upper), the controller instructs the pump to adjust insulin delivery rate accordingly.

More specifically, the controller uses a supervisory control algorithm to adjust insulin administration to keep the patient’s BG level within a pre-specified safe range. The control algorithm decomposes the operation of the insulin pump into three discrete modes:

1. Braking: This mode continuously adjusts the basal rate based on the level of risk implied by the projected BG level. The risk level, \( R(t) \), implied by a future BG level is calculated as follows: if the BG level after one hour, denoted as \( BG_{60min} \), >= 120 mg/dl, \( R(t) \) is set to 0; if \( BG_{60min} <= 20 \) mg/dl, \( R(t) \) is set to 100; otherwise, \( R(t) \) is calculated as a non-linear logarithmic function of \( BG_{60min} \). The basal rate is then reduced by a fraction proportional to \( R(t) \).

2. Meal Supervision: The system transitions into this mode if it is currently not in the Braking mode, and the patient is about to have a meal. Upon entering this mode, the control algorithm allows the patient to indicate the meal size (from three options), and then computes the dosage of insulin needed to compensate for the meal accordingly.

3. Correction Bolus: The system transitions into this mode only when all of the following conditions hold: 1) it has been more than two hours since the last meal bolus, 2) it is not currently in the Braking mode, 3) at least one hour has passed since the last correction bolus, and 4) \( BG_{60min} \) is predicted to be greater than 180 mg/dl. In this mode, a correction bolus is delivered to the patient, the size of which is calculated as a linear function of \( BG_{60min} \).

Modeling Artificial Pancreas with Hybrid Automata

Hybrid Automata (HA). An HA consists of a finite set of discrete states and transitions among them, where each state contains a set of variables and each transition is labeled with a condition on the variables (of the source state). Each state of a HA is also defined with a set of differential equations to govern the values of variables in it. If all differential equations in a HA are linear, i.e., taking the form of equation 1, this automaton is linear.

\[
\frac{dv}{dt} = Av + B \tag{1}
\]

Given an HA \( A \), each of its executions start from its initial state with a distinct initial condition, which defines the values of \( A \)'s variables at the beginning of the execution. As the execution proceeds, the differential equations in \( A \)'s current state are solved to update the values of all involved variables. These values are then used to evaluate the conditions labeled on transitions outgoing from \( A \)'s current state. If any of such conditions are satisfied, the automaton takes the transition and enters into its destination state. Notably, entering into a new state can cause a new set of differential equations to be solved in the future, reflecting the changes in system dynamics.

Modeling Patient Insulin-Glucose Reaction.

Formalizing the example AP design in Section 2 requires modeling the CGM sensor as well. However, if the focus is to evaluate the safety and correctness of the control strategy embedded in this design, then the engineering details of the CGM sensor can be replaced by a patient physiological model, such as the Bergman Minimal Model (BMM). 10

The BMM defines the interaction between insulin and the patient’s blood glucose (either stored internally or provided through meals) as a set of non-linear ordinary differential equations, as illustrated in Equation 2, where \( G(t), X(t), \) and \( I(t) \) are the patient’s BG level, and interstitial and plasma insulin concentration, respectively. In addition, in Equation 2, \( k_1, k_2, k_3, k_4, k_5, k_6, I_b, \) and \( G_b \) are patient-specific constants, derived either from empirical data or using diabetic patient simulators. 10

\[
\frac{dX(t)}{dt} = -k_1X(t) + k_2(I(t) - I_s) \\
\frac{dG(t)}{dt} = -X(t) \cdot G(t) + k_3(G_b - G(t)) \\
\frac{dI(t)}{dt} = -k_4I(t) + k_5(G(t) - k_6)t
\]

The example AP design also needs input from the patient to indicate the timing and size...
of meal intakes. We adopt a zero mean Gaussian random process to model the patient’s dietary behavior, where we assume the meal size, $w(t)$, can only take values from the set $\{0,2.5,3,5\}$, as a way to abstract potential meal sizes for the sake of simplicity.

Constructing an HA Model for Artificial Pancreas. The HA model constructed for the example AP design contains three discrete states, each corresponding to one of the aforementioned operational modes. An additional state is introduced to represent basal infusion. Figure 2 depicts the structure of the model, in which each state shares a same set of variables, including $X(t)$, $G(t)$, and $I(t)$. All these variables are governed by Equation 2.

This automaton always starts execution from the Basal Infusion state, and then transits to other states based on corresponding transition conditions: It transits to the Braking state when $BG_{60\text{min}}$ is predicted to be less than 120 mg/dl, and returns back if it becomes greater; the transition to the Meal Supervision state is triggered if a meal is taken ($w(t) > 0$), and the automaton exits from this state after two hours ($\pi > 120$ mins); the automaton starts a correction bolus if $BG_{60\text{min}}$ is greater than 180 mg/dl, and resumes the basal infusion one hour later.

Analyzing Hybrid Automata

In-silico HA models have been very useful in testing algorithms to ensure that they run appropriately and permit the investigator to test the range of parameters that the algorithm can handle. For example, simulating a HA model can reveal, to the extent permitted by simulation time and initial conditions, the presence of unsafe states. While in-silico models have allowed us to decrease the reliance on animal testing and allowed some decrease in developmental time, we have found that the algorithms generally have to be adjusted once testing with human subjects has begun. These models appear to be useful in the initial stages of system development but are not sufficient to test the range of dynamic changes and demands that are unique to each patient.† Therefore, the current models would not obviate the need for well-designed clinical studies to evaluate the final system.

We used the Breach package from the matrix laboratory (MATLAB) tool suite,11 to simulate the HA model presented in Section 3. Breach is a simulation and verification tool for analyzing dynamic systems with non-linear differential equations. Using Breach, we can establish desired safety boundaries and then see if the treatment boundary is exceeded. We used a generally acceptable lower boundary of 60 mg/dl§ and upper boundary of 250 mg/dl; recogniz-

While in-silico models have allowed us to decrease the reliance on animal testing and allowed some decrease in developmental time, we have found that the algorithms generally have to be adjusted once testing with human subjects has begun.

†This is especially true for type-1 diabetic patients as potential users of AP devices. These patients usually demonstrate great diversity in internal glycemic systems, reaction to insulin, and personal behavior patterns, which require treatment plans unique to each patient.

§60 – 70 mg/dl is a common lower bound for an average patient. We used 60 mg/dl for our research.
The time bound for the simulation was set as 10,000 seconds, and the initial states of the simulation were defined as $[X(t), G(t), I(t)] = \{[0, 0.1], [60, 180], [0, 100]\}$. Figure 3 illustrates the portion of state space explored during the simulation (shaded regions). As Figure 3 reveals, the model might lead diabetic patients into harmful situations such as hypoglycemia, because unsafe states (regions beyond the red threshold) were reached during the simulation.

Simulation on HA models can expose the presence of device design errors if appropriate simulation time and initial conditions are selected. Developers will still need to establish the cause(s) of these errors and make appropriate corrections.

It is possible to analyze HA models more comprehensively using mathematical-based verification techniques, such as those described in Alur, 2011. We chose simulation to analyze the HA model because of the nonlinearity of the model. Complex systems such as human physiological systems typically demonstrate certain nonlinearities, i.e., the system output is not directly proportional to the input. Thus, the HA models constructed for these systems are nonlinear (see Equation 2 for instance). Mechanical reasoning of these models requires finding closed-form solutions for their nonlinear differential equations, which is often computationally expensive, and sometimes impossible.

**Discussion**

This preliminary study applies the HA technique to a simple AP design. Many challenges, both technical and theoretical, have to be addressed when the HA technique is applied to real-world, complex devices. For example, to model realistic AP systems one has to consider noise factors and errors from CGM measurements, diffusion delay of insulin in subcutaneous tissues, and predictive models of human activities and physiology.

