

Human Factors in Labeling and Training for Homecare Technology

Patricia A. Patterson

In this article, Patricia A. Patterson, a contributor to the recently-released standard ANSI/AAMI HE75:2009 Human factors engineering—Design of medical devices, highlights information from the standard important to developing labeling and training for homecare devices. She also describes one approach to developing labeling and training materials.

According to The National Association for Home Care & Hospice, annual expenditures for home healthcare have surged past \$50 billion.¹ Jeffrey Shuren, MD, director of the U.S. Food and Drug Administration’s (FDA’s) Center for Devices and Radiological Health (CDRH), says “What we are seeing is an explosion in home healthcare.”² Yet consumers are often poorly prepared to use homecare technology. One source of this problem is the fact that manufacturers are often migrating devices from professional clinical environments to home use without the requisite changes in design, labeling, and training to make them safe, effective, and accurate in the hands of lay patients and their caregivers.

AAMI recently released HE75:2009, *Human factors engineering—Design of medical devices*.³ With this new standard, AAMI has raised the bar for manufacturers, emphasizing that human factors analysis and testing needs to be incorporated into the product development process for medical devices, including homecare devices.

The FDA considers device labeling (also called “user documentation” in HE75) and training as part of the user interface. As such, these components need to be given the

same analytical, data-driven attention as the device itself. While there is no substitute for a well-designed device, instructions and training materials are as critical to safe and accurate user performance as other user interface components.

So how can manufacturers develop labeling and training materials that meet the needs of the diverse and growing population of homecare device users? One approach is performance-based labeling and training. Performance-based labeling and training is derived from examining what the user needs to accomplish using the device and the requisite skills and knowledge to achieve that outcome.

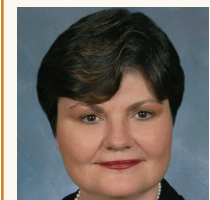
Traditional training and educational methods ask the question, “What does the user need to know?” A performance-based approach asks the question, “What does the user need to produce?” The first question often results in lots of content about the device that is then evaluated based on individual opinion. The second question is more likely to result in information that is designed to support user performance when and how they use the device and is evaluated based on measurable performance criteria.

Different Users, Environments: New Risks

The use of complex devices in the home environment can represent a serious health risk for patients. From 1997 through 2009, the FDA says it has received more than 19,000 reports of adverse events including fatalities involving medical devices used in homes.⁴

First, it’s important to understand what type of people use homecare devices. Data from the National Association for Homecare (2008)¹ suggest that the home healthcare population numbers 7.6 million individuals and is growing by 20% per year. Of these, 75% receive skilled nursing care and 69% are over 65 years old. Forty-four million people are caregivers of someone over the age of 18. Two-thirds of these lay caregivers are women.

Chapter 25 of HE75 is titled “Home Health Care” and provides an introduction to the issues involved in medical



ABOUT THE AUTHOR

Patricia A. Patterson is a certified performance technologist and president of Agilis Consulting Group, LLC. She is a contributor to HE75:2009, *Human factors engineering—Design of medical devices*, and a member of the new AAMI Home Healthcare Committee, AAMI/HA Medical Devices and

Systems in Home Care Applications. Email: ppatterson@agilisconsulting.com

device use in the home environment, including general considerations, design guidelines, and an extensive list of references on the topic.

According to HE75, the typical user of a homecare device is a 75-year-old woman caring for her 72-year-old spouse who has visual and auditory limitations due to age-related deterioration of vision and hearing; is weakened by age-related decreases in muscle strength; has various infirmities and disabilities such as arthritis or diabetes (over 50% of the elderly have at least one disability that interferes with carrying out activities of daily living); has no education beyond high-school education; has some memory problems and needs more time to learn new tasks than someone younger; is under stress due to her husband's condition and the associated changes in the home routine; and has limited support available should difficulties arise during the care.

