Medical Device Home Use Initiative

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Center for Devices and Radiological Health

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Executive Summary

Assuring the safety and safe use of medical devices in the home is becoming an increasingly important public health issue. The aging of the U.S. population and shifts toward shorter hospital stays continue to make home healthcare more common. With these trends, a significant number of medical devices, including infusion pumps, ventilators, and wound care therapies, are now being used in the home.

Home healthcare can provide significant benefits to patients, in terms of both quality of life and cost of care. However, the use of medical devices in the home also presents unique challenges and potential safety risks. Home medical care is often provided by lay caregivers, who may not have received proper training in the operation of the medical devices on which their loved ones rely. Moreover, many medical devices that are currently used in the home were not designed for use by lay caregivers or outside of a controlled clinical environment.

The U.S. Food and Drug Administration (FDA) recognizes the importance of safe, high-quality home healthcare and medical devices that are capable of meeting patients' needs in the home.

This document announces the launch of FDA's *Medical Device Home Use Initiative*. Through this initiative, FDA will take the following actions to support the safety and safe use of medical devices in the home:

1. Establish guidelines for manufacturers of home use devices;
2. Develop a home use device labeling repository;
3. Partner with home health accrediting bodies to support safe use;
4. Enhance postmarket oversight; and
5. Increase public awareness and education.

These steps will help address the challenges associated with the use of medical devices in the home and provide greater protections for patients receiving home healthcare.

Background: Technology Going Home

Home healthcare is becoming increasingly common. The population of the United States is aging, and people are living longer with chronic diseases that require daily medical care at home. It is projected that in 20 years, 72 million people will be over the age of 65.[1] In addition, more patients of all ages are being discharged from the hospital to continue their medical care at home. For patients who need extended follow-up to complete their recovery, home care can be a more desirable and affordable alternative to a long-term hospital stay.

Approximately 7.6 million individuals in the United States currently receive home healthcare from roughly 17,000 paid providers.[2] Although good data sources are lacking, it is estimated

[1] He Wan, Manisha Sengupta, Victoria A. Velkoff, and Kimberly A. DeBarros, U.S. Census Bureau, Current Population Reports, p. 23-209, *65+ in the United States: 2005*, U.S. Government Printing Office, Washington, DC, 2005. Available online at http://www.census.gov/prod/2006pubs/p23-209.pdf.

[2] National Association for Home Care & Hospice (NAHC), "Basic Statistics about Home Care," 2008. Available online at http://www.nahc.org/facts/08HC_Stats.pdf.

that in 2007, annual U.S. expenditures for home care were as high as 57.6 billion dollars.[3] These estimates do not account for lay caregivers who take over responsibility when a home care agency no longer makes visits to a patient. From October 2008 through October 2009, an estimated 36.5 million U.S. households (more than 31%) had at least one unpaid family medical caregiver present.[4]

Home care patients, also called care recipients, often need some type of medical device to help them recover outside of a hospital setting. FDA defines a home use medical device as a device intended for users in a non-clinical or transitory environment, which is managed partly or wholly by the user, requires adequate labeling for the user, and may require training for the user by a healthcare professional in order to be used safely and effectively. This includes permanently and temporarily implanted devices and any type of equipment that a person may use to recover and rehabilitate. Because care recipients expect to be able to stay independent, mobile, and active, the term "home use" extends beyond the home, *per se*, to encompass all environments in which a person plans to use his or her medical device in day-to-day life. The device must be capable of safely accommodating the many needs of the person using it.

1. Benefits of Home Use Medical Devices

As medical devices have become more compact and portable, it has become possible to conduct a variety of medical treatments in the home. Home use devices can provide significant benefits to care recipients.

Quality-of-Life Improvements. Home healthcare offers more comfort and convenience to care recipients than hospital-based care. Technological advancements have allowed care recipients to remain ambulatory and independent. For example, telemedicine and wireless monitoring devices have made it possible for healthcare providers to observe and communicate with home care recipients remotely. Advances in robotics and electronics have allowed for more automated delivery of care, with less need for the intervention of a medical professional.

Cost Savings. As shown in Table 1, below, the use of medical devices in the home can also generate a cost savings for care recipients and the healthcare system.