Failing to address these issues may result in significant discrepancies between a HA model and a real world system. The delta between model and real-world properties can be reduced but not eliminated through principled collaborations between designers and HA domain experts. Thus, system-level validation and clinical experimentation are still necessary to account for these facts.

A challenge limiting the applicability of HA models in closed-loop medical devices is the state space explosion phenomenon. For a complicated control system, its corresponding HA model can contain a large number of variables. Consequently, the state space of the model can be too large to handle. For example, the Kalman filter in Section 2 computes the predicted BG level as a linear function of previous BG values.

Modeling this predictor requires a large set of variables to store historic BG readings, because HA models are memory-less. One solution to this issue is to convert equations that imply a large state space into continuous differential equations. The tradeoff in this solution, however, is the potential discrepancy between the model and the “real world” system.

**Conclusions**

In this paper, we used a simple artificial pancreas design as an example to show that the hybrid-automata framework can be used to characterize and analyze the design of closed-loop devices. This work is only a first step in our effort toward using hybrid automata to assess and improve the safety of (home-use) closed-loop medical devices. Future work might include a) applying hybrid automata techniques to more complex AP models or b) investigating additional verification techniques, such as reachability analysis for hybrid automata models, which may enable a more comprehensive assessment of home use device safety.

**Acknowledgements**

The work of Ayan Banerjee and Dr. Sandeep K.S. Gupta was funded in part by NSF grants CNS-0831544 and IIS-1116385.

**References**


Avoiding Conflicting Requirements
Development of Home Healthcare Devices Through an Interdisciplinary Approach

Carolynn R. Johnson and R. Craig Campbell

Manufacturers of home healthcare devices face a daunting product requirements challenge. Whether developing a new product or transitioning one from the clinic into the home, developing products for home healthcare entails recognizing, understanding, and mitigating a vast number of differences between home and clinical healthcare paradigms—differences that often lead to consequences that cannot be taken lightly, such as conflicting or poorly defined requirements, particularly when not well understood by all stakeholders.

For marketing and product management, conflicting and poorly defined requirements often cause missteps and rework, resulting in longer development schedules. For human factors and design, conflicts risk the development of a device that accommodates technologies and costs, rather than supporting the user and the treatment goals of the device, resulting in a less usable product that may fail to achieve certification from regulatory bodies due to increased risk, and one that fares poorly in the market. For engineers, aggressive product cost, quality, and development schedule goals may be missed.

Compared to medical professionals, home users are likely to be less experienced and knowledgeable about their device, the medical condition it is intended to treat, and how it operates. They are likely to be lacking the general medical knowledge and experience that allows medical professionals to quickly train on a new device. They may be less inclined to use advanced features of interest to medical professionals, and be more interested in their own circumstances rather than the potential range of their medical condition.

Depending on the condition being treated and the expected user population, home users may be faced with cognitive, sensory, and physical impairments caused by aging or their condition. They are more emotionally invested in the treatment, thus may experience a greater amount of stress when dealing with off-normal conditions. These differences between professional and home environments necessitate the development of design requirements that mitigate such user issues.

Similarly, the home environment brings other differences: the need for portability; different sterilization practices and standards; and different resources, including support equipment, processes, and personnel that require implementations specific for home use. Differences that relate to the device itself must also be addressed through well-defined require-
Trade-offs and compromises between engineering, human factors and design, and product management requirements that attempt to address these paradigm differences are inherent, but there are also opportunities for innovative solutions. Technology can quickly change both what is possible and what is expected of a device. The ability to understand these issues and make the right decisions is the key to developing a successful product.

All approaches necessitate a thorough understanding of the market, user needs, use environment, technology, engineering, regulatory, human factors, training, support, cost, schedule, risk, and manufacturing issues that cannot be achieved through a siloed approach. An interdisciplinary team, following a structured approach and sharing common goals is the best path to success.

In any product development process, three functions represent the key roles necessary for successful product development. Marketing/product management must address the questions of what needs the product will address; who will buy it; what the market size and value are; what competing devices will be studied; what the lifecycle will be from sale to disposal; and which design, regulatory, manufacturing, training, support, and service schedules and costs will result in an attractive business model.

Human factors and design must be used to address the issues of who will use the product and how tasks will be accomplished; they must identify the use cases, and understand the use environments and what will be required from the user and the device to accomplish the intent. Design extends to outlining the form of the product requirements that meet these needs but does not necessarily extend to how the requirements are implemented.

Engineering must identify the technologies, components, and performance specifications that are required to meet the needs after they are defined, and how they can be implemented within the constraints of the business model, including assessments for cost, risk, and schedule. These functions may be filled by groups or individuals within the organization, or may be outsourced to subject experts and consultants.

An interdisciplinary, user-centered approach utilizing the principles and techniques of design thinking and design research results in the convergence of requirements. Design thinking is an inherently user-centered method of practical, creative identification and resolution of problems or issues. The better the team understands the user’s needs and desires, the more successful the final product will be in regulatory review, patient compliance, outcomes, and the market. This process includes exploring existing products and technologies, including those of other fields, and developing insight into how they can contribute to innovative—even disruptive—solutions.

The standard Medical devices – Application of usability engineering to medical devices (ANSI/AAMI/IEC 62366:2007, Annex D)1 details a user-centered design approach to ensure that medical devices, including those intended for home healthcare, are designed for usability and for the safety of the user. The process also emphasizes the need for user research to be conducted throughout the design cycle once the therapy has been validated by clinical research: from exploratory research conducted before any product development decisions are made, through validation of the design approach and verification of implementation, through post-market surveillance to mediate any undetected issues.

In effect, this argues for the involvement of the designer in all phases of the product development lifecycle: The designer is the steward of the user’s needs and desires, often either conducting the research that informs these decisions or being closely involved with those who do. To ensure that requirements address the needs of the user without overly constraining the implementation, engineers...
should also be involved throughout the design phases and be intimately aware of the research that informs the requirements. Product management should take an active part in design and user research to ensure that the product requirements represent the full, intended use market and do not become too narrow or uncompetitive.

It is the designer’s mission to understand the user population and scenarios of use defined by product management, converting them into requirements. It is the engineer’s charge to actualize design requirements based on those needs in a way that meshes with product business requirements set by product management. Often one camp sees the others as just not “getting it” – but the “it” differs; designers don’t “get” the myriad trade-offs and limitations inherent in the engineer’s world, and engineers don’t “get” those based on the user. Marketing does not understand why design and engineering are so slow and complex when the world is filled with impressive very low-cost, high-tech consumer products (that are not subject to long regulatory reviews and do not require the reliability and longevity of medical devices.)

Both designers and engineers feel pressured by overly aggressive schedules, features, and cost goals. This is often the result of organizations and individuals operating in silos, in which each function accomplishes the tasks assigned in isolation, resulting in a “throw-it-over-the-wall” transaction. An interdisciplinary effort utilizing design thinking principles and techniques brings designers, engineers and product managers together in such a way that each is privy to and understands the factors that drive the others.

For this approach to be effective, it is important for all involved to step away from the preconceived notions that they hold about the users, product, market, technology, engineering, software, regulatory, cost, schedule, and corporate history that inhibit innovation and creativity. By focusing on the shared goal of identifying and implementing the best (right) product, a team can more efficiently work together, streamlining development and regulatory reviews, especially when empowered with organizational commitment and appropriate decision-making authority.

One of the most effective means to accomplish the development of a shared goal is to ensure that product managers, engineers, and other stakeholders participate in user engagements early in the process. Too often, designers and human factors specialists are the only stakeholders actively engaged with the user. Obviously, it is the designer’s task to develop a keen understanding of the user, his goals, the obstacles that may lie ahead, and his needs and wants when accomplishing the application.

However, the results of this siloed approach are design requirements drafted during exploratory research that satisfy the user-side of design by offering solutions presented as take-it-or-leave-it requirements that do not match marketing’s vision and/or that prove difficult for engineering to actualize within the project constraints. Utilizing an interdisciplinary approach during this early user research phase helps to ensure a common understanding and enhances communication between the functions. The result is that requirements accurately distill the core needs of the user, without introducing unnecessary engineering constraints, and ensures requirements that mesh well with engineering implementations.