Users of homecare devices, whether patients or caregivers, are obviously not trained medical professionals and are using devices in environments that differs greatly from a medical facility. Specifically, risks in device application arise from:

- Users' emotional instability. Users experience stress due to illness or worry about learning to use a new device. They can be fatigued or distracted.
- Different and often limited educational backgrounds, questionable literacy, and native language capability. Conversely, some lay users may feel more equipped to operate a complex device than is appropriate.
- Limited cognitive and physical capability. Particularly older users may have inconsistent memory or cognition. Medications can interfere with cognitive abilities (drowsiness, etc.). Users of all ages may use devices without having received sufficient advice, support or training, particularly when they purchase devices over the Internet or receive them as a gift from a private party.

In addition to individual variables, environmental conditions may interfere with safe, accurate device use. HE75 summarizes the challenges:

Homes differ significantly from the clinical environments for which many medical devices were traditionally designed. Among the environmental characteristics that could differ are the following:

- *Homes have fewer electrical fixtures than health care facilities, and these fixtures might not comply with building codes normally enforced in health care facilities;*

- *Ambient lighting may be lower than in institutional environments;*
- *Homes are usually quieter than institutional environments, and their occupants expect less noise;*
- *Stairs and carpeting could be barriers to the portability and/or maneuverability of medical devices;*
- *Children and/or pets in the home could pose issues for security. A medical device might require additional protection against inadvertent operation.*
- *It might not be easy for caregivers to receive assistance or technical support for medical device failures or malfunctions.*

The greater variability of home environments vs. institutional environments, with respect to these factors, and a host of others, including humidity, temperature, air quality, and cleanliness, must be considered in the design of medical devices to be used there.

It's also important to note that patients and caregivers can also use the devices in moving vehicles, on airplanes, in hotel rooms, schools, department stores and other variable, uncontrolled environments that may not be conducive to confident application.

HE75 cautions that:

Because of the nature of the user population and health care in the home, this recommended practice's specific design guidance should not be followed blindly. Doing so could result in design solutions that are unacceptable for home care. The problem should be managed in two ways: (a) use of design data specific to the home user population; and (b) extensive human factors testing of medical devices being designed for the home care market, with an emphasis on those elements for which home-user-based design data are not available.

Clearly, the number of variables increases dramatically once devices migrate to a home environment. Consumers may not be able to interact safely and confidently with homecare devices unless individual and environmental risks are taken into account in the development of labeling and training.

Labeling and Training for Home Use Devices

Home care users have very different information needs because they are not professional clinicians. In addition, they don't operate in a sterile, controlled setting. Manufacturers often view technology as the solution to everything, but medical devices are not cell phones. Pressing the wrong button on a new cell phone may result in a dropped call. Pressing the wrong button on a medical

device may prove harmful to the user.

The FDA requires that every device intended for use by a layperson has to have a printed “user guide,” also called “instructions for use.” Manufacturers are not permitted to rely on users having access to a computer; a passive video on a manufacturer’s website is not considered training. Some manufacturers add a “quick reference guide” to the print material. Face-to-face or interactive electronic training may also be needed for certain devices, whether required by the FDA or volunteered by the manufacturer.

According to the FDA, the primary responsibility for measuring and monitoring the quality of homecare medical devices lies with the manufacturer. To ensure labeling and training are effective in supporting user performance, they have to be “validated.” That means they have to be tested and proven effective with members of the actual user group before the product is launched, even before it is submitted to the FDA for marketing approval.

In *Analysis of a “Simple” Medical Device* (Ergonomics in Design, Winter 2001),⁵ Wendy A. Rogers et al. analyzed a blood glucose meter whose accompanying videotaped instructions stated that “It’s as easy as 1, 2, 3. Simply set up the meter, check the system, and test your blood.” It turned out that implementation of those three steps required 52 user subtasks! Another commonly used meter required 61 subtasks. The authors stressed the critical importance of well-designed training programs and instructional materials, following instructional system design models. Among their suggestions for manufacturers were to ensure that: readability levels are appropriate for the intended user population; vocabulary is simple and explicit without jargon; information does not require users to draw inferences; and that numbered steps describe procedures in the same order they need to be executed.

HE75’s Chapter 11 on “User documentation” explains that:

Verification of user documentation includes activities and processes that ensure that the documentation material has adequately covered all aspects of required device interaction and that nothing has been omitted. Validation refers to processes that evaluate the documentation for effective and safe use by device users. Verification answers the question, “Is the documentation complete and correct?” while validation focuses on the question, “Is the documentation useful to the user?” The review team should include members who are independent of the device design team.

