

# Home Alone: Designing Information for Device Users

Understanding how patients interpret instructions can help manufacturers design better labeling and improve customer performance and satisfaction.

*Patricia A. Patterson*

In 2002, FDA held a series of meetings to address the safety and effectiveness of home-use medical devices. Based on those sessions, the agency concluded that current labeling and instructional materials are inadequate for home use and may be difficult for patients to understand. Furthermore, it determined that medical device manufacturers should carefully consider whether training and education are necessary for the average person to use their devices.

Manufacturers must consider the goals, needs, and limitations of the patients or caregivers when they create medical device labeling. Home users are often overlooked because the manufacturers are focused on device technology. By listening only to medical professionals involved in recommending or prescribing a device, manufacturers fail to understand that users interpret and apply application information differently. For example, one person described her learning experience with an insulin pump as “trial and error, mostly error.” Another person said that while it took him only

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**A woman checks her blood pressure at home. Manufacturers must consider patients' limitations when creating device labeling.**

two weeks to learn how to use the pump, three months passed before he experienced the promised benefits. This is a long time for patients to wait for their quality of life to improve. In

fact, sometimes customers just abandon a product, try another product, or give up on treatment entirely.

Profits are often generated from sales of consumables rather than from

the devices themselves, as in the case of glucose test strips. Thus, patients abandoning devices can be costly to manufacturers. William Herman, director of the division of physical sciences in FDA's Center for Devices and Radiological Health (CDRH), calls home-care systems "the fastest growing segment of the medical device industry." To benefit this from growth, a different approach to both labeling and training needs to be examined.

## Traditional Approaches to Labeling

Traditional approaches to labeling and training stem from an educational- and knowledge-based model. Before a new device can be introduced into the marketplace, manufacturers must create the labeling and instructions. They often hire a team of people with marketing, advertising, communication, training, or graphic design backgrounds to generate these materials. Once the instructions are created, they are reviewed and edited many times based on the opinions of the team. The instructions are then placed into as many media as possible, including owner's booklets, videos, and Web sites, so customers can access the information in many ways.

Knowledge-based labeling relies on people being able to read, interpret, and apply information. Studies measuring the effectiveness of this information transfer conclude nearly all types of labeling are dismal failures. The fact remains that people interpret and apply information with a great degree of diversity. Changing the method of delivery by using different technologies does not improve the results because although the formats are different, the company is disseminating the same information.

The majority of manufacturers fail to use performance data that may be available through their customer support department. The customer support staff are the ones who interact with customers who have questions or difficulty using particular devices. One customer support manager described most of the calls about one device as the kind that called for reiterating the information in the owner's booklet. Unfortunately, he never reasoned that

the owner's manual should not generate questions; it should answer them. He observed that most of the firm's customer support staff were conducting training sessions on the phone. Not only does this situation indicate the failure of the current approaches to labeling, but also that every phone call unnecessarily consumes profits directly from that product's bottom line.

## Inadequate Labeling Causes Errors

For several reasons, the current approaches are failing, and, in turn, costing manufacturers greatly. Often, the information is not written for the intended user; rather it is written to the educational level of those who are knowledgeable about the device and medical technology.

Many factors contribute to how patients and caregivers alike interpret labeling information. Although performance-based labeling and information cannot fix all of the problems, this method can eliminate or minimize the impact of the following:

- Infirmities.
- High stress.
- Fatigue.
- Limited training.
- Insufficient sources of advice and support.
- Distractions such as children, other family members, or house pets.
- Level of education.
- Language differences.
- Literacy issues.
- Learning ability.
- Inconsistent memory.

One reason labeling-related user errors occur is that information is presented in such a way that it relies on people's memory. A study by the Communications Research Institute of Australia found that after reading a medicine label, only 18% of those studied could answer the question, "What can this medicine be used for?" Only 6% could answer, "When should you stop using this medicine?"

Other labeling-related errors result from presenting product-centric information. For example, headings such as "How the Device Works" or "How to Read the Display" can hinder a pa-

tient's understanding of the information's value. More patient-focused headings would be "How to Prepare for Your Test" or "How to Interpret Your Test Results."

Furthermore, many instructional materials are not designed to help the patient achieve fluency with the product. Fluency is achieved when the patient can, say, use a home testing device with both speed and accuracy. Most device instructions fail to provide ample opportunity for users to practice and to get feedback on performance.