Table 1. Cost of Inpatient Care (Per Patient, Per Month) Compared to Home Care [5]

Condition	Hospital Costs	Home Care Costs	Dollar Savings
Ventilator-dependent adults	$21,570	$7,050	$14,520
Oxygen-dependent children	$12,090	$5,250	$6,840
Chemotherapy for children	$68,870	$55,950	$13,920
Congestive heart failure in the elderly	$1,758	$1,605	$153
Intravenous (IV) antibiotic therapy	$12,510	$4,650	$7,860

[3] National Association for Home Care & Hospice (NAHC), 2008.
[4] National Alliance for Caregiving, in collaboration with AARP, "Caregiving in the U.S.: Executive Summary," November 2009. Available online at http://www.caregiving.org/data/CaregivingUSAllAgesExecSum.pdf.
[5] National Association for Home Care & Hospice (NAHC), 2008.

2. Unique Challenges

Because the home environment is fundamentally different from the clinical environment, home use of medical devices presents unique challenges, many of which have the potential to impact patient safety.

Caregiver Knowledge. Although manufacturers have successfully made some medical devices less costly and more user-friendly, many devices are still too complex for a layperson to use safely and effectively without proper training. In many cases, home care recipients may use devices that were designed for use by trained healthcare professionals in an acute care facility, not by lay caregivers in a non-clinical setting. In addition, lay caregivers may lack awareness of how to respond in the event of a device malfunction or failure.

Device Usability. Many individuals who receive or provide care in the home use older medical devices, which often come with minimal or no labeling or instructions for use. In such cases, the home healthcare provider must develop his or her own basic instructions for use, maintenance, and cleaning, to share with the care recipient. Even when the device comes with a user manual, instructions are not typically written for a lay audience, and, as a result, the lay caregiver may not be able to use the device safely and effectively. Device labeling may include complex or difficult-to-comprehend warnings, precautions, and contraindications that confuse lay readers.

Another concern is that home care recipients may not be able to choose the devices that are provided to them, and therefore may not receive devices that are optimal to meet their individual needs. A device used in the home must be compatible with the care recipient's and caregiver's educational level, emotional stability, cognitive and physical abilities, lifestyle, and typical environment. Home use medical devices are frequently prescribed by physicians. However, a physician may not take into consideration which specific brand or model of a device would best suit a particular patient in his or her home environment, or may not have adequate training to make this type of determination. In addition, a physician may not control which device is provided to the patient. Rather, the patient may be dependent on an equipment supplier, who may prefer certain device brands or models over others.

Although the Internet offers care recipients more control over their equipment purchases, it also presents its own set of risks. The quality of devices and associated materials and services provided by Internet-based device distributors can vary. Some websites, for example, offer assistance in the operation and servicing of a device. Others sell prescription devices without requesting a prescription or assessing the cognitive and functional abilities of the purchaser, and do not offer maintenance, servicing, instructions for use, or information about compatible accessories.

Environmental Unpredictability. Unlike the clinical setting, the home is an uncontrolled environment. Home use medical devices may be exposed to environmental risks that may adversely affect performance. These risks include space limitations, the presence of children or pets, electromagnetic interference, sanitation issues such as vermin or dirty household items, and safety hazards such as clutter or neighborhood crime. In addition, the location of the home (e.g., elevation, urban versus rural, etc.), noise levels inside and outside of the home, air quality, temperature, and humidity may affect device performance. Finally, unlike trained hospital staff, home users may not be equipped to handle medical emergencies in the event of a natural disaster or an electrical outage, particularly in the absence of the back-up power and/or water supply that a healthcare facility may have.

3. Reported Problems

From 1997 through 2009, FDA received over 19,000 reports of adverse events in which the reporter listed the location where the incident took place as "home." Not all of these adverse events are directly attributable to the challenges described above, and it is not possible to separate out those events that are. However, these challenges have contributed to a number of the reported problems. Table 2 provides specific examples of adverse events that have been reported.