As an example of the conflict between the human factor and implementation, consider devices that include a graphic display. Lower margins, long battery life, and reduced interface complexity may lead the product management to desire the use of a smaller display, but if the product is intended for use by older patients with aging eyes the designer will likely suggest a larger display. Through the inclusion of an interdisciplinary team following a structured requirement development process, it is often possible to re-cast the conflicting requirements into an uncompromised solution. In this example, cost and battery life are on one side, with human factors and broad user population on the other. This conflict is the result of a complex set of assumptions involving the product features,

Often one camp sees the others as just not “getting it” – but the “it” differs; designers don’t “get” the myriad trade-offs and limitations inherent in the engineer’s world, and engineers don’t “get” those based on the user.

Utilizing an interdisciplinary approach during early user research phase helps to ensure a common understanding and enhances communication between the functions.
user interface, user demographics, intended use(s), competitive and market influences, technology, cost, schedule, risk, and complexity.

The purpose of an interdisciplinary design process is to avoid these hidden assumptions before dealing with the more fundamental elements of the requirements. This opens the solution up to the appropriate mix of approaches and technologies that are available and understood by the interdisciplinary team, including disruptive solutions. The answer is not to compromise on the size of a display, but to understand the intended use application, user population, use environment, available technologies, costs, engineering risks and complexity, and regulatory requirements to develop the right product requirements.

In the case of screen size, important options for discussion might include improved information presentation, fixed labels versus dynamic screen content, buttons versus touch screen, pre-set versus configurable settings, daylight readability and backlight brightness, monochrome versus color, dedicated function indicators, and user needs versus support and service needs. Once these issues are exposed, engineering and technology can be added to the discussion to cover the cost, complexity, risk, performance, support, service, and product life impacts of the various solutions.

In this process, screen size is simply not a requirement worthy of discussion until the underlying requirements for functions, readability, fixed versus dynamic content, and use environment have been resolved. Technology options like wireless connectivity to smart devices or to remote monitoring, service, and support capabilities can be added to the team discussion, where the common goal and interdisciplinary expertise leads to efficient and innovative decisions.

Once this has been done, the size, type, sourcing, and cost of the screen options, if one is needed, can be resolved based on business and market inputs without compromising function, as long as the display meets the underlying requirements. As engineering proceeds with implementation, the detailed understanding of the users, scenarios of use, and motivations that resulted in the requirements informs the detailed engineering decisions, minimizing the risk that the device will have verification problems.

As another example of the need for the requirements of the user meshing well with the engineer’s implementation, consider the common push from product management to include the latest technology in a device. An interdisciplinary approach enables design and human factors or engineering to convey the risk of doing so. A multi-touch interface utilizing complex gestures, though appealing from a marketing perspective, may be inappropriate for user populations not accustomed to their use or for users with physical limitations, such as diabetic neuropathy, that inhibit their use. Conversational voice-driven interactions, though leading to impressive demonstrations, require high processing capabilities and still prove too frustrating for broad use.

The challenges of developing the right set of requirements for a home healthcare device are significant and require techniques that address engineering, regulatory, and business concerns, while designing for the needs of the broader and more diverse user population and environments in home care. While the high level processes and procedures are similar to those already utilized by many manufacturers of medical devices, the interdisciplinary team approach advocated here and the techniques required to make it effective and efficient are new to most development teams. The time and effort needed to implement such an approach are negligible when compared to the cost of false starts, rework, and product failures that otherwise result when conflicting requirements fail to articulate the fundamental needs of the users, the environment, and the application.

Reference
Improving Patient Safety and Essential Device Performance

International Standards for Home Respiratory Care Equipment

Debra R. Milamed, Hubertus Lasthaus, and John Hedley-Whyte


Publication of IEC Collateral Standard 60601-1-11 on home healthcare environment followed in June 2010,1,2 with recognition in the Official Journal of the European Union as of Jan. 18, 2011.3 This International Standard is also used to demonstrate the presumption of conformity with the Essential Requirements in the framework of the European Medical Device Directive, the precondition to enter the European market. Subsequently, the leadership of ISO/TC121/SC3 reviewed its Work Programme to identify respiratory care devices commonly used in the home. Existing standards covering those devices were also identified (Table 1).

Emergency power supply needs, increased fire risks during oxygen therapy, alarms systems management, and alarm signal transmission to remote places within the domiciliary environment are essential considerations.

Establishment of a New Joint Working Group

In April 2011, a project team of ISO/TC121/SC3 met at the British Standards Institution (BSI), London, to begin revision of ISO 18779:2005, Medical Devices for Conserving Oxygen and Oxygen Mixtures—Particular Requirements (Table 1). By October 2011, a committee draft had been circulated for comment as part of a new work item proposal—the new JWG’s first work item. JWG12 held its first official meeting in Lübeck, Germany, Oct. 24-28, 2011, where the first dual logo (IEC/ISO) Draft International Standard was completed for oxygen-conserving devices, as well as Working Drafts for revised standards on oxygen concentrators and sleep apnea therapy devices. The JWG is now addressing the remaining devices within its remit, shown in Table 2.

Challenges of Respiratory Care In the Home Environment

JWG12’s standards must address challenges specific to home respiratory care.4,5 Emergency power supply needs, increased fire risks during oxygen therapy, alarms systems management, and alarm signal transmission to remote places within the domiciliary environment are essential

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*Photo: University of New South Wales and Teaching Hospitals, Department of Medical Illustration, Ref. no. 35887
**Design Considerations**

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<th>Published International Standard</th>
<th>Revision</th>
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</tr>
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</table>

**Table 1. International Standards for Respiratory Care Devices used in the Home Healthcare Environment**

---

**Home use devices should be labeled to indicate that they are safe for use with emergency generators.**

Considerations. Recording and transmission of ventilatory, monitoring, and technical data, cleaning and disinfection, environmental issues, pediatric applications, instructions for use, patient and caregiver training, allocation of responsibilities, and the usability requirements specific to home-care patients and their environment must be addressed. JWG12 must study both typical and extreme environmental conditions, as well as deployment of these devices in less-resourced settings. In the U.S., the American Thoracic Society has outlined respiratory disorders that may require care in the home environment. In addition, the Joint Commission has issued National Patient Safety Goals for its Home Care Accreditation Program, but aspects of this setting remain unregulated. In other jurisdictions, clinician societies have developed guidelines for home-based respiratory care, which serve as an important resource for JWG 12.

**Increased Fire Risks During Oxygen Therapy**

In the home environment, prevailing safety codes are poorly enforced. The 2013 Joint Commission Patient Safety Goals Home Accreditation Program ‘National Patient Safety Goals’ provides for “identification of safety risks associated with home oxygen therapy such as home fires.”

A requirement for a kind of thermal fuse, located as close as possible to the patient’s interrupted residential electrical service for days or weeks and can do it again. Home use devices should be labeled to indicate that they are safe for use with emergency generators.

In clause 8.4, IEC 60601-1-11 specifies general requirements for home-care safety and performance during interruption of the power supply. The application of these requirements varies according to device type. The risk to life when the power supply for a ventilator-dependent patient is interrupted exceeds the risk to a patient using a sleep apnea therapy device. This device only assists the patient’s breathing and is designed to allow resumption of spontaneous breathing during power failure.

**Interruption of Power Supply**

While healthcare facilities are equipped with emergency generators, natural events, such as hurricanes, ice storms and earthquakes have
Design Considerations

application accessory (e.g., the nasal cannula) is specific to oxygen concentrators. Early in 2012, the German mirror group to JWG12 proposed immediate implementation of this safety feature as a fast-track amendment to ISO 8359:1996, Oxygen Concentrators. This amendment was accepted internationally.

