



Safe Medical Product Use:

Six Steps to Minimize the Risks of Homecare Medical Product Usage

By Patricia A. Patterson

In June 2002, the Food and Drug Administration (FDA) held meetings to discuss safety and effectiveness issues for medical devices used in the home environment. Summaries of these meetings reported universal dissatisfaction with the quality of instructional materials for home use medical devices, and concluded that training and labeling for homecare customers are woefully deficient. At

the same time, William Herman, director of the division of physical sciences in FDA's Center for Devices and Radiological Health (CDRH), which regulates medical devices, calls homecare systems "the fastest-growing segment of the medical device industry." Given the growth of homecare devices and their expected role in improving healthcare while reducing costs, this seems a good time to examine why current labeling efforts are failing and consider a possible solution.

What Is Wrong with Traditional Labeling Approaches?

Almost everyone agrees the fundamental purpose of labeling is to help people use a product. Yet, when manufacturers are asked what value they get for their labeling investment, mandatory or not, the response is often shrugged shoulders and a quizzical look of "who knows?" Research on labeling efficacy suggests the correct answer is "not much." Spend an hour simply observing what happens in a typical customer support service department, and you will hear representatives conducting repetitive and time-consuming mini-training sessions with customers who have difficulty learning to use devices. If nothing else, it is a sure sign something is amiss with instructional materials when manufacturers are paying double duty—first for ineffective labeling design and then for the same instructions to be given over the phone. What about the customers who don't bother to call?

The traditional labeling approach presents four areas of concern:

- Labeling content focuses on the device, not the user.
- Design of instructional information is not aligned with how people read, interpret and use information.
- Content is written with an insufficient level of detail to minimize trial and error and reduce misuse.
- Early user manual drafts are not subjected to frequent, small-scale usability or performance tests.

Inadequate homecare medical device labeling may mean customers cannot or will not take advantage of a product's advanced features, in some cases nullifying its competitive advantages. In other cases, frustrated customers simply abandon the device altogether. Even worse, people can make mistakes that lead to injury or death. Inadequate labeling represents a cost to everyone and produces value for no one. There is a better way.

Six Steps to a Better Labeling Approach

A better approach to labeling is one that uses a performance-based method guided by how people read, interpret and use information. A performance-based approach to labeling is not driven by the device; rather, it is driven by what the customer wants to accomplish when interacting with the device. The emphasis is on the device in the hands of the user and how the labeling supports that interaction. This shift in emphasis from device to human has proven to yield marked differences in device use accuracy, satisfaction and after-sales support costs.

Performance-based labeling can be achieved by implementing these six steps:

1. Identify who will use the device. Although manufacturers work with user demographics, the profiles they generate may not take into account how users' physical and cognitive abilities can impact their interaction with the device. For example, if the device is intended for people with diabetes, labeling and instructional materials (print and online) should accommodate possible visual impairment. Devices intended for global sale need to consider the use of icons and how meanings can vary between cultures. Further, consider the fact that people using the device may be on certain medications that impact their ability to interpret and apply complex information.
2. Carefully consider how people will learn to use and remember to use the device. Traditional training approaches are device-centric rather than human-centric. 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.¹ 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.)²

The task analysis is the backbone for both the labeling and any additional support training

that might be needed. For example, a nagging question in labeling is what to include and what to exclude. Has anyone ever wondered how a relatively simple device can spawn a 200-page user manual? A task analysis helps demystify this issue. In general, if users cannot perform the task without the information presented, then include it. If they can, then either omit it or put it someplace else. Determining whether they really can or cannot execute the task based upon the information presented leads to the next step in minimizing the risks of homecare medical product use.

3. Conduct labeling usability testing “early and often.” A focus group with diabetes educators discussed the question of how long it takes a patient to become self-sufficient when using a new insulin pump. The general response was two to three months. No one challenged whether or not this learning curve could be improved. It was simply accepted as a given.

Producing labeling can sometimes be described as the creation of endless drafts, culminating at the final deadline for submission to FDA. Along the way, drafts are discussed among project team members, reviewed internally and often submitted to a focus group. The latter usually involves asking people to read sections of text, answer questions and offer their opinions about the text’s clarity. While these activities are useful, none substitutes for an objective, observable assessment that answers the simple question: to what extent does the labeling help users execute the task? Incorporating this type of hands-on performance test early in the drafting phase is the surest way to avoid the 200-page user manual. Testing usability early and often may only require one or two target audience members. More formal usability testing will come later in the product development process, but early testing can save time and money.

There is a common assumption that people do not read instructions; so, aside from the fact that they are mandatory, why spend so much time on the process? The real question is: why don’t people read them? People will not obediently march through information that is not immediately useful. The cornerstone of usability is, “don’t listen to users; observe them.” Careful labeling usability testing nearly guarantees users will find the end product valuable in achieving

their goals. In addition, FDA is now looking for evidence of systematic human factors analysis throughout the product development process.

4. Describe the types of user errors and their consequences. In January 2006, FDA launched a new post-marketing medical device safety program. The Post-market Transformation Initiative aims to more quickly identify, analyze and respond to problems in the field. It also is intended to alert the public to potential device problems faster. CDRH Director Daniel Schultz explains, “With this initiative, FDA intends to improve the way it monitors the safety of medical devices and provide a strong safety net to protect the public health.” If the best defense is a good offense, it makes sense that pre-launch is the time to investigate how labeling and training could impact use-related errors.

