Design Considerations for Medical Devices in the Home Environment

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Patient demographics, economic forces, and technological advancements contribute to the rise in home care services. Advanced medical devices and equipment originally designed for use by trained personnel in hospitals and clinics are increasingly migrating into the home. Unlike the clinical setting, the home is an uncontrolled environment with additional hazards. The compatibility of the device with the recipient's knowledge, abilities, lifestyle, and home environment plays a significant role in their therapy and rehabilitation. The advent of new device technologies such as wireless devices and interoperability of systems lends a new and complex perspective for medical device use in the home that must also be addressed. Adequately assessing and matching the patient and their caregiver with the appropriate device technology while considering the suitability of the home environment for device operation and maintenance is a challenge that relies on good human factors principles. There is a need to address these challenges in the growing home care sector. In this article, the authors take a look at some important considerations and design issues for medical devices used in the home care environment.

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There is a marked rise and growing demand for home care services; however, caring for a patient in the home environment is a complex matter.[1] A number of converging trends are beginning to focus attention on the challenges associated with home care.[2]

The aging population, with multiple care needs, is placing new demands on home healthcare and, as such, the home is now serving as a place where medical monitoring and therapies can take place.[2] Economic forces contribute to the rise in home healthcare services. Because of shorter hospital stays, beds in short supply, and staffing shortages, patients are discharged sooner, yet are still in need of care in order to recuperate, rehabilitate and recover from their illnesses and diseases. Also, people are living longer with chronic conditions that must be managed in their home. Home care can be a more desirable and affordable way for people to continue their recovery or return to their previous state of health.

Medical device technological advancements contribute to the challenge of ensuring patient safety in the home environment.[3,4] Sophisticated medical devices and equipment originally designed for use in hospitals and clinics by trained personnel are increasingly moving into the home. Unlike the clinical setting, the home is an uncontrolled environment with additional risks and safety hazards that need to be considered.[1,2]

The advent of new device technologies such as wireless communication and interoperability of systems lends a new and complex perspective for medical device use in the home that must be addressed. Even more difficult for healthcare professionals who provide home care are the difficulties they may encounter when matching patients, homes, and caregivers to certain types of devices. While emerging device technology is often developed to better cater to the user, this may not always be the case. New technology may, in fact, present new sources of confu-

sion for the user and provide more opportunity for error, especially when used in a home that may not be suited to accommodate this device technology.[2]

Variations also exist among patients and their home care providers in terms of knowledge (educational level), skills (cognitive ability), abilities (emotional stability and physical capability), and willingness to manage new technologies, all of which must be taken into consideration when placing a medical device into the home. Finding a suitable match among patients and providers, the related tasks required of them to perform, and the device technologies most appropriate for the care recipient is challenging.[2] Adequately assessing and matching the patient with the proper device technology while considering the suitability of the home environment for device operation and maintenance is crucial. The compatibility of the device with the care recipient's knowledge, abilities, lifestyle, and home environment plays a significant role in the recipient's therapy and rehabilitation.[2]

Home Care Environmental Considerations

The home care setting is a challenging healthcare environment for a variety of reasons. Many of the same well-defined healthcare risks—the spread of nosocomial infections, the development of resistant organisms, medicine errors, and device malfunctions—are also prevalent in home care.[5,6,7] However, the home environment is not controlled like the hospital environment. Consequently, care may be delivered under substandard conditions that may exacerbate the aforementioned risks.[1]

Environmental considerations include a wide range of issues, from safety hazards associated with the macro-environment to environmental concerns specific to the home, all of which can present a threat to patient and provider safety.[8] Many of these issues are addressed below.

Geographic Location

Home care patients and home health providers may be at risk of exposure to a range of unsafe conditions related to the macro-environment. Geographic location may impact the provider, caregiver, and patient's access to appropriate medical devices. Care in rural areas is more difficult than in urban areas due to few formal providers and inadequate staffing.[9] When out in the field alone, home care providers may encounter lack of supplies or back-up support.[8] Moreover, patients receiving care in rural settings may experience difficulty accessing supplies and seeking help if they experience a device malfunction. Power outages are a concern, especially during public emergencies, and many devices do not have back-up plans because they were not intended to be used outside of a clinical environment. Proximity to broadcast towers or other sources of electromagnetic interference (EMI) may also be a hazard, as several devices may malfunction or stop working in the presence of EMI radiation.[10] Operation at high altitude may have an adverse effect on the performance of ventilators and various kinds of pumps, or affect the heating and cooling properties of a wide range of devices. Exposure to direct sunlight may degrade materials, limit visibility of displays, or cause equipment to overheat.

