Fifty years ago, the term *home healthcare device* might have conjured up images of hospital beds and wheelchairs. But much has changed since then, and the combination of an aging population and increasingly sophisticated, easy-to-use medical equipment has led to an explosion of home and other non-hospital-based healthcare.

From infant apnea monitoring and home dialysis to the defibrillators now common in public spaces, sophisticated and life-saving equipment and treatments are no longer confined to the hospital or clinic. The trend has presented new challenges for the medical device industry, from manufacturing and regulations to device maintenance.

About 7.6 million Americans currently receive home care from 83,000 providers due to acute illness, long-term health conditions, permanent disability, or terminal illness.1 And the 78 million baby boomers—those born between 1946 and 1964—who are now entering their 60s are expected to swell the ranks of those receiving home care even further.

The trend “is to move more healthcare out of the hospital setting and into other kinds of facilities—whether that’s a home or some kind of intermediate care facility,” says Chuck Sidebottom, director of corporate standards for Medtronic, Inc., and chairman of AAMI’s Board of Directors. “I don’t think anybody sees this abating any time in the foreseeable future.”
Mary W. Brady is deputy director, Division of Surveillance Systems, Office of Surveillance and Biometrics in FDA’s Center for Devices and Radiological Health (CDRH). She notes several issues and concerns about homecare devices—both “premarket” (for manufacturers) and “postmarket” (for hospitals/consumers/users).

“Most devices are not labeled for use by a non-healthcare professional, which poses safety concerns with devices used in the home environment by people who are not trained to use these devices,” she says. Among postmarket concerns Brady cites are:

- Usually a patient will receive a leased piece of equipment that goes from home to home. The labeling may get lost along the way or sometimes it doesn’t even make it to the rental equipment company.
- Many devices now become the property of the patient and are being sold on the Internet. In many cases they are being sold without proper maintenance instructions; without proper labeling for appropriate accessories or components; and without proper instructions for cleaning, disinfecting, or calibrating.

Given these factors, the issue of developing standards for a range of homecare devices becomes increasingly important. Sidebottom is currently involved in a joint effort with AAMI, the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC) to develop a general standard (IEC 60601-1-11) for medical electrical equipment and medical electrical systems intended for the home care environment, a subset of home care devices.

“When you get into medical electrical equipment, you have applied parts that typically have a closer connection to the patient,” he says. “And you have potentially more stringent requirements on those because often those applied parts have a direct electrical connection to the patient.”

While always important, electrical safety is essential in the home-use environment—where equipment is usually operated by individuals who are not healthcare professionals. Sidebottom says that without an “informed intermediary—the trained operator,” medical devices can be used in unintended ways or under unusual circumstances.

In the home, a device intended for indoor use, for example, might be used outdoors or subjected to liquid spills. Therefore, in developing standards for homecare equipment, the question must be asked, “What additional requirements might we need to deal with in that environment?”

Sidebottom cites the need for “ruggedness” of certain homecare devices. For example, a home ventilator attached to a motorized wheelchair may experience more shock and vibration than the same equipment would in a hospital setting.

The Human Element

In light of these issues, manufacturers are trying to make their devices as foolproof as possible, says Rohit Vishnoi, PhD, vice president product development, renal, for Baxter International, Inc., of Deerfield, IL.

“When we make the product easy and intuitive to use, patients are more likely to be compliant,” he says.

Therefore, perhaps more so than with devices designed specifically for hospital use, home-use equipment must take into account “human factors.” In a July 18, 2000, FDA Guidance Document, Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, the agency states:
“For any device, the abilities and limitations of the user population might be relatively uniform. On the other hand, the user population might contain sub-components that have significantly different abilities. Examples are young and old users, or home users and professional healthcare providers. Fatigue, stress, medication, or other temporary mental or physical conditions can temporarily affect ability levels of device users.”

To this end, Vishnoi notes that, “we consider the needs and capabilities of a variety of users who may face particular challenges in their therapy, such as those who are visually impaired, experience cognitive or physical challenges, are illiterate, or speak a different language.

“Various graphic user interface options are tested repeatedly with patients and clinicians to ensure the graphics are universally and easily understood. The patient should never feel intimidated by the device.”

He says patients and their family members are “essential contributors” to the design of home devices. Throughout the development process, “it is the rule, not the exception” to test home devices with patients in simulated use.

Companies are also developing new ways for patients to connect with healthcare providers through electronic data management and user features. “In the future, patients may have the ability to enable a device to speak to an expert via phone about matters that may be beyond a user’s understanding,” Vishnoi says.