Often, the marketing staff, engineers, or researchers who develop the printed materials to accompany devices have little or no background or expertise in writing instructional materials to guide performance in a safe, effective, and predictable way. HE75’s “User documentation” chapter sets high expectations for the efficacy of instructions and training. It states that:

“During the Design Output and Review process, documentation prototypes should undergo a heuristic review process by a team of experts, including training and instructional design personnel involved in clinical education. Heuristic reviews can be augmented by cognitive walk-throughs with users if a device prototype is also available... Users are asked to perform critical tasks with the device prototype and refer to the documentation (e.g., quick reference guide, early-concept manual, etc.) as they perform the tasks. These formative evaluations can uncover critical issues that can be eliminated or mitigated to enhance user understanding of the written and graphic material before the documentation proceeds to production-level design stages.” (emphasis added)

In the past, many manufacturers tested instructions, if at all, by relying on computerized assessments of grade reading levels and multiple-choice tests. Now HE75 emphasizes the importance of observational testing of training materials and user guides to validate the utility of the material in performing user tasks. Medical devices cannot be evaluated based on user preference or popular design like consumer products. Manufacturers cannot afford to rely on trial and error by users, and users cannot afford to make mistakes; users’ lives might be at stake.

One Approach: Performance-Based Labeling and Training

Performance-based labeling and training is a subset of the discipline of human factors engineering (HFE) called human performance technology (HPT). HFE is the study of how users interact with a technology and information, and how the user interface supports safe and accurate user performance. HPT focuses on the user’s information needs and how best to help users access and acquire the skills and knowledge that will support safe and accurate performance.

Performance-based training is training that is designed to support cognitive and manual user performance interacting with a device. A performance-based approach to labeling is driven not by the device. Rather, it is driven by what the user wants to accomplish when interacting with the device. The emphasis is on the device in the hands of

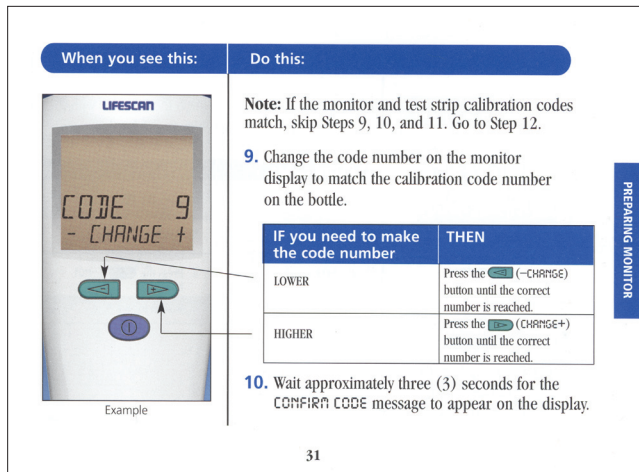


Figure 1. Sample device labeling. Better instructions make both sequential and decision-making behaviors overt and easy to follow.

the user and how the labeling supports that interaction.

Specifically, the performance-based approach aims to:

- Teach people how to use a device in the context of achieving their goals (desired medical outcomes), given their situation.
- Design information based on users’ goals and limitations and deliver it according to how they will access and use it.
- Give people easy-to-use, easy-to-follow instructions they can use real-time with the device. It asks, how does this information (labeling or training, whether printed or in the form of audible instructions) support safe and accurate user performance?
- Focus on users’ performance and satisfaction as they use the device.
- Use a scientific, systematic, repeatable process and the best empirical data available on how people process information.
- Base evaluations on measurable performance criteria.

Performance-based labeling and training generally follows these six steps:

1. Identify who will use the device.

In this case, know the homecare population and its environment.

2. Carefully design how people will learn to use the device.

Traditional device-centric approaches are typified by headings that read “How the Device Works,” “How to Use the Device” and “How to Troubleshoot the Device.” The crux of performance-based labeling and training is describing the user’s performance requirements, analysis,

observation, and formal usability testing. This begins with a task analysis, a technique that captures the skills and knowledge the user will require when interacting with the device. The task analysis expresses in precise behavioral terms what the user is expected to perceive (see, hear, feel, etc.), comprehend or understand, and physically manipulate (press, move, insert, touch, etc.).

3. Conduct usability testing of labeling early and often as an objective method to assess the efficacy of the information.

There is no shortcut to an objective, observable assessment that answers the simple question: to what extent does the labeling help users execute the task?

4. Identify the types of errors users can make and the consequences of those errors.

What in the labeling might confuse consumers? What might they misperceive? I participated in a recent usability study on a blood glucose meter which found that people who thought they were setting the device “clock” time were actually setting the time for a reminder alarm. No amount of conference-room reviews by the program team will find these types of errors. Only testing the labeling and the device in the hands of actual users can reveal them.

5. Understand how the labeling and training can mitigate use errors and facilitate users’ ability to learn how to use devices.

Write materials at a level of detail that minimizes trial and error. Deliver labeling and training in a format that aligns with the expected performance. For example, most devices require the user to perform both sequential (step by step) and decision-making (if this then do that) behaviors. Yet the instructions often appear to be sequential with important decisions embedded within paragraphs. Figure 1 offers a better alternative by clearly numbering each step and calling out important decisions.

6. Ensure consumers’ experience with the device is a pleasant one.

The tendency is to give people a wealth of information in all different formats—printed manuals, videos, audio tapes, websites, CDs—with the assumption they can pick and choose what they like. In reality, too much information only overwhelms them. The focus should not be on quantity, but on quality of information.

What happens when manufacturers don’t incorporate labeling and training into the development process from the start? The project team can be rushing to meet its FDA submission date only to discover the accompanying

Horizons Extras

Want to read more on this topic? See the online Home Healthcare Horizons at www.aami.org/publications/horizons/index.html for interviews with Mary Brady, Chair of the FDA's home healthcare task force, and the University of Washington's George Demiris, chair of the human factors special interest group of the American Telemedicine Association and the lead convener of the technology and aging group of the Gerontological Society of America, on human factors and labeling issues.

labeling is out of date with the device and has never been tested.

Training materials need to be integrated and aligned with each other. Since every device requires a user guide, wouldn't it make sense to develop it first and have it be the basis for any additional labeling and training? It's simple and effective. It means less rework, less redundancy, and less use error.

Looking Ahead

Development of labeling and training needs to be integrated into the product development process. It is equal in importance to human factors analysis, quality, and risk assessment. It should be, and can be, integrated from the start.

HE75's introduction to user documentation states that "The planning and designing of documentation should begin with initial product design," and that, "... documentation, including user documentation, must be

developed as part of the overall user-interface design and must be evaluated as a part of the overall risk management with regard to its usability and mitigation of use-error risk."

The use of technology in home healthcare will no doubt continue to grow. As people live longer and medical costs rise, home care is evolving into a major driving force in the healthcare arena. This opens a huge market for manufacturers, but also brings tremendous new risks. To ensure safe and effective outcomes for home care device users, manufacturers need to understand this new population and its unpredictable environment, and design equipment—including labeling and training—to meet those needs. ■

References

1. The National Association for Home Care & Hospice (Updated 2008) *Basic Statistics about Home Care*, Washington, DC: Centers for Medicare & Medicaid Services, Office of the Actuary (January 2008).
2. Dooren, JC. FDA Pushes Oversight of Devices. *Wall Street Journal*, April 20, 2010. Available at: <http://online.wsj.com/article/SB10001424052748704671904575194310283186290.html>.
3. Association for the Advancement of Medical Instrumentation. ANSI/AAMI HE75:2009, *Human factors engineering – Design of medical devices*.
4. Food & Drug Administration, Center for Devices and Radiological Health, Medical Device Home Use Initiative, April 2010. White paper: Ensuring the safe use of medical devices used in the home. Available at <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/UCM209056.pdf>.
5. Rogers, WA, Mykityshyn, AL, Campbell, RH, & Fisk, AD. Analysis of a "simple" medical device. *Ergonomics in Design*, 2001:9, 6-14.