Home Construction and Maintenance

Home construction and maintenance conditions can be a source for hazards. Excess moisture, whether caused by ventilation problems, plumbing or roof leaks, or groundwater intrusion can contribute to a number of health hazards, including mold growth and structural deterioration leading to vermin proliferation.[11,12] Settled and airborne dust may also be problematic; dust that finds its way into or onto a medical device may impact its ability to deliver patient care.[11] Ambient temperature extremes and poor indoor air quality in the home environment are especially important with regard to ensuring device safety and effectiveness. For example, faulty ventilation may contribute to condensation on medical devices in the home and, thus, may contribute to device malfunction. Mold may also result from high temperatures and may be present on a device.[11] Safe and effective medical device use in these conditions may be difficult. Using medical devices in unsanitary conditions such as these may pose more harm to the patient. Establishing safe cleaning and

FDA Home Use Device Initiative

The FDA's Home Use Device Website—www.fda.gov/homeusedevices—provides resources and information about medical products used in the home environment, as well as information about the agency's medical device home use initiative to improve the 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, as well as to provide more information for home care recipients and caregivers to support their safe use.

disinfection practices in the home setting to address these health hazards and potential device implications should be considered.

Older homes may lack the prerequisites for accommodating certain medical equipment or devices, such as three-pronged electrical receptacles with appropriate grounding.[13] Moreover, the structure or layout of the home may also present a risk to patients. Poorly designed stairs that do not have handrails pose a risk to patient safety in the home environment.[14] The transition from one floor surface to another is a challenge because the adjoining surfaces often differ in height. Home-bound patients with disabilities affecting ambulation often find these differences in height or texture difficult to navigate and may present a tripping hazard.[15] Older homes may have smaller doorways, hallways, and rooms which may not accommodate large medical equipment, thus impacting patient care.

Unsafe Conditions

Poor lighting has been shown to result in injuries, especially patient falls. While frail older persons experience higher overall fall rates, vigorous older persons experience more falls where environmental hazards such as poor lighting, clutter, and loose rugs are present.[14,16,17] Sometimes, these conditions may result from the inability of patients to maintain a safe and orderly household.[18] Inadequate lighting can also make it more difficult for a patient or caregiver to see and operate a medical device, more specifically device screen displays with varying contrasts.

There is a lot of ambient noise in the home environment, for example, vacuums, televisions, telephones, and even noise from people arguing. Outside noise is also common, for example, trash trucks and ambulance sirens. All loud noise can interfere with the ability to hear whether or not a medical device is operating correctly or whether an alarm has sounded.

It is important to consider all these environmental issues when designing medical device technologies for patients receiving home care. Manufacturers are encouraged to consider the new international home healthcare standard IEC 60601-1-11:2010: *Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*[19]

Home Users and Human Factors

With the migration of medical devices into the home, the responsibility for safe use is relegated to either patients or their caregivers. Caregivers, apart from home healthcare professionals, are frequently patients' family or friends who are usually lay persons not acquainted with the intricacies of these devices. Home medical devices are therefore in the hands of a diverse group of individuals with different educational levels, cognitive, and physical capabilities.

Factors that impact competence in operating these devices include literacy, dexterity, vision, hearing, learning ability, memory, training, experience, and language barriers. In addition, difficulties may be experienced using certain devices because of advanced age, medications, or the actual medical condition that requires use of the device. For instance, the labeling on the device may be too small for users with weak eyesight, or may contain unrecognizable symbols. The buttons on the console panel may be too small for some users. The equipment may be placed on an existing piece of furniture or on the floor, limiting users' access to the display and controls. The back lighting on the display console may not be adequate for dimly lit rooms.

These and other such concerns need to be addressed when providing a safe and ergonomic design for the device. Manufacturers should consult human factors experts when designing their products if they do not have access to in-house expertise on the topic.