Alarms Management

Remote alarm systems provide transmission of the alarm signals to a caregiver’s location, such as in another part of the house, and this important issue is addressed in clause 13.1 of IEC 60601-1-11. IEC 60601-1-8:2006 (with its 2012 amendment) on Medical Alarm Signals constitutes a “collateral standard,” i.e. an International Standard with broad applicability to many specific types of electromedical equipment.

We have previously noted that a distributed alarm system is an alarm system involving more than one item of equipment, the signals of which may be transmitted to one or more remote locations, such as central monitoring stations. These distributed alarm systems should address prevention or mitigation of adverse events caused by “caregiver fatigue, defect in alarm signal generation or transmission, and other alarm system failures.”

Recording and Transmission of Electronic Data in the Home Healthcare Environment

This feature applies to ISO IEC 80601-2-72, Medical electrical equipment—Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients. We have previously noted that a distributed alarm system is an alarm system involving more than one item of equipment, the signals of which may be transmitted to one or more remote locations, such as central monitoring stations. These distributed alarm systems should address prevention or mitigation of adverse events caused by “caregiver fatigue, defect in alarm signal generation or transmission, and other alarm system failures.”

### Table 2. JWG12 Progress to Date: IEC ISO Dual Logo Standards for Respiratory Care Devices Used in the Home Healthcare Environment

<table>
<thead>
<tr>
<th>Work Item</th>
<th>Scope</th>
<th>Highlights of Proposed Revision of ISO Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO IEC 80601-2-67, Medical electrical equipment—Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment</td>
<td>Medical electrical equipment used in combination with its accessories for conserving oxygen by delivering supplemental oxygen intermittently and synchronized to the patient’s inspiratory flow, when used in the home healthcare environment</td>
<td>• Extension of scope to include not only conserving equipment but its accessories • Identification of essential performance for conserving equipment and its accessories • Requirements for fire prevention • Addition of tests for oxygen delivery performance • Tests for cleaning and disinfection procedures • Consideration of contamination of breathing gas from the gas pathways</td>
</tr>
<tr>
<td>ISO IEC 80601-2-69, Medical electrical equipment—Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment</td>
<td>Oxygen concentrator in combination with its accessories, intended to increase oxygen concentration in gas for delivery to a single patient; May include devices suitable for transportable use; May be used in professional healthcare facilities; Does not include requirements for oxygen concentrators for use with a medical gas pipeline system (see ISO 10083)</td>
<td>• Extension of scope to include not only the oxygen concentrator but its accessories • Identification of essential performance for an oxygen concentrator and its accessories • Requirements for fire prevention • Addition of tests for oxygen delivery performance • Tests for cleaning and disinfection procedures • Consideration of contamination of breathing gas from the gas pathways</td>
</tr>
<tr>
<td>ISO IEC 80601-2-70: Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment</td>
<td>Sleep apnoea breathing therapy equipment and accessories Excludes devices intended for neonates</td>
<td>• Rationale for non-applicability of Essential Performance requirements • Tests for therapy performance</td>
</tr>
<tr>
<td>ISO IEC 80601-2-72: Medical electrical equipment—Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients</td>
<td>Home care ventilators for ventilator-dependent patients</td>
<td>• Extension of scope to include not only the ventilator but its accessories • Identification of essential performance for a ventilator and its accessories • Requirements for connection to electronic health record, distributed alarm system, remote control • Modification of the obstruction of the expiratory limb alarm condition requirement • Tests for cleaning and disinfection procedures • Consideration of contamination of breathing gas from the gas pathways</td>
</tr>
</tbody>
</table>
The new International Standard will require “means to indicate visually, either automatically or by operator action, the cumulative hours of operation of the ventilator,” as well as “means to indicate visually the time until the next recommended preventive maintenance” (clause 201.105). Clause 201.106.2 will provide that the ventilator “should be equipped with a signal input/output part that permits data transmission from the ventilator to an electronic health record.” This data transmission will benefit both the patient’s family and the supervising authority.

Pediatric Considerations
The pediatric use of home care ventilation was pioneered in the 1980s on the foundations of earlier in-hospital programs such as that of the Children’s Hospital of Philadelphia.18 A recent study found that 4% of oxygen prescribed for home use in England and Wales was intended for pediatric use,19 and a Canadian study reports that 10% of participants in home ventilation programs are children.20

Documentation and Instructions for Use
Clause 201.7.9.2 of IEC 60601-1:2005 (known as “The General Standard”) and its amendments21 address instructions for use. Particular standards cite exceptions and additions for each type of device.

Patient and Caregiver Training
The requirements of IEC 62366:2007,22 Clause 7, Training are essential for both the lay operator of a home respiratory care device and the designated representative of the responsible organization. Consequently, training on the specific device is required for the safe and effective use by the intended user. The manufacturer must provide materials needed for training or ensure the availability of such materials, or provide the actual training. The documents accompanying the devices must include a detailed description of the training provided, and the training systems must be designed for the typical user.

Allocation of Responsibilities
The work program of JWG12 is an international one, and regulatory environments differ widely between jurisdictions. Therefore, these International Standards provide informative guidance.

Usability Requirements for Home Care
JWG12 includes as clause 206 in each Particular Standard the requirement that Collateral Standard IEC 60601-1-6:2010 and Amendment 1, Medical Electrical Equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral Standard: Usability23 applies, with specific exceptions or additions.

JWG 12 realizes that most of the instructions for use for medical devices, including the warnings contained therein, are never read. So devices intended to be used in the home must be designed as intrinsically safe. These considerations will strongly influence the revisions of all the standards in JWG12’s remit.

Additional Requirements of IEC 60601-1-11:2010, Collateral Standard
IEC62A-ISO/TC121/SC3/JWG 6 expressed their agreement on the importance of proper cleaning and disinfection of equipment, documentation and instructions for use, electromagnetic compatibility, and other areas. Therefore, clause 211 of particular standards specifies that IEC 60601-1-1124 applies. Differences for specific devices are cited as exceptions, or as additional subclauses.

Future Directions
ISO/TC121 on Anaesthetic and Respiratory Equipment, resolved* to support the efforts of its subcommittees and JWG12 to “reduce the risk of long-term oxygen therapy (LTOT) related fires through appropriate means, improvements in clinician training, patient education and accurate reporting of LTOT-related fires to the appropriate authorities.” At its meeting in St. Denis, Aug. 27-31, 2012, JWG12 experts suggested tracking fires and other adverse events to document the effectiveness of retrofit measures.

We have previously described the range of levels of supervision for electromedical device use in the home, and the challenges of user and caregiver education. The best documentation is only useful if it is comprehensible to its intended readership. JWG 12’s new editions will emphasize this consideration.

At future meetings, JWG12 will apply the standards-writing fundamentals we have outlined above with the overall goal of increased safety, reliability, accountability, information management, and improved quality of life for patients in the home healthcare environment.

The reference to IEC 62366:2007, Ed.1: Medical devices—Application of usability engineering to medical devices,23 will also play an important role in this context.

Less-Resourced Settings
The World Health Organization (WHO) has addressed the limited supply of medical oxygen for use in less-resourced areas and pointed out the difficulties in documenting such shortages.24,25 While it has been suggested that the use of oxygen concentrators can improve outcomes in hospitalized patients,26 the importance of a reliable power supply must be emphasized for all electromedical devices used in the home healthcare environment.26,27 Of equal importance are quality of maintenance, education, and training for both healthcare facilities and the home.26,27

*ISO/TC121 Resolution 121 (Kyoto 2012) 9, 11 and 15 June 2012 (ISO/TC121/N1014)
References


U.S. HOME HEALTHCARE DEVICE STANDARDS

Jennifer Moyer

About the Author
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In addition to the international standards listed in Table 2 of the preceding article, ISO IEC 80601-2-67, 80601-2-69, 80601-2-70, and 80601-2-72, AAMI has the following standards publications related to home healthcare:


IEC 60601-1-11, 1st edition, specifies basic safety and essential performance of medical electrical equipment and systems that are intended by the manufacturer for use in the home healthcare environment. The United States adopted the IEC standard as ANSI/AAMI HA60601-1-11 in 2011 with national deviations. The primary differences are the removal of elder care facilities as a home environment; the modification of certain compliance statements to include inspection of the usability engineering file; and the inclusion of the consideration of the abilities of the lay operator. In addition, some modifications were made to the wording to improve clarity.


