

## A Roundtable Discussion...

# From Hospital to Home: How Will Equipment and Care Evolve?

Mary K. Logan, Moderator

**I**n light of changes that will continue to push healthcare out of hospitals and into homes, AAMI asked a panel of experts representing a variety of perspectives to discuss home healthcare delivery today and the challenges that lie ahead. How will the work be different? What new devices and techniques are coming? What issues need to be considered as this change accelerates? What follows are highlights of their discussion.

**Mary Logan:** *What forces are causing a shift toward the increasing use of medical devices in the home environment?*

**Andrea Dickerson:** From the nurses' perspective, medical devices help with managing the number of visits needed to see patients. Telemonitors relay vital patient information which is reviewed by a nurse daily. This capability translates to fewer visits, as the devices collect information and remind patients not only which signs and symptoms they need to report, but also to take their medication. These technological enhancements make our clinicians work more efficiently and give us hard data to offer doctors immediately so we can be more effective in getting treatment changes for patients.

**Mary Weick-Brady:** Care recipients want to be more independent. They're living longer with chronic diseases, and they're looking to incorporate medical devices into their lifestyle versus being beholden to them in a hospital. So manufacturers are looking to develop things that are more compact, portable, and useful in a home environment.

**Reginald E. Cyrus:** The main force is the cost of doing medicine inside hospitals. Hospitals know that getting patients out at the end of the times authorized by insurance carriers keeps them financially viable. So of course, the patient care equipment has to go out into the community as well.

**Brady:** People want to be in control of and understand their health. They're demanding this technology in their homes so they can self-monitor and be knowledgeable about what these devices are doing to them.

**Logan:** *What innovative new technologies are we seeing in the home healthcare market?*

**Brodie Pedersen:** We're seeing a lot of communication technologies, like new home monitoring systems that communicate with various telemetry devices and send that data to a medical record to be viewed by a physician or to a personal health record like Microsoft Health Vault or the Google Health.

**Chuck Parker:** We're also seeing a lot of innovative models on how we should deliver care. You can actually equip an entire home and use it as a remote facility. We're starting to link these components together and create different ways of monitoring individuals effectively.

**Cyrus:** About a year ago, a vendor showed us a vest for a newborn infant, which was basically a bilirubin (neonatal phototherapy system) light. The infant wears the vest and the parent wears a control about the size of a soda can around their neck. The child is able to get phototherapy at home and can be discharged sooner.

**Dickerson:** Wound advisor, a program that allows photographs of wounds on our laptop, lets our certified wound nurses review online weekly photographs of patient wounds. The nurses are able to consult with the doctors based on the photographs, which saves a nursing visit to the home and also saves the patient from having to leave the home.

**Brady:** The whole idea of telehealth, telemedicine, tele-screening, telediagnosing, teletreating, is getting bigger, especially for remote areas. Alaska depends heavily on

telehealth and telemedicine. Robotics will also be influencing how care is given at home.

**Logan:** What strikes me the most about these changes are the scope of healthcare issues that now can be addressed remotely, along with the range of ages of patients who can benefit from home healthcare technology. Historically, we have tended to think of home healthcare as something to help support elderly people. It's easy to see now that the future of home healthcare is with the rest of the population and with a much broader scope of care, from cradle to grave, so to speak.

**Logan:** *What are the problems and challenges encountered with devices in the home environment?*

**Dickerson:** Maintenance and cleaning. A lot of our patients have dangerous infections like Methicillin-resistant

*Staphylococcus aureus (MRSA) and Clostridium difficile (C. diff.),* so we have to be very careful about what we take into the home and follow regulations for cleaning devices.

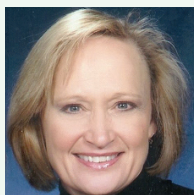
With telehealth, we're running into the problem of phone lines. The original telemonitors hooked to phone lines to carry information. But we're finding more people now do not have home phone lines, so we're trying to switch over to cellular. Our goal is to get ten customers switched over in the next month or two. Hopefully, we won't have issues with connectivity.

**Brady:** We consider a home an uncontrolled environment with uncontrolled users. You have problems with storage, children, temperature, pests, vermin, air quality, humidity, and so forth. You don't encounter guns in a hospital, but you do in homes. Or a person driving over 40-foot-long tubing with their wheelchair. If you're pro-

### Roundtable Participants



**Mary K. Logan, JD, CAE,** is president of AAMI. She came to AAMI in April 2009 with 17 years of experience in association management with the American Dental Association. Logan saw a need for AAMI to focus on home healthcare after conducting a major organizational assessment in 2009, and by drawing from her experiences caring for her elderly mother and setting up mobile dental clinics throughout the world.