Device design should focus on the users' abilities, limitations, and operating environments. The design should accommodate users with various levels of expertise, reduce user error, and require less operator training. The device should include well-organized, intuitive, and uncluttered control and display arrangements to provide proper identification and reduce the user's memory load. There should be adequate intensity and pitch of auditory signals and screen displays should have sufficient brightness and color contrast to optimize legibility. Devices should be sized for mobility and constructed from durable materials to withstand accidents. The user should be able to identify controls, switches and displays, reach and accurately set controls, and read displays accurately. The design should include patient alarms and therapy monitors to help ensure that patients use them correctly.

Device Migration

Medical devices migrating into the home may be legacy devices, (i.e., older devices that are being replaced in clinical facilities by newer versions), devices purchased directly from previous owners, Class II prescription de-

vices, or Class I over-the-counter devices. The majority of the devices in Class II have not obtained U.S. Food and Drug Administration (FDA) clearance or approval for home use, as it isn't required unless the manufacturer specifically indicates that the device will be used in a home setting. Examples of these types of devices are infusion pumps, peritoneal dialysis, ventilators, and apnea monitors. Class I devices are typically found over the counter and usually come with patient labeling. However, this labeling is not thoroughly reviewed by FDA and may be confusing or difficult to read by the lay person. Examples of these types of devices are exam gloves, toothbrushes, and non-powered wheelchairs. In addition, existing labeling and instructions may be either missing or are not intended for non-clinical users. Users may not be equipped with scientific, clinical, or engineering expertise to independently evaluate the safety and effectiveness of the devices they use.[20]

Migration of more complex devices, such as ventilators and infusion pumps, into the home increases the need for training and education of providers at all levels. Training material should be provided to both end users and healthcare professionals. Clinicians should also be given instructions for training home users in the correct use of the device. Continuing education is essential for healthcare professionals to keep them well-informed and to make the consumers aware of how the devices should be used.[21]

It is widely recognized that the home represents a growing market for medical devices.[18] This growth affords the opportunity for manufacturers to develop mitigations for many of the unique hazards posed by home use. For example, remote monitoring and control features and enhanced event logging features might be provided to facilitate troubleshooting and intervention by distant clinical or technical support professionals.

In addition to a growing market segment of devices designed specifically for the home, we see the emergence of clinical devices that are programmable or configurable with a simplified user interface and/or reduced feature set appropriate for the home use environment.

As these more specialized devices, with their additional mitigations of risk through human centered design, become more widely available, the use of legacy devices that lack these features may become increasingly unacceptable.

Device Labeling

The focus of device labeling should be towards the users. Labeling information should be written based on the skill level of the expected user and include details of what the user will see, hear, and feel with use of the device.[22] If in-house expertise is not available, manufacturers should consult experts when designing user material. Labeling should be supplied to patients or their lay caregivers for devices used in the home care settings.

Consumer material, whether in electronic or booklet format, should be written in plain language. Information should be organized according to the type of illness or function with illustrations made in color photographs, and/or diagrams, and/or symbols. Manuals should be printed with large type, viewable by users with various sight impairments. Manufacturers should ensure that there is compliance under the American with Disabilities Act. These materials should be easily available from healthcare practitioners, hospitals, home care agencies, book stores, pharmacies, libraries, and even newsstands.[21]

Emerging Technologies

Technological advances have enabled medical device migration into the home. Traditionally, medical devices have been designed to operate in a stand-alone manner. However, recent years have seen a growth in their ability to communicate information, allowing them to interoperate with other systems. It is becoming common to find network technology and the use of the Internet included in medical device designs. These technology trends have the potential to deliver many advantages in patient care such as patient health context awareness, reduced medical errors, and improved patient safety. However, poor device design can negate these advantages or bring to light deficiencies through complaints or Corrective and Preventive Action (CAPA) processes.

In a home care setting, technology provides the ability to easily link patient connected bedside medical devices to a single monitoring device or a computer network, thus facilitating the efficient exchange of medical device information and vital signs to and from the healthcare facility. Home monitoring systems regularly and automatically deliver data on blood pressure, heart rate, and glucose levels over the network to databases that physicians can access.

While there are obvious benefits offered by networked medical devices, this evolving technology raises new safety issues that must be considered when using these in a home care environment.