HE75 is a general human-factors oriented medical device design standard that contains a chapter on home healthcare outlining what needs to be considered when designing a device that is intended for use in a nonclinical setting by a variety of users.

AAMI/TIR49, Design of training and instructional materials for medical devices used in nonclinical environments.

This technical information report and guidance document, which is under development and nearing completion, applies human factors principles and processes throughout the design and development of training and instructional materials for medical devices, in addition to that of the medical device itself, will enhance the user’s and the patient’s safety.
You have the unique perspective of having worked as an HTM professional in the hospital as well as nonclinical environments. Tell us a little about your background and work history.

I got my start in the U.S. Navy, and spent 20 years as a hospital corpsman, which meant I received my medical training at the U.S. Navy’s Hospital Corps School, and my medical repair training at the US Army’s medical repair school, since the Navy does not have its own medical repair school. At first I worked in a Navy hospital in the states, then on to a Marine field unit, a hospital overseas, another hospital stateside, a nuclear aircraft carrier for three years, and I retired from the Naval Hospital in Portsmouth, Virginia in 2001. Since I left active duty, I have worked in two civilian hospitals for five years, followed by a home care company with a very comprehensive home medical equipment inventory for five years, and have spent the last two years at a university research foundation. So I have experience in both clinical and nonclinical environments.

What was your job as a Navy hospital corpsman like?

The duties of a BMET on an aircraft carrier are the same as those in a hospital, but with a few differences. On the carrier, there was a heavier emphasis on operational readiness with a lot more inspections of all sorts as well, but the experience was very rewarding! It was not just taking care of medical and dental equipment on a carrier at sea, but for the eight-ship carrier battle group as well.

One of the most interesting periods was between August 1990 and March 1991. During the First Gulf War, I fixed medical equipment in the desert: A unique experience, because you are isolated and you have to prepare for medical casualties and know what resources are available to you, and how to make the most of what is available—that was quite a challenge.

It was a war effort. You didn’t know what type of casualties and how many you would get, and had to find out what basic equipment you needed for each specific mission or activity. The first thing to think about was the activity, which would then direct the equipment you would need, which would then drive the next step of readiness. Because you have to be prepared for anything, an HTM professional on the battlefield has to have a good operating knowledge of all equipment, old and new!

Because you have to be prepared for anything, an HTM professional on the battlefield has to have a good operating knowledge of all equipment, old and new!

How did your duties in the three different environments—aircraft carrier, homes, and hospital—compare?

Many times, a BMET has to help the operator learn the “knobology” of a different model of medical equipment.
equipment in the field, unlike in a hospital. For example, in hospitals, it is almost routine for the sterilization department technician, without thinking about it, to operate a sterilizer. Now transfer the entire activity to the desert, where the sterilizer being used may not be state-of-the-art. If it isn't working as the operator expects, you have to know and understand the equipment better than the operator and teach that person the features and controls—which is very different from what it is used for. It comes back to understanding the activity the equipment will be used for.

There are many differences between the hospital and the home environment. Hospitals tend to have big purchasing budgets and buy things in bulk from the same manufacturer. In the home environment the buying power is lower, but the amount of choice is higher, and what the insurance company will pay for drives what the patient will receive. The patient, prescribing healthcare practitioner, and the insurance company drive the ball in home healthcare, more so that in the hospital, and this is completely different to another nonclinical environment, such as an aircraft carrier or the desert.

A BMET’s job in home healthcare is fundamentally different from that in either hospitals or say on a navy ship, because of the financial chain of events that occurs in home healthcare.

For patients in the home, insurance pays for some things, but not for others, and the bottom line is who is going to pay. An HTM technician in a hospital never faces that question as they are about to repair a device: Is this reimbursable or whom is paying? You know the rest of the field is not dealing with this payment issue.

The financial side drives the survivability of either the company, supplier, or whoever is providing the service to the home patient. About 90% of the time this is a stand-alone home medical equipment (HME) company that is not affiliated with a hospital; increasingly, hospitals are creating their own HME companies. The saying “time is money” is highly relevant for an HTM professional in a home care environment. When you get a request for service, whether it is training a patient or repairing equipment, the first question is: Am I or the company going to be reimbursed for this service?

What are some examples of how insurance companies and the reimbursement system affect equipment maintenance and repair?

The best example is what is known as the “golden commode.” After surgery, a person may have trouble or may not be able to get in and out of the bathroom in their home. In this situation, their healthcare practitioner will write a prescription for a commode that can be used at the bedside and can also be put in place over the bathroom toilet to give them a higher seat with armrests to assist with sitting and standing. Keep in mind, a patient may need this device for the rest of their lifetime.

The “golden commode” refers to the era during the 1970s and early 1980s, when HME suppliers could rent a device to a patient and keep billing Medicare monthly for that item indefinitely. This practice allowed HME suppliers to be overpaid for simple pieces of hardware such as the bedside commode, hence the name “golden commode.” The federal government has strengthened its regulatory controls on Medicare HME expenditures with legislation such as the 13-Month Rental Cap (13MRC) rule. The monthly rental rate is determined by dividing Medicare’s total reimbursement amount for the device or service supplied by 13.

HME suppliers used to be able to bill insurance companies a monthly rental rate for this item indefinitely and collect payments that far exceeded the device’s value. With the 13MRC in place, the patient now owns the device after 13 months. Also, during the 13MRC period and through the warranty period, the HME supplier is responsible for the maintenance and repair of the device. Responsibility for maintenance and repair transfers to the patient after the 13 MRC.

You have to have complete understanding of the reimbursement system, as well as different insurance companies and policies if you repair home equipment.
allow batteries to be replaced every 6 months, while others may only allow batteries to be replaced once a year. If the technician replaces the batteries without the right paperwork, insurance may not reimburse the cost and the patient or the HME company ends up footing the bill. In many cases, the company asks the patient to pay the cost. For retirees on fixed income or burdened with medical bills, battery replacement costing hundreds of dollars might be a lot to ask.

The other thing to understand is the role of the doctor in the process. The doctor and the prescription they write are mandatory. Nothing in the home care arena is going to be approved without the doctor’s prescription, and in many cases a certificate or letter of medical need (CMN/LMN)—even for batteries—is needed. If the doctor writes that new batteries are needed because the wheelchair is medically necessary for this patient, insurance will most likely cover the cost.

In many cases, the technician is the hub. I talk to the patient and tell them to call their doctor, insurance company, and case manager at their insurance company if they have one assigned to them. The best option is a family member in charge, as there are many patients who cannot manage everything that has to be done. Once the technician figures out what needs to be done, he or she can move forward with requesting authorization from the insurance company for the repair.

**What type of equipment is typically serviced in a home environment? Is equipment becoming increasingly complex?**

You see the whole spectrum of equipment: from a manual blood pressure cuff to the merging of IT world in the home—mainly telehealth, in which people talk to their doctor over their computer video. There are increasing numbers of ventilators: It is more cost effective to move long-term ventilator patients home than to keep them in the hospital.

So—as this is one similarity with work as a Navy BMET—in home healthcare, you have to know about state of the art equipment, as well as a wide range of other equipment. Currently, HTM professionals working in the home environment do not have a structured or credentialed electronics technology-based training requirement—no trade school, college, or university has a HME program or curriculum. However, there is complex medical equipment in the home care environment, but staff level of knowledge is usually lower than that in a hospital, resulting in an increased level of risk to the patient.
biomedical equipment repair training programs and curriculums can be found in both civilian and military schools. Also, salaries are higher in the hospital. It is a paradox: There is complex medical equipment in the home care environment, but staff level of knowledge is usually lower than that in a hospital, resulting in an increased level of risk to the patient.

