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.


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.

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

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...
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?

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 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.

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 If the burden of operating and maintaining devices is too heavy, users will abandon the devices.
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 re-invented and found new solutions at every turn will demand 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

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.

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