Table 2. Examples of Reported Adverse Events that Occurred in the Home

Challenge	Examples
Lack of Usability by Patients or Lay Caregivers	Inadequate Information or Training for Users: *Example 1.* A patient received a cardiac monitor and electrodes by mail. She was instructed by phone how to apply the electrodes and use the equipment. The patient applied the electrodes to her chest, activated the device, and felt a burning sensation on her skin at the points of contact. She informed the instructor over the phone, and he directed her to remove the electrodes and try again with another set of electrodes that had come in the shipment. The patient followed these instructions and experienced the same burning sensation. After a few failed attempts at using the device, the patient removed the electrodes from her chest and, in the process, lost some skin. The patient went to the emergency room for treatment of her wounds. *Example 2.* A patient had been using an infusion pump that delivered medication in mL/day. He was given a new pump that administered medication in mL/hour. He was not trained in the use of the new pump. However, it looked similar to his previous pump, and he programmed it assuming that it was the same. As a result, the patient's medication was delivered too quickly. The patient recovered after the error was noted. Absence or Failure of Safety Features: *Example 1.* A seven-month-old patient was at home on a ventilator with a back-up. The patient's parent found the patient attached to the ventilator, but the ventilator was no longer cycling, and no air was coming out of the circuit. The ventilator alarm did not sound. The patient died. *Example 2.* A patient on an infusion pump was receiving a constant flow of medication. When the patient attached a new cassette for infusion, the patient forgot to remove a cap from the infusion line, which blocked the flow of medication. The pump did not alarm for high pressure, and the patient did not receive medication. The patient was hospitalized as a result. (Continued)

Lack of Usability by Patients or Lay Caregivers (Continued)	<u>Lack of Consideration of Users' Physical Capabilities</u>: *Example 1.* A patient doing home nocturnal dialysis was found by her husband, unresponsive. She was disconnected from the dialysis machine, and her tubing was in a closed circuit filled with saline. There was a syringe attached to one of her lines, but the other line was open, and the patient had lost a significant amount of blood. It appeared that she had been unable to clamp her catheter by herself. The patient died due to blood loss.
Environmental Hazards	<u>Electromagnetic Interference</u>: *Example 1.* An individual with an implantable cardioverter defibrillator (ICD) was playing his electric guitar at home. As he was unplugging the guitar from the amplifier, feedback started to come from the amplifier, and the individual felt a painful vibration at the site of his ICD. His left arm became immobile for almost two minutes. The painful sensation stopped when his wife unplugged the amplifier. *Example 2.* An individual with an ICD was playing with a Wii video game. As he was playing with it, his device began to have intermittent pacing. The problem stopped when he stopped playing the game. *Example 3.* An individual with an ICD was playing with his son. The son drove a remote-controlled car over the man's chest. Each time the car passed over the ICD, the device beeped. <u>Noise Levels</u>: *Example 1.* A pediatric patient was receiving ventilator therapy in the home, and the ventilator tubing became disconnected. The patient's mother was asleep and did not hear the ventilator alarm. There were other ambient noises in the home (e.g., television), and they may have interfered with the mother's ability to hear the alarm. The patient died. <u>Presence of Household Pets</u>: *Example 1.* A patient was put on peritoneal dialysis because of her failing kidneys. She lived in a one bedroom apartment with her cat. The cat's litter box was initially in her closet, but she moved it into her bedroom after the closet became filled with dialysis supplies. Although the patient kept the cat out of her bedroom while she was undergoing dialysis, there was cat fur and dander throughout the room. Cat fur got into the patient's dialysis tubing and entered her peritoneum, and she contracted peritonitis. The patient was subsequently treated and has recovered.

Medical Device Home Use Initiative

FDA is launching the *Medical Device Home Use Initiative* to improve the safety and safe use of medical devices in the home. Through this initiative, FDA will take proactive steps to assure the safety, quality, and usability of devices labeled for home use, and to provide more information for home care recipients and caregivers to support safe use.

1. Establish Guidelines for Manufacturers of Home Use Devices

To date, FDA has not articulated a clear regulatory pathway for devices intended for home use, describing the unique factors manufacturers should take into consideration when designing, testing, and labeling such devices. In order to facilitate the development of medical devices that are safe for home use, FDA will develop a guidance document recommending actions that manufacturers should take to receive FDA approval or clearance of devices intended to be used in the home, including usability testing with lay users in a non-clinical setting. The new guidance will also recommend postmarket surveillance that manufacturers should undertake to identify and address adverse events that occur in the home. Finally, the guidance will define circumstances under which FDA may exercise its authority to clear a device as "substantially equivalent with limitations," and require the manufacturer to indicate in its product labeling that the device has not been cleared for use in the home. By clarifying FDA's expectations, this guidance will establish a more predictable pathway for home use medical devices.

FDA's new guidance will be informed by input from manufacturers, the healthcare community, and others. FDA intends to hold a public workshop on May 24, 2010 to discuss steps manufacturers can take to design and test devices for use in the home, and to develop user-friendly instructions for home care recipients and caregivers.