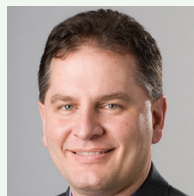
**Mary Weick-Brady, MSN, RN,** is senior policy analyst and center coordinator for the home use device initiative with the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH). She has worked as a hospital clinician, providing long-term and home care for many years. Brady has chaired the center's home health committee since 2001.



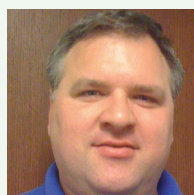
**Reginald E. Cyrus, CBET,** is a medical equipment specialist for the durable medical equipment (DME) and respiratory department at Sentara Home Care Services in Chesapeake, VA. He has been working in DME and respiratory home care for the last three years of his 24 years as a BMET.



**Andrea Dickerson, RN,** is a care management supervisor for the cardiac team and for the chronic obstructive pulmonary disease and congestive heart failure telemonitoring program for Christiana Care Visiting Nurse Association.



**Chuck Parker** is the executive director of Continua Health Alliance, a non-profit, open industry coalition of healthcare and technology companies collaborating to improve the quality of personal healthcare.



**Brodie Pedersen** is quality manager of product development for Nonin Medical, Inc. He is a member of the ISO TC121 standards body writing groups for pulse oximeters, home healthcare medical electrical equipment, respiratory gas monitoring, and alarm systems.



**John G. Rhoads, PhD,** is cochair of the technical committee of the Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PHD) domain. He represents Philips Healthcare Informatics – Patient Monitoring, Andover, MA, in organizations, including HL7, IEEE 11073, and the Healthcare Information Technology Standards Panel.

viding dialysis in a home, you have to know if it's a well or a city water supply, and what the content of that water is. There are also emotional aspects of the caretaker or care recipient to consider—their cognitive and physical capabilities, and their education level.

**Cyrus:** When a piece of equipment is going into the home, the first thing you have to consider is the utilities necessary for it to operate properly. You have to make sure wiring in the home is adequate to withstand the equipment's electrical load. You have to notify the power company that this person has life sustaining equipment so they don't automatically shut their power off if they're late on their bill. Also, maintenance and servicing are challenging, depending on how far a beneficiary lives from a home care company or equipment source.

**Brady:** If you have power outages, you have to make sure there's a backup supply, because most devices haven't been designed for home use.

**Dickerson:** Another surprising concern is what a device looks like. People don't want something that looks medical and scary sitting in their house. They want something unobtrusive that can sit in the corner and not scream out, "I have a medical problem."

**Cyrus:** We once had a device that worked well in hospitals, but not in homes. We met with the manufacturer, and found it was because we were delivering it in cold weather. That temperature fluctuation, along with a key stress point on the equipment, caused the chassis to crack, and it went into a critical failure mode with a consistent error code. The manufacturer kept saying nobody else was having this problem. But once they started collecting their service data differently, they saw they were having enormous problems in home care with this device and voluntarily pulled it from the market.

**Parker:** Another challenge is human factors engineering—making sure the technology is usable by a wide range of individuals. For example, spacing interactive activities so you get positive feedback, ensuring a device is appropriately sized for the user, and ensuring you have the right connectivity so information flows back and forth.

**John G. Rhoads:** The cognitive aspects of human factors engineering are very often not addressed. Health devices

deserve extremely careful design and validation with actual patients, because you can't always figure out what's going to happen in the real world. And the consequences are a lot more serious with home healthcare, where no medical professional is available to deal with emergencies.

**Brady:** In home care, you often have a complicated device with numerous steps that doesn't give feedback as to whether it's being operated correctly, and a user who's not properly trained on it. Many devices don't come with labeling or instructions. Or if they do come with instructions, they're too complex for somebody with emotional and cognitive issues. So the margin for error is big.

**Dickerson:** And with newer devices, it's assumed that everybody has a computer, but many people don't, or aren't technologically savvy. Our telemonitors are very basic—please stand on this scale, sit down, put on your blood pressure cuff. One problem, though, with older people is potentially causing them to fall. We have to keep reminding them that they don't need to hurry, that this machine will wait until they get there to do what they need to do.

**Pedersen:** Since it's expensive to develop and build a device, many companies prefer to have one model to suit all needs. But that's not going to work as the markets diverge between hospital, home, and transport. Manufacturers need to offer simple-use devices for homes, and more sophisticated, feature-rich devices for hospitals.