The difference in training is at a base level; a formally trained BMET has been introduced to and has a better understanding of electrical and electronic theory. An HME Technician with a sound understanding of electrical and electronic theory is not the norm. There is also very little regulation/guidance for equipment outside the home—it would be good to have clinical or biomedical engineers and BMETs guiding decisions at the Centers for Medicare and Medicaid (CMS).

Is there a degree of unpredictability involved in home healthcare?

Oh yes. There are many things out of the HTM professional’s control. Electrical condition for example: Newer technology mostly uses three-prong and polarized power cord plugs, but many older or historic homes have two-pronged outlets. Some equipment needs to be electrically grounded to work properly and be deemed electrically safe. So before a doctor “releases” a ventilator to a patient home, he or she will require the HME supplier to perform a home assessment. However, due to staff level of knowledge, the home assessment is not done to required situational detail in some instances.

Connectivity is also unpredictable. In hospitals we can talk to the manufacturer’s tech support. In home care, we sometimes go to rural and remote areas. I once had to go out into the middle of a field to get cell phone tower reception to contact a manufacturer. In the city, of course, people take wireless for granted, and have iPads, BlackBerrys, and other gadgets. So many resources that come into play that are taken for granted in a hospital.

I once had to go out into the middle of a field to get cell phone tower reception to contact a manufacturer.

Such as removing equipment from service or picking it up. When someone passes away, the home medical equipment company is called to pick up the deceased patient’s equipment. There may be a body, there is grieving, and you have to be very mindful and sensitive that you are in someone else’s home, working in a highly emotional environment and still have to disassemble equipment and get paperwork signed. The HME technician has to have above average soft skills.

Although this is a very rewarding job, one can get into some difficult situations. Some home healthcare providers refuse to go certain client’s homes. In other cases, they won’t go without a police escort. I worked on a wheelchair once, and had to put up with a bird flying around the patient’s house. It would land on my shoulder, talons digging into my skin, while I was repairing the power wheelchair.

More often than not, however, the most unpredictable element in home care is the degree of training of the caregiver or patient using the equipment. The HTM professional has to work with very different aptitude levels, as well as patients who are in pain or are medicated, and loved ones who are upset. You have to remember that you are in their house, not a neutral area, and that this is an environment—to include family members, friends, and pets—not under your control.

How do you ensure the best quality of care at the home and other nonclinical environments versus at the hospital?

I would recommend that to maintain the same standard of care, we have to ensure the same level of staff knowledge. For example, nurses, physical therapists, and professionals that work with equipment in nonclinical environments should have the same training as those who work in hospitals, because much of the equipment is the same. We also need need more specific and detailed standards for community-based healthcare in nonclinical settings.
Our integrated telehealth system provides better care for your patients and improves the efficiency of your home health company. It’s what we do and have done for more than a decade - Cardiocom, The Experts In Telehealth! Visit us at cardiocom.com or call 888.243.8881.
A Holistic Tool for Developing a Wireless Home-Based Health Monitoring System

Priyanka Bagade, Ayan Banerjee, Sunit Verma, Joseph Milazzo, and Sandeep K.S. Gupta

Early detection and diagnosis of potentially fatal physiological conditions such as heart attacks, require continuous monitoring of patient health following transfer from hospital to home. In response to this need, wireless home-based health monitoring systems (WHMS) are being proposed as a low-cost solution. A WHMS (Figure 1) consists of physiological sensors that store, process, and communicate physiological data through a wireless communication network to a local manager (LM) such as a smartphone, which in turn uses cloud services for diagnosis.

Such WHMS should satisfy strict safety, security, reliability, and long-term real-time operation requirements, as mandated by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and by policies such as the Health Insurance Portability and Accountability Act (HIPAA). Development of a WHMS that satisfies these requirements is a challenging task, and several tools have been proposed for this purpose. However, such tools are often lacking in several aspects of the WHMS life cycle, including design, development, and maintenance. The principal challenge in developing a holistic, wireless, home-based health monitoring tool comes from its potential diverse set of users. A WHMS life-cycle management tool should be usable by the following set of users each having their own needs and knowledge base:

a) Physicians have expert knowledge on diagnosis of a patient using WHMS. In this regard, they might need monitoring and display of physiological signals, usage of signal processing algorithms for diagnosis, and storage of medical records. However, we do not expect them to have knowledge of intricate engineering processes in a WHMS, such as architectural details of sensor hardware and programming languages.

b) Developers possess the required technical skills to implement WHMS hardware and software. They need to perform platform
specific coding, manage the computing resources in sensors, and ensure that the design meets the requirements. However, they might not have detailed knowledge about the diagnostic needs of a physician.
c) Medical device regulators set forth the safety, security, reliability, and operational standards of WHMS. They might need automated tools for verifying whether a prototype meets the standard requirements. But at present they rely only on documentation from manufacturers for the engineering details and from physicians for intended use.
d) A common user can be a patient or a health-concerned person who might wish to monitor his/her physiological health. Common users possess a high-level understanding of a WHMS, but they may lack both technical and medical requirements to implement WHMS.

To satisfy the different needs of the users, a WHMS life cycle management tool should have several key features, one of the most important being the capability to guarantee that the WHMS implementation satisfies software safety requirements set forth by regulatory agencies. Safety checks on implementations are currently done using separate tool chains such as CodeSonar, which requires domain-specific knowledge from manufacturers and regulators, thus necessitating a learning period.

To quicken the process of safety verification, a WHMS tool can incorporate automatic safety checks of implementations. Hence, the capability to provide relevant levels of abstractions to the right set of users is necessary for a holistic WHMS tool. In this regard, a model-based approach, representing WHMSes using different levels of abstractions, is well suited for capturing user-specific requirements as well as for providing a foundation for in-depth analysis.

In this paper, we first identify the key features that should be supported by a holistic WHMS life cycle management tool. Based on these features, we classify existing tools and identify drawbacks. Finally, we analyze Health-Dev, an example of a model-based approach towards a holistic WHMS life cycle management tool that is in development to illustrate the key features discussed.

**WHMS Life Cycle Management Tool Requirements**

A WHMS life cycle management tool should consider its design, development, and maintenance in an automated manner as shown in Figure 2.

a) Design
A WHMS tool should enable the following design options for users:

**Choice of Hardware:**
Sensor: A large variety of wearable physiological sensors are available in the market. The WHMS tool should allow the user to choose sensors from this heterogeneous set, depending on their requirements. Most of the available WHMS development tools support only TinyOS-based sensors, while a few also support C-based language.

LM device: The LM device can be a smartphone or a personal computer. Tools generally focus on gathering and storing data on personal computers. They have limited capability of developing interactive applications for the user. The WHMS tools will be usable if they support customizable design of interactive applications. Some tools such as Mobile Middleware support this functionality (Table 1).

Cloud services: Computation power and memory capacity of LM devices, such as smartphones are limited. Thus, for heavy computation and a large amount of data storage cloud services are preferred. The tool should provide interfaces for developing apps that can interact with cloud services.

Network protocols: New network protocols such as Bluetooth low energy profile, are targeted towards embedded devices. The WHMS tool should allow the user to exploit all

![Figure 2. WHMS life cycle management tool requirements](image-url)
the functionalities of these new protocols and ensure interoperability among them. Most of the existing WHMS development tools support only the ZigBee network protocol, and do not consider communication with LM devices, which generally use Bluetooth or Wi-Fi (Table 1).

**Interoperability:** Often a WHMS needs a heterogeneous set of sensors to match the monitoring or diagnosis need of a patient. These sensors may have different data formats and communication protocols or customized Operating Systems (OS). Tools such as SPINE and RapTeX support WHMS development with sensors having different OS. The framework by Mozumdar et al. facilitates development for heterogeneous sensors supporting C-based programming dialects. A common drawback is that almost all the tools ignore LM design and therefore do not support interoperability of the sensors with the LM.