Information Security

Information security affects both the safety and privacy of home use patients. The term information security includes protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction (44 U.S.C. § 3542).[23] Often, when a patient is cared for in the home, information regarding their treatment is transmitted to a primary healthcare facility. This information may include the patient's profile, electronic health data, and billing information. When such confidential data is transmitted outside the home, it must be done in a manner that is both reliable and secure.[24] Measures need to be incorporated to ensure that these transmissions conform to security standards and protocols at the system, infrastructure, and device level.

Network Communication

Major considerations for devices using network technology include availability and response time. A networked device, when in use, may rely on the assumption that the network is reliable and available as and when needed. If the network connection is slow or broken, the device might be unable to send and receive data in a timely manner. Devices that use the network to transmit or receive actuation commands may malfunction if they do not have the provision to revert back to a default manual mode.

Security is another pressing concern when sensitive information—patient data, actuation commands, alarm information—is exchanged.[25] If this data is captured by malicious entities, it may lead to a breach in patient privacy or cause safety hazards such as an unwarranted device actuation. To prevent such attacks, authentication, confidentiality, integrity, and authorization must be provided for all actions during data communication to ensure that individual devices on the network are not compromised.

Wireless networks present additional challenges such as transmission interference from home appliances or other nearby medical devices. EMI can be caused by 802.11b and 802.11g wireless devices, Bluetooth devices, baby monitors, cordless telephones, and microwave ovens.[26] Poorly designed or defective electrical components such as light dimmers, switches, and doorbell transformers may also become inadvertent EMI sources. EMI from any of these sources can affect medical devices by disrupting their function and may pose significant risks to the patient or device user.[10] Important means of reducing EMI include the use of bypass capacitors and voltage filtering. Manufacturers also need to carry out tests for radio frequency (RF) immunity of the parts to be used in the system to provide protection from EMI radiation.

Device to Device Interoperability

An emerging technology destined for the home care environment is device interoperability. Interoperability refers to the capability of two (or more) devices (or systems) to exchange data and control their device's functions. If one or more devices drop out, it could result in the system breaking down, or endlessly waiting for information from the missing component. On the other hand, if two or more devices vie for the same resource at the same time, it could lead to a deadlock or race conditions. Interoperable devices and systems need to have a degree of robustness to handle such situations and must ensure the integrity of communication between devices.[27]

Authentication mechanisms must be provided to ensure that a device is on the correct network. Moreover, since interoperable systems could get very complex, intuitive and simple user-interface designs need to be incorporated in these devices to communicate to the user any audio/visual alarms and display messages for individual devices in the system.

Another important consideration when deploying an interoperable system in the home is ownership. A

Adverse Event Reporting

Manufacturers, healthcare professionals, and home users all play a part in reporting adverse events related to medical devices to the FDA. Manufacturers need to ensure that all adverse events are correctly reported through FDA's MedWatch Medical Device Reporting (MDR) reporting program. Healthcare providers should also report adverse events to the manufacturer and to the FDA according to their organization's general adverse event reporting protocols. Healthcare workers, informal caregivers, and patients are encouraged to voluntarily report medical device malfunctions, problems, complaints, potentially harmful events, as well as adverse events directly to the FDA. Voluntary reports can be submitted by calling the FDA at 1-800-FDA-1088 or by mailing in the MedWatch 3500 form, available online at: http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf.

person must be identified for maintaining the system or individual components in the system. This could be the device (or component) provider, the primary healthcare professional, or even the home care provider. In each case, sufficient training should be imparted to provide maintenance and regular upgrades to the system.

Summary

As medical devices migrate to the home, manufacturers need to take into account additional hazards and safety considerations to ensure patient and caregiver safety in this new environment. In this article, we have discussed some typical hazards related to the home's physical environment, human factors issues, and the impact of technological advances on home healthcare. This is by no means a comprehensive list. More research in this growing field is necessary.

Manufacturers need to address all foreseeable risks and hazardous situations when designing devices intended for home use as well as review existing standards related to home care and human factors device design. Regulators, for their part, need to ensure that adequate risk control measures have been implemented and that the device is sufficiently labeled and documented for home use. With due diligence from manufacturers and regulators, we can make the home a safer setting for healthcare delivery. ■

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