Expecting patients to use a home medical device without providing a tutorial or some other method for becoming acquainted with the device can cause people to get frustrated and lose focus. This will create an increasing frequency of user errors, and the severity of errors will widen. Over time, customer support calls will either increase because people are experiencing problems, or decrease because patients don't realize they're using the device incorrectly or they have stopped using the device altogether.

## Labeling-Related User Errors

There are generally two types of user errors: active and latent. Active errors have immediate consequences, and typically cause some sort of major catastrophe, such as confusing two sets of results from a diagnostic test. These types of errors can lead to the administration of an incorrect and possibly fatal medication.

Latent errors occur on an ongoing basis. They may not be as readily evident as the cause of a loss or an injury, thus making them difficult to identify. They have been called "resident pathogens" because they lie dormant until the conditions are right for them to cause problems. It is a fact that many user errors occur and that labeling plays a part in creating these errors. Clearly, a different method of labeling is required.

## Application of Human Performance Factors

While the knowledge-based approach focuses on content and behaviors, it rarely considers why the patients are using the devices. Customers

have specific goals in mind when beginning to use a device, and their goals often reach beyond the physical operation of the device. Similarly, if a teenager wants to use the family car, teaching him or her how a combustion engine works and how to physically drive the car only addresses content and behavior. Yet, the ultimate goal is that the teenager arrive home safely, which requires a completely different level of instruction.

Customer goals are about quality of life, not just about using a device competently. Human performance factors analysis can define those goals in measurable terms, including all the steps required to effectively meet each goal. There are typically eight steps in using this approach:

- Describe the patient’s desired medical outcome using the device.
- Determine measurable success criteria such as time, accuracy, safety, quality, or cost.
- Describe the behaviors required for achieving successful performance, including both observable behaviors (i.e., what button to push) and the more challenging nonobservable behaviors (i.e., deciding if the test result is accurate).
- Decide where the patient should access information. Here there are basically three options:
  - Expect the patient to memorize the instructions.
  - Make the information available in an external resource such as paper or electronic storage.
  - Store the information using some combination of memory and external storage. (For example, devices that require the patient to perform a behavior very quickly, literally in seconds, may require specialized techniques to get the information into the person’s long-term memory.)
- Select the best format(s) for displaying the information and the appropriate media for delivery.
- Draft the information.
- Observe and measure potential users’ performance using the labeling and the device in real-world

TRADITIONAL APPROACH	PERFORMANCE-BASED APPROACH
Teaches people how to use the device from the context of engineering or marketing	Teaches people to use the device in the context of achieving their goals (desired medical outcomes), given their situation
Gives users a lot of information in as many different formats (print and electronic) as possible	Designs information based on customers’ goals and limitations, and delivered according to how customers will access and use it
Relies on the users’ memory	Gives people easy-to-use, easy-to-follow information so they’re not likely to forget
Focuses on the device	Focuses on customers’ performance and satisfaction as they use the device to meet their needs
Presents information based on expert opinion, undertaking numerous drafts and reviews until the project schedule runs out	Uses a systematic, repeatable, scientific approach and the best empirical data available on how people process information
Bases evaluations on focus groups and survey	Bases evaluations on measurable performance criteria

Table I. A comparison of a traditional versus a performance-based approach.

situations.

- Compare patient performance with the success criteria and revise as needed.

Table I illustrates the difference between a traditional and a performance-based approach.

The analysis of human performance factors is not a new methodology; it has been used for many years in industries varying from high technology to automotive. However, it is a new concept in the medical device field. With the rapid growth of the home-care industry and FDA’s determination regarding the inadequacy of current labeling, it could be very beneficial for device manufacturers.

Shari Kipp, a former senior marketing manager for LifeScan Inc., a Johnson & Johnson company (Milpitas, CA), encountered the human performance factors approach while working on the Harmony INR monitoring system, a home device for measuring the clotting ability of blood. “The device and the impact of its training and labeling were studied at a very detailed level,” says Kipp.

“Our human factors consultant

broke down what we initially considered to be three simple steps into 35 steps. I came to understand that what the experts perceive as a simple task, the consumer might view as difficult. This does not mean the owner’s booklet must now be longer; it must merely be created to address the issues of the nonexpert.”

Alan Jacobson, MD, who was the lead researcher for the Harmony device’s clinical trials, concurs. “You can teach people