What labeling item might confuse consumers? A recent usability test showed that most participants found terms commonly used in the clinical environment, such as “monitor” and “review reports,” confusing. What might users misunderstand? Use-related labeling errors can be classified as either active or latent. Active errors have immediate consequences and typically cause more significant incidents. Latent errors set the stage for later accidents, often separated by time and space from the loss and injuries they cause. Latent errors have been called “resident pathogens” because they lie dormant until the conditions are right for them to cause problems. For example, failure to confirm the linkage between two wireless device components could mean the user gets someone else’s readings. Usability testing can help identify and mitigate use-related errors in ways focus groups and committee reviews might never do. Remember, FDA expects manufacturers to explain how they systematically identified, removed, controlled and tracked use errors.



5. Describe how labeling and training can mitigate use errors and facilitate users' ability to learn to use devices. First, materials must contain sufficient detail to minimize trial and error. In attempting to make something seem easy, manufacturers have a tendency to omit detail that is necessary to avoid problems. Following a study of blood glucose meters, Rogers et al. 2001³ reported that one meter's videotape training claimed that using the meter was "as easy as 1, 2, 3," when, in actuality, users had to perform 52 steps to set up the meter, check it and test their blood. "With 52 total steps for calibrating, testing, and using the meter, there are many opportunities for error," the authors stated. Further, when they analyzed text content to determine whether it might contribute to user error, they found that approximately 23 million people aged 25 or older in the US would not be able to read and understand the materials provided for the meter's test strips, which were written at a ninth- to tenth-grade reading level.

Second, labeling and training must be delivered in a format that aligns with the expected performance. Do not mix "how-to" information with "why-to" information or "about the device" commentary. Second, very clearly specify what information users must understand in order to use the device safely—what they must have memorized because there will be no time to look it up. In labeling and training, life-saving facts about the device need to be treated differently from information of secondary importance or for reference purposes only.

6. Ensure consumers' experience with the device is a pleasant one. Manufacturers tend

to give people an abundance of information in varying formats—printed manuals, videos, audio tapes, websites, CDs—assuming users will pick and choose what they like. In reality, too much information only overwhelms them; they have no idea where to begin or what to use in a given situation. The focus should be on quality, not quantity of information. For example, many consumers prefer to keep the use of a wearable medical device private. Maintaining privacy requires fluent use of the device, where fluency is defined as accuracy plus speed. Good labeling supports accurate performance. Performance-based labeling supports fluent performance by focusing on the users, including their goals and limitations.

Similarly, manufacturers often assume people like videos. Actual user interviews have proven this to be false. Unless video is required to teach a specific performance, in general, people prefer simple text.

If multiple pieces of information are necessary, at least, make them consistent. Make sure the meaning of a word is the same from one citation to another. Finally, ask whether the information helps facilitate safe, fast, easy, successful, first-time performance. Are people able to learn how to use the device easily the first time? If so, chances are they will like the device, describe it as well-designed and helpful, and recommend it to others rather than abandoning it for a competing product. If, on the other hand, the device is cumbersome to set up, learn and use, their first impression will be negative.

At a recent conference of the Association for the Advancement of Medical Instrumentation (AAMI), Peter Carstensen, Senior Systems & Human

A Performance-based Approach Lowers After-sales Support Costs

LifeScan Inc., a Johnson & Johnson company based in Milpitas, CA, used a performance-based approach in developing its Harmony INR monitoring system (a homecare device for measuring the blood's clotting ability), including labeling and training materials. When training efficiency and effectiveness were measured in a 36-month clinical trial, which also focused on the Harmony owner's booklet, 68 patients who completed the study were able to produce accurate test results, within +/-0.5 units of lab results, 97% of the time, with no additional training. Considered as a group, these patients had no experience using a medical self-testing device, no prerequisite skills or knowledge and no consistent reading or language skills. The marketing manager estimated that this level of accurate, first-time performance could help reduce Harmony after-sales support costs by as much as 60%.⁴

Factors Engineer of FDA's CDRH, stated that more than one-third of medical device incidents involve use error and more than half of recalls due to design problems involve the user interface. The increasing use of computers and application of convergence technology in home-use devices will add complexity and new issues for the user interface. Implementing the proper procedures now for instructional material usability testing will give manufacturers a head start in dealing with future complexities.

Do No Harm

The medical profession's Hippocratic Oath dictates, "Above all, do no harm." When instructional materials do not support patients' actual device use, they can cause great harm. That is why, according to its new Human Factors Initiative, FDA expects manufacturers to conduct usability testing of both devices and the accompanying instructional materials upon which users will rely for safe device use. Consumers, themselves, are becoming increasingly selective in purchasing homecare devices. Many publications, such

as *Consumer Reports*, and websites compare competing devices and provide feedback on ease of use and degree of satisfaction. For better initial use experience, lower after-sale delivery costs and FDA's approval, performance based instructional materials are the answer to safe and efficient devices.

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