**Parker:** From a standards perspective, how do you make sure all companies are talking the same language and ensure they're moving toward the same goal? If a red light goes off on a device, does it mean the device is on, is it an alert, or is it sending data appropriately? In the United States, we know green is on the bottom of a stoplight, red on top, and yellow in the middle. We have to do the same thing from a device perspective so we can ensure we have common understanding and operability. And how do you make sure the semantic interoperability is correct so you can link data to clinical records?

**Rhoads:** This is a big technical challenge for standardization efforts. The Continua Health Alliance, a non-profit, open industry coalition of healthcare and technology companies, is working to provide an industry model for standardized solutions in the personal connected healthcare environment. Continua has put together an end-to-

end solution where you can trust the system to convey information accurately in a standardized way. But there's a lot of work to be done as this information gets used in different contexts.

Interoperability demonstrations have shown that it is possible to take device information from, say, a simple blood pressure cuff and weight scale, and actually transfer it into a clinical electronic health record.

**Cyrus:** Alarms and warnings can also be a problem in the home healthcare environment. Too many bells and whistles going off at home, particularly with newborns and apnea monitors, make families nervous. We receive a lot of support phone calls because of different equipment lights and sounds.

**Logan:** *How is the servicing and management of devices in a home care environment different from a hospital environment?*

**Cyrus:** When a nurse or a clinician calls me from a hospital and says they have a problem with a monitor, I readily think of them as legitimate experts on that equipment. So I take this or that tool with me, and know it ought to fix it. But when a family member calls, I only know there's a problem at this home. I'm going to have to go loaded with a full range of tools, because often what I'm told has nothing to do with what I find when I get there. Many times a device has stopped working because it's plugged into an outlet activated by a light switch, and somebody inadvertently turned it off.

**Dickerson:** The central station nurse has a list of questions to ask callers to try to determine the cause of any malfunction of our devices. With the majority of our patients, we have to start at the very beginning because they are elderly and only understand how to turn the devices on and off.

The other problem is how to follow the Joint Commission, state, and manufacturer rules to make sure equipment is appropriately cleaned to move from house to house. We stopped doing glucometer testing in homes. We can assist the patient, but if we touch the glucometers, we have to do a two-type test on the patient's machinery, which uses up their strips.

**Brady:** Another issue relates to medical devices that people sell when they no longer need them. Often they sell them

without proper maintenance and cleaning instructions, or a list of compatible accessories. Policies and protocols for how to address this reality need to be developed.

**Pedersen:** With people owning their own equipment after so many months of rental, there are going to be problems with long-term maintenance. If they're not under the direct care of durable medical equipment (DME) companies, whose responsibility is it to maintain that equipment long-term? It's really the user's responsibility, who may not have the capability. That's a big concern for everyone. DME's aren't going to get paid to service those things, so they can't take responsibility for them. But at the same time, that's really what's necessary.

**Cyrus:** From the hospital environment to the home care environment, there is a boundary. On the other side of that boundary are the DME supplier companies. As we all know, hospitals assist with the equipment people use at home. But the DME supplier in the community is really the source of most DME and managing the equipment in the home environment, particularly during a warranty period. The home care setting is driven not so much by the hospital side, but by the Centers for Medicare and Medicaid Services (CMS) and commercial insurance companies, and what they will and won't pay for. It has an impact once the rental cap is met and the remaining warranty transfers to the patient. What are the patients going to do, with their now owned equipment, to get their equipment serviced when required?

**Logan:** *How is the move to home healthcare going to challenge medical device companies to look at their products and markets differently?*

**Dickerson:** For home care nurses, a product has to be small enough for us to put it in the home, and portable enough for us to get it there. Some of my nurses have become very creative at figuring out how and where to put devices, and moving furniture or climbing under beds to hook up phone or electric lines.

**Cyrus:** A home assessment is critical for manufacturers to know the market they're going to be servicing. You measure doorway widths, look at the electrical capacity of circuitry, and other features. A lot of historic homes that haven't had electrical circuitry upgraded have only two-pronged outlets. If you have a three-prong device,

you've got to use a cheater plug and hope it works properly. Also, there is no requirement in homes for an outlet tension test, where you check to make sure an electrical outlet has the ability to hold the plug in place.