**Data management:** Managing health data storage on either LM devices or cloud servers, in a privacy-ensured manner is important. Although current WHMS development tool supports data storage in sensors or LMs, they have to be integrated with secure storage services such as Microsoft Health Vault.

**Requirements verification and full system simulation:** Software errors account for a considerable percentage of medical device failures, as documented in the U.S. Food and Drug Administration (FDA) MAUDE database. WHMS design should have strict safety, security, and reliability requirements, as mandated by the FDA and Health Insurance Portability and Accountability Act respectively.

A WHMS tool should not only provide capability of automated safety verification of the design (e.g., BAND-AiDe analyzes a WHMS design with respect to safety requirements), but also allow users to choose from a wide variety of security protocols, such as elliptic curve cryptography or physiological signal-based cryptography.

Furthermore, the WHMS tool must support full system simulation before implementation. An important factor in WHMS is the cyber

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The table below compares existing tools for wireless and security in the context of WHMS development.

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification Input</th>
<th>Verification</th>
<th>Validation</th>
<th>Simulation</th>
<th>Code Generation</th>
<th>Supported Platform</th>
<th>LM Device</th>
<th>Users</th>
<th>Programming knowledge required</th>
<th>Physiological algorithm support</th>
<th>Supported Network protocol</th>
<th>Software Type</th>
<th>Health monitoring application development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framework for modeling, simulation and code generation</td>
<td>State flow diagram (MATLAB)</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Auto (Sensor)</td>
<td>TinyOS, MANTIS</td>
<td>No</td>
<td>Developer</td>
<td>No</td>
<td>No</td>
<td>ZigBee</td>
<td>Proprietary (MATLAB)</td>
<td>No</td>
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<tr>
<td>TOSDe</td>
<td>GUI/wiring diagram</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Manual (Sensor)</td>
<td>TinyOS</td>
<td>No</td>
<td>Developer</td>
<td>Yes</td>
<td>No</td>
<td>ZigBee</td>
<td>Open source (wxCWidget)</td>
<td>No</td>
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<tr>
<td>VipTOS</td>
<td>GUI/wiring diagram</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Network Simulation</td>
<td>Auto (Sensor)</td>
<td>TinyOS</td>
<td>No</td>
<td>Developer</td>
<td>Yes</td>
<td>No</td>
<td>ZigBee</td>
<td>Open source (Posix, TinyOS)</td>
</tr>
<tr>
<td>SPINE</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Manual (APIs - sensor and base station)</td>
<td>C-based Dialect sensors</td>
<td>Personal computer (PC)</td>
<td>Developer</td>
<td>Yes</td>
<td>No</td>
<td>ZigBee</td>
<td>Open source (Java, TinyOS)</td>
<td>Yes (activity monitor)</td>
</tr>
<tr>
<td>Mobile middleware</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Manual (APIs - sensor and base station)</td>
<td>TinyOS, Windows phone (C#)</td>
<td>Windows smart phone</td>
<td>Developer</td>
<td>Yes</td>
<td>No</td>
<td>ZigBee</td>
<td>Proprietary (Visual Basic for C#)</td>
<td>Only for windows phone &amp; TinyOS based sensors</td>
</tr>
<tr>
<td>ANDES</td>
<td>AADL</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>NA</td>
<td>NA</td>
<td>Developer</td>
<td>Yes</td>
<td>NA</td>
<td>NA</td>
<td>Open source (AADL)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>RapTeX</td>
<td>GUI/wiring diagram</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Network Simulation</td>
<td>Auto (Sensor)</td>
<td>C-based Dialect sensors</td>
<td>No</td>
<td>Developer</td>
<td>Yes</td>
<td>NA</td>
<td>ZigBee</td>
<td>Open source (Java, TinyOS)</td>
</tr>
<tr>
<td>BAN-AiDe</td>
<td>AADL</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>NA</td>
<td>NA</td>
<td>Developer &amp; Manufacturer</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
<td>Open source (AADL)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Health-Dev</td>
<td>GUI/AADL</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Auto (sensor and smartphone)</td>
<td>C-based dialect sensors</td>
<td>Android phone, PC,</td>
<td>Patient, Developer &amp; Manufacturer</td>
<td>No</td>
<td>Yes</td>
<td>ZigBee &amp; Bluetooth</td>
<td>Open source (AADL, Java)</td>
<td>Yes</td>
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</table>

**Table 1. Comparison of Existing Tools**
physical interactions of the sensors with the human body on thermal effects and drug diffusion dynamics. These interactions may induce serious safety violations\textsuperscript{11} and must be analyzed before implementation. Although several tools, such as the one by Mozumdar et al.\textsuperscript{9} VipTOS\textsuperscript{10} and RapTex\textsuperscript{15} simulate the overall system before actual implementation, they ignore cyber-physical interactions.

\textbf{b) Development}

Figure 3 shows the different phases of WHMS development:

\textbf{Specification}: The design specification interface for a WHMS has to be usable by a varied set of users. Model-based specification is typically easy to use and can also be detailed for specific needs of the users. This approach is widely used by the researchers to develop health monitoring systems\textsuperscript{9-11, 15-17}

\textbf{Implementation}: Automated implementation is useful for rapid prototyping of WHMS and for incorporating requirements guaranteed in the implemented software. Available tools support the following:

1. Code generation using Application Programming Interface\textsuperscript{12,13} (API)
2. Automatic code generation\textsuperscript{9,11,15}

Automated code generation can abstract the engineering details from the user. This might be useful for physicians and common users. However, for a developer to optimize an implementation or for a regulator to check its correctness, access to the source code is necessary. To satisfy different needs, we hypothesize that the WHMS tool should support automated code generation and customization of the source code.

\textbf{Validation}: The code generated by the WHMS tool should be validated for correct operation using techniques such as unit testing and black box testing. For this, the WHMS tool should support automated test case generation.

\textbf{c) Maintenance of WHMS}

Because WHMS are meant to be pervasive, the maintenance operation should be minimal and seamless. In this regard, several approaches are applicable.
Software updates to LM and sensors: On-the-fly reprogramming of sensors is an active area of research and is currently achievable for very limited types of sensors. In addition, a WHMS tool should support software updates to the LM without service interruption.

Notifications: When a sensor malfunctions, requires replacement or simply recharging, a user needs to be alerted through simple notifications.

Seamless addition of new sensors: Addition of new sensors into WHMS should be as simple as possible. The user should not have to re-configure the WHMS.

Sustainable WHMS: In order to minimize service interruptions due to lack of power, WHMS components should use energy management techniques and scavenge energy from the human body and the environment.

Table 1 shows a comparison of existing tools with respect to the lifecycle requirements of WHMS. It shows that no single tool supports the required phases of the WHMS life cycle. In the following section, we discuss the advantages and extensions of Health-Dev as a holistic WHMS tool.

**Health-Dev—A Model-Based WHMS Life Cycle Management Tool**

An example of such a tool, and still in development, is Health-Dev—a model-based approach for WHMS design, development, and maintenance that fulfills the key requirements discussed in Section 2. As shown in Figure 4, Heath-Dev takes design requirements through an intuitive architectural analysis and design language (AADL)-based UI (Figure 5), and automatically generates downloadable codes for the sensors as well as for the LM device such as a smartphone or a personal computer. It also provides an interface with AADL for finer control or adding new functionalities. The tool facilitates model-based abstractions for physicians and common users through UI, developers, and device regulators through AADL.

Health-Dev supports code generation for a heterogeneous set of sensors having different

![Figure 5. Health-Dev User Interface](image-url)
OS (TinyOS or Arduino) and Android-based LM. It supports frequently used network protocols such as ZigBee and Bluetooth. Table 2 shows that Health-Dev uses Safe TinyOS to verify the generated code does not undergo memory related errors such as an array of out-of-bound, pointer deference, or race conditions. Furthermore, the tool generates a more optimized code as compared to manual implementation that has been verified by TinyOS static code analyzer, cXprop.