Further, companies such as Baxter are manufacturing “telecommunication interfaces” that enable the secure transmission of data from vital sign monitors in a patient’s home to a central healthcare database, either wirelessly or via landline or cellular modems. This and other technology solutions can remove the element of human error from patient monitoring.

In addition to a device’s usability and safety, manufacturers also consider “the quality of life of the patient

Patients and their families are essential contributors to the design of home devices.
by making devices as small, portable, suitable for the home, serviceable, and quiet as possible,” according to Vishnoi.

**Patient Benefits**

Among the more sophisticated medical equipment deployed to the homecare setting are hemodialysis machines. And for patients, the devices’ portability and downsizing has made it easier to dialyze at home or to travel with a relatively compact machine (see Voices of the Patients for more information on the health and quality-of-life benefits of home dialysis).

Still, only a small percentage is choosing to dialyze at home, according to the National Kidney and Urologic Diseases Information Clearinghouse in its report *Kidney and Urologic Diseases Statistics for the United States*. In 2005, more than 91% of U.S. residents on dialysis were receiving treatment in dialysis centers (in-center). About 28,000 patients were dialyzing in a non-hospital or non-clinic setting: about 2,100 received home hemodialysis, and nearly 25,000 received continuous ambulatory and continuous cycling peritoneal dialysis, both primarily home treatments.

> When you have a piece of equipment that goes out into a home, it’s got a lot more exposure that can cause it to fail.

Many home dialysis patients have been able to return to work and say they are healthier and enjoy a better quality of life. Being able to dialyze at home enables more frequent dialysis—perhaps six times a week—than the typical in-center regime of three days per week. Thus far, comprehensive data on comparing in-home versus in-center dialysis has been lacking. The Centers for Medicare and Medicaid Services and the National Institutes of Health are conducting two clinical trials, with results expected in 2011.

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**Voices of the Patients**

Manufacturers, standards developers, and biomedical equipment technicians focus on the patient’s safety, but rarely hear from the patients themselves. Two dialysis patients shared their stories on what home hemodialysis—made possible by the dedicated work of medical technology professionals—has meant to them.

Nicole Fisulka’s nephrologist told her to prepare to go on disability while she awaited a transplant—and “maybe permanently”—after her kidneys failed last year. She was hospitalized and placed on dialysis. Like many patients, the 34-year-old found the experience frightening and physically and emotionally draining being surrounded by patients sicker than she and in a lot of pain.

Fisulka eventually opted for home hemodialysis, like a small but growing number of end-stage kidney disease patients. They are the direct beneficiaries of advances in healthcare that have brought a variety of medical devices out of the hospital and into the home.

Fisulka couldn’t imagine dialyzing in-center, after her hospital experience. “There is absolutely no way I could have worked, even part-time, being on in-center dialysis,” she says. “It was so draining on me. I would go home after a treatment and sleep for almost 24 hours. I couldn’t drive myself home because I was so weak.”

After a week of training with her husband, she began dialysis at home, six days a week for three-and-a-half hours per session. Her mother was also trained to serve as a backup.

> “When I’m sitting at home doing it, spending time with my family instead of in a room with a number of really ill people, it makes huge difference mentally,” she says. “I can’t stress enough how much better I felt doing it daily with the milder treatments than I did the couple of times a week.”

Fisulka was able to work—often 50 hours per week—while on home dialysis. “I could work my dialysis around my schedule instead of being locked into a certain time.” She didn’t have much spare time but says, “when I did have spare time, I was actually energetic and able to do what I wanted.”

Bill Peckham has enjoyed equal success with a different form of home dialysis—while he sleeps. He began nocturnal self-dialysis treatments earlier this year, after receiving another form of home hemodialysis for several years. He dialyzes himself, unassisted.

On dialysis since 1990, Peckham, 45, had dialyzed in-center in 19 countries on five continents before beginning home dialysis in 2001. It wasn’t until his care provider, Northwest Kidney Center, began offering more frequent dialysis at home that he thought it
Whether it’s dialysis machines, ventilators, or home infusion devices, the common denominator in keeping them safe and standards-compliant is the biomedical equipment technician (BMET) who maintains and services home care devices. By and large, BMETs say they are working on the same devices as they do in their hospital shops, so there is little technical learning curve. Glen Burgess says his training to test and service hospital equipment has been transferable to outpatient equipment. However, one of the biggest challenges he faces is keeping up with the volume of work.