Another problem is critical failures with devices. A power wheelchair stops working if the electrical circuitry senses a momentary voltage drop below a certain operating level in some products. If a person is stuck in the middle of the street when their wheelchair stops, it poses a big problem if they're out by themselves. Manufacturers have to realize people don't always have someone there to assist them. There must be some kind of technological consideration for this event, and allow the power supply to reset—not just a critical failure with no battery power available.

**Pedersen:** Cleaning agents and high-level disinfectants in the home are also an issue. It's critical to follow manufacturers' instructions on what types of agents to use, because different materials used to make devices rugged, lightweight, and portable are susceptible to some agents, even ones used in hospitals. Devices in the home need to be easily cleaned and disinfected with safe and simple agents so people aren't using caustic agents outside manufacturers' labeling that might damage equipment.

**Dickerson:** And it needs to be cost effective. If people have to make a choice between buying a special cleaner and paying for their medications, or even their next meal, they're not going to buy the expensive cleaner.

**Logan:** *What regulatory or standards initiatives are underway to ensure the safety and effectiveness of home healthcare devices?*

**Pedersen:** Usability factors and power issues will be called out by the new international standard on home care titled *IEC 60601-1-11, Medical electrical equipment—Part 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*. This standard is being published shortly. It allows only two-wire cords for home care products to provide safe connection to electrical outlets. Some of those things are difficult to achieve in certain technologies.

That works along with the general standard IEC 60601-1 to enhance issues related to use, environmental conditions, pests, pets, children, and other things in the home environment.

Another important standard is the new Integrated Clinical Environment (ICE) standard (*ASTM F2761, Medical Devices and Medical Systems—Essential Safety Requirements for Equipment Comprising the Patient-Centric Integrated Clinical Environment (ICE), Part 1: General Requirements and Conceptual Model*). Granted, that's a bit more focused on the hospital environment, but it certainly talks about using portable electronics to monitor or control equipment through a network configuration, which certainly could work with equipment in the home.

**Cyrus:** I tried to find a document like *NFPA 99: Standard for Healthcare Facilities* from the National Fire Protection Association, which we use in clinical engineering in hospitals, and found there is no equivalent in the home setting. Much of what we apply in home care comes through accreditation requirements. So I see a lot happening down the road with respect to standards being developed for home care.

**Brady:** Also the human factors standard, *ANSI/AAMI HE75:2009, Human factors engineering—Design of medical devices*, was just published. Human factors plays a huge role in the safety of home use devices.

In addition, the FDA announced our Medical Device Home Use Initiative in April (see related article in this publication). FDA is immediately taking steps to support the safety and safe use of devices going into the home. We have held a public workshop to gather information for a guidance document that will assist manufacturers to design and develop medical devices labeled for home use that meet the unique considerations for the user and the environment.

We are working on a labeling repository that will house all devices labeled for home use so healthcare practitioners and end users can easily find the labeling for devices they are using in the home. We are working to partner with the major accrediting bodies for home care agencies to ensure that medical devices are being addressed in the accreditation process. We are developing methods to enhance our postmarket surveillance of adverse events that occur in the home and how to mitigate that risk. Finally, we are working on outreach programs to educate people on what a medical device is and how to use it safely in the home.

**Logan:** *What do you see for the future of home health-care?*

**Parker:** Very positive strides are being made in this area. While there are certainly challenges involved in using medical equipment in the home, there is a significant cost savings demonstrated by the industry. We have a limited number of clinicians, and the move toward home care actually helps solve that problem for us. While there are initial bumps in the road, healthcare institutions must take a look at this trend and move forward to address it.

**Brady:** I agree. Even though we did talk about things to be wary of in the home environment, this is the way healthcare is going. It's our job to ensure that what's going into the home is safe for the people using it and for the environment in which they're using it.

**Pedersen:** And looking at the number of people who participated in the home care standardization or the IEC 60601-1-11 effort, it shows a commitment among manu-

facturers and others to make sure people are thinking about these things as we create devices and technologies to go into the home. I'm hoping you guys are seeing products that are easier to use and lighter, and do a better job for the customers in your field so you know customer needs are being met at a higher level than they have in the past.

**Dickerson:** I'm very excited about the new technology. Tomorrow's Medicare patients are going to be more technologically inclined than ever before. I'm looking forward to working with whatever comes.

**Logan:** At the beginning of this conversation, we heard a comment about consumers wanting more independence, wanting to make adjustments to chronic diseases that will allow them to continue to live their lives. That's an inspiration for all of us. It's important to work through the challenges and consider the changes that need to happen so we can support stronger patient autonomy. That's a wonderful common goal that everyone in healthcare can support. ■



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