Any WHMS life-cycle tool should support physiological signal processing algorithms to be used on both the sensor and smartphone sides for developing smart context-aware applications. Using these physiological algorithms, the model-based tool can be easily extended to include security algorithms such as PSKA. Sustainable sensor operation is implemented by incorporating radio power control algorithms that maintain reliable communication. Health-Dev also enables the development of interactive applications in smartphones.

Figure 6 shows an example of using the tool as a physiological data provider for an Android-based health app, PETPEEVES, which monitors user’s exercise habits and estimates the number of calories burned. As an input, it uses heart rate, which can be obtained from the LM software of the WHMS developed using Health-Dev for electrocardiogram (ECG) monitoring. In addition, the implementation generated by the tool is validated in Ayushman, an experimental test bed developed at the IMPACT (Intelligent Mobile and Pervasive Applications and Computing Technologies) Lab at Arizona State University.

The WHMS life-cycle tool Health-Dev, presented here as an example, should be extended in the following aspects to get closer to a holistic WHMS tool: It should provide support for full system simulation before implementation; since it has AADL as specification framework, analytical tools such as BAND-AiDe can be easily integrated for simulation support; and its functionality should be enhanced by adding cloud services to upload health data for physician’s reference.

A verification module has to be integrated with the tool to ensure the correctness of the generated code. TUnit, the unit testing framework, can be used to validate Health-Dev generated TinyOS-based sensor code. To support maintenance requirements of WHMS, over the air programming should also be added to support software patch updates in the existing system without rebuilding it. In order to enable sustainable WHMS, design support for controlling renewable energy sources is necessary in such a tool.

### Table 2. Percentage Change in Code Size for Regular TinyOS (Unsafe)

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Safe TinyOS</th>
<th>cXprop</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFT</td>
<td>+32.3%</td>
<td>-8.2%</td>
</tr>
<tr>
<td>FFT*</td>
<td>+35.06%</td>
<td>-9.36%</td>
</tr>
<tr>
<td>Peak Detection*</td>
<td>+32%</td>
<td>-8.8%</td>
</tr>
<tr>
<td>Peak Detection</td>
<td>+35%</td>
<td>-9.78%</td>
</tr>
<tr>
<td>FIR</td>
<td>+31.4%</td>
<td>-8.16%</td>
</tr>
<tr>
<td>FIR*</td>
<td>+40.7%</td>
<td>-10.5%</td>
</tr>
<tr>
<td>Differential Encoding*</td>
<td>+38.02%</td>
<td>-9.1%</td>
</tr>
<tr>
<td>Differential Encoding</td>
<td>+41.80%</td>
<td>-11.1%</td>
</tr>
<tr>
<td>Out of range</td>
<td>+34.2%</td>
<td>-8.68%</td>
</tr>
<tr>
<td>Out of range*</td>
<td>+39.2%</td>
<td>-9.97%</td>
</tr>
<tr>
<td>Statistics</td>
<td>+31.2%</td>
<td>-8%</td>
</tr>
<tr>
<td>Statistics*</td>
<td>+33.4%</td>
<td>-8.29%</td>
</tr>
</tbody>
</table>

* Health-Dev generated code + BNbench Code (manually written)

**Conclusion**

A WHMS tool should provide a developer, regulator, physician, and common user with the necessary functionalities for rapid prototyping of safe home-based health monitoring systems with required data processing capabilities. This paper identifies the key requirements for a holistic WHMS life cycle management tool that considers the design, development, and
maintenance of WHMS. It surveys currently available WHMS development tools and classifies them according to focus areas. The classification reveals significant gaps in existing tools and requirements. To address these gaps, the paper discusses the advantages and extensions of Health-Dev as an example and potential solution for a holistic WHMS development tool that provides a usable model-based WHMS specification interface to the user and automatically generates software. It incorporates static analysis of the software to eliminate memory- related errors and race conditions, and ensures safe execution.

Acknowledgment
This research is funded by in part by NSF grant CNS-0831544 and IIS-1116385.

References


Medical Device Security—A New Frontier

Arnab Ray, Paul Jones, and Yi Zhang

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Over the years, software for home-care medical devices has become increasingly complex and pervasive. For example, software not only controls the operation of an insulin infusion pump, but also its wireless remote controller, and the communication between them. Many home-care devices now come with supporting software that allows users to set the device remotely or pull data from it onto a personal computer. Mobile Android or iPhone apps that interface with home-care devices through interfaces like Bluetooth are currently in high demand. In the future, the critical role of software is expected to increase even further with home-care devices communicating and controlling each other, as well as remote control/monitoring of home-care equipment via the Internet.

A new age of patient comfort (quality of life), treatment efficacy, and efficiency through increased software control and electronic interconnectivity also brings many challenges, a major one of which is security. Manufacturers must now consider the possibility of bad actors exploiting this new level of connectivity for malicious purposes. Recent public demonstrations of security vulnerabilities in insulin pumps\(^1\)\(^2\) for example, have shown how the safety of a patient may be critically compromised by hackers. Further, patient information stored in home-care devices provides bad actors a new source of identity (theft) information.\(^3\) In summary, home care device security is a serious challenge for manufacturers, caregivers, and patients.

There are specific aspects of the home-care domain (rather than a healthcare organization) that exacerbate the security problem. Hospital environments typically include systematic security mechanisms, such as network firewalls, mandatory authentication and authorization procedures, as well as controls on physical access to medical devices. Home users cannot be expected to reliably maintain such a secure operational environment for their home-care devices, personal computers, or smartphones.

Medical device software will thus have to run side-by-side with malware, spurious apps, and unpatched operating systems. Malware-carrying computer-based products brought into the home-care domain by family and friends can potentially compromise resident medical devices. Unfortunately, engineering and economic factors, such as appropriate (wireless) security communications standards and market investments complicate rapid implementation of robust, dependable security protection measures.

Manufacturers need to fully anticipate potential security risks in home environments and address security from the initial requirements elicitation and hazards-analysis phase through to design, implementation, and testing. State-of-the-art technologies and tools for developing safety- and security-critical systems can be adopted to assure the correct implementation of expected security features.

In the new security design paradigm, manufacturers need to carefully balance security with device performance and usability. For example, adding a password-protection feature to the device should not make it so inconvenient to the patient that he or she either stops using the device or turns off the security features. Home-care devices also need to provide “break-glass measures” such that caregivers can bypass normal authentication measures in an emergency.

Caregivers should educate end users about device security in the same way that they educate them on device safety. Patients need to understand how security breaches can affect their health and privacy, so they become self-motivated in adopting good security habits, such as not writing passwords on the device.

Ultimately, practical solutions for device security will require collaborative efforts among manufacturers, regulators, healthcare givers, and patients. The FDA takes the security issue very seriously, and is working on solutions to encourage and ensure that manufacturers take responsibility for adequately mitigating foreseeable security risks in their devices.

References


AAMI/FDA Summit on Healthcare Technology In Nonclinical Settings

Technology is moving out of hospitals and into homes and other nonclinical settings, reducing hospital costs and increasing patient comfort and convenience. However, there are also risks and challenges to consider as more technology moves into the hands of nonmedical professionals. To address some of these issues, AAMI and the U.S. Food and Drug Administration (FDA) will host a two-day summit:

October 9-10 2013
Hyatt Dulles Hotel
Herndon, VA
www.aaami.org/summit2013
Georgia Tech HomeLab is a network of older adult users (age 50+) enrolled to conduct in-home evaluations of the usability, accessibility, and effectiveness of technologies that promote independent living.

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HomeLab’s goals are to assist you to:
• Conduct ethnographic research
• Inform concept development and product design
• Test product safety
• Provide documented evidence for marketing or regulatory compliance needs

Georgia Tech’s experts can provide you with an independent evaluation to clearly differentiate your product in a crowded or emerging market.

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