“When you have a piece of equipment that goes out into a home, it’s got a lot more exposure that can cause it to fail,” says Burgess, a BMET at St. John’s Regional Health Center in Springfield, MO. “We test it many more times than we would for a comparable device that remains in-house.”

An infusion device in a hospital setting might undergo testing or preventive maintenance annually, with the staff cleaning it between uses. So a hospital BMET might see it once a year, he says.

“We have a lot of home infusion devices, and they will have the kind of exposure that is beyond anything we need in a hospital,” says Burgess. “I’ve had to develop new training, just to get to the level I need to be at. I have to do it more frequently, do it more often.”

Horace Hunter

Maintenance Challenges

was worthwhile. According to research, more frequent treatments remove more toxins from the blood and leave the patient feeling better.

“At home, I was able to get a higher dose of dialysis,” says Peckham, who travels frequently and does graphics production and computer-aided design for trade shows. Since starting home dialysis, he’s been able to decrease some medications, feels “a little sharper” mentally, and has gained 28 pounds.

Peckham dialyzes five nights a week—three on, one off, two on—using a “relatively” compact machine that he can travel with. Including its carrying case, the machine tips the scales at 99 pounds.

“I don’t pretend it’s for everyone,” he acknowledges. “But I definitely can’t imagine myself not doing it.” Peckham had a kidney transplant in 1988, but within two years a recurrence of his disease—focal segmental glomerulosclerosis (or FSGS)—diminished its function, and he went back on dialysis.

“My best choice is to dialyze as much as I can and stay healthy, and hope for a medical advancement.”

Fisulka is equally sanguine about her time on home dialysis.

“The biggest benefit was just being as healthy as I could be while I was waiting for a transplant, being in the comfort of my own home. When you’re not having to go to a center, it kind of makes it seem a lot less invasive in your life,” she notes.

She received a successful kidney transplant from her brother-in-law in March 2008.

go out [to] a customer and be on them for maybe three or four days and come back…. You have to do testing on that device after each use. So we will test it probably 50 to 60 times in a year, whereas we test the one in the hospital once in the same time frame.”

For example, oxygen concentrators are tested every six months, whereas some manufacturers state they can be tested annually. “But we think that’s an excessively long time to leave a piece of equipment in somebody’s house and not test it.”

Another challenging aspect of homecare devices is the technicians’ greater exposure to patient information. “You have patient names, phone numbers, contacts. That throws you into Health Insurance Portability and Accountability Act (HIPAA) situations that you’re not exposed to in the hospital”—where a technician might only know that a device is “up on the sixth floor,” Burgess explains. “You don’t know who it’s used on or why.”

Horace Hunter agrees that inspecting and testing is a high priority: “The care of medical equipment is what determines the care of the patient,” says Hunter, who is the head of Archbold Memorial Hospital’s biomed shop in Thomasville, GA. His staff serves hospitals and clinics within a 150-mile radius in south Georgia, the Florida Panhandle, and southeastern Alabama.

For clinicians such as respiratory therapists and technicians who deliver and set up equipment, Hunter says, “the challenge that is put on the in-house program is the distance and travel, and the personal contact within a person’s home.”

He and Burgess agree that while patients receive training on the operation of medical devices, such as oxygen concentrators, ventilators, and apnea monitors, there is little the home user can do to maintain them besides changing filters and checking that alarms are working.

As for dealing with equipment-related emergencies, Hunter says, “we try not to have any, especially in the homecare arena. We try to have backups, spares, and emergency preparation plans in place.” Burgess adds that he usually has sufficient stock to swap-out malfunctioning equipment. “So our emergency is just to get them another one of our stock pieces or something from the warehouse.” And then he repairs the broken device.

As more medical devices move out of the hospital into the home, Burgess and Hunter believe the current crop of biomeds will be well equipped to service them, using the same training they received on in-house equipment. “My experience started in the hospital setting, and the training that I received through manufacturers and classes easily got me into this,” Burgess says. The one caveat he has found, however, is that it is difficult for some “hospital-minded” biomedical technicians to get used to the concept of “a piece of equipment … leaving your facility.”

But manufacturers, regulators, clinicians, and technicians all expect more devices to be doing just that—leaving the hospital and giving patients a more direct role in their own care.

“You’ll never see a home computed tomography (CT) machine or a home magnetic resonance imaging (MRI) machine,” says Sidebottom, “but you will see more and more equipment moving out of the hospital into the home care. There’s also more equipment being developed specifically for the home care market.”

Reference


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