2. Develop a Home Use Device Labeling Repository

After FDA has approved or cleared a device for use in the home, it is important for care recipients and caregivers to have ready access to information about the proper use of the device. To facilitate safe use, FDA will create an online labeling repository for medical devices that have been approved or cleared for home use. This repository will be available to the public on the agency's website.

As a first step, FDA is announcing a pilot program through which manufacturers of devices labeled for home use may voluntarily submit their labeling electronically to FDA for the agency to post in a central location on its website. Posting medical device labeling in a single online location will make it easier for home care patients and caregivers to find important information about how to safely use their device. The pilot program will begin mid-summer 2010 and will last for 10 months. FDA will work with manufacturers who are interested in participating, to help them understand the formatting and the information needed. In the coming weeks, FDA intends to provide additional information about the pilot program in the Federal Register.

3. Partner with Home Health Accrediting Bodies to Support Safe Use

Some individuals receive care from home health practitioners. Assuring that these practitioners are adequately trained in the use of medical devices in the home can be daunting, given the wide variety of technologies that are used, on or off label, in the home. Although accreditation programs for home health agencies already exist, they generally focus on the practitioner's

ability to provide care to patients, rather than also assessing the practitioner's ability to properly use devices in the home or to train lay caregivers and care recipients on the safe use of these technologies.

Therefore, FDA is partnering with two major accrediting bodies for home health agencies, the Community Health Accreditation Program (CHAP) and the Joint Commission, to review and strengthen accreditation criteria that relate to medical device safe use practices for the home environment.

4. Enhance Postmarket Oversight

In order to promote high-quality reporting of home use medical device problems by home care agencies, FDA will continue to strengthen the HomeNet arm of its Medical Product Surveillance Network (MedSun). FDA recently completed a HomeNet survey to collect information about safety concerns related to home hemodialysis. The agency is in the process of conducting a similar survey on the use of negative pressure wound therapy devices in the home.

Improved reporting will help the agency develop a better understanding of common home use safety issues and take appropriate actions to address them. Lessons learned from FDA's experience with marketed devices could inform future regulatory actions. In addition, FDA will continue to use its Patient Safety News platform to provide relevant, up-to-date information to home care recipients and caregivers about identified risks associated with home use devices.

Enhanced postmarket surveillance will also help identify situations in which devices not intended to be used outside of a healthcare facility are being used in the home. In such cases, FDA may require that premarket submissions for these devices contain either labeling for home use and use testing specific to the home environment, or a statement in product labeling clearly indicating that the device is not intended for home use. For example, based on postmarket experience, FDA is sending a letter to manufacturers of negative pressure wound therapy devices, informing them that this type of information may be necessary to support clearance of these devices.

5. Increase Public Awareness and Education

FDA recognizes the importance of providing home care recipients, caregivers, and healthcare practitioners with information about potential safety concerns and steps to address them. FDA has already been actively engaged in outreach and education related to home use, and the agency will continue and expand this work.

FDA is launching a new Home Use Devices website, featuring information about using medical devices in the home, and strategies to reduce the risks associated with home use.[6] FDA has already developed three informational brochures about home healthcare: a home medical device checklist; an infusion therapy checklist; and a blood glucose meter checklist. These brochures are now available on the new Home Use Devices website.

FDA is developing additional resources to provide through its new website in the coming months, including a series of educational videos for healthcare professionals and caregivers to learn about medical devices and how they are used in the home environment. These videos will

[6] The new Home Use Devices website is available at http://www.fda.gov/homeusedevices.

be available by the end of 2010. FDA will also provide on its website a power outage booklet for care recipients to keep on their refrigerators. This booklet will give care recipients and caregivers one central place to look for all of their medical device information and the appropriate people to contact in the event of an emergency in the home.

In addition, FDA is collaborating with other organizations within and outside of the federal government to educate the home health community about medical device safety. FDA is working with the Centers for Disease Control and Prevention (CDC) to incorporate medical device training into the CDC's Healthy Homes training curriculum for community health workers. FDA is also working with the American Association for Homecare to educate providers, manufacturers, and others involved in home health about medical device safety and FDA's role with respect to home use devices.

Conclusion

The use of medical devices in the home continues to expand. Home use of medical devices has provided significant benefits to patients, including quality-of-life improvements and cost savings. However, home use is also associated with unique challenges and risks. Through the *Medical Device Home Use Initiative*, FDA is taking proactive steps to assure the safety and safe use of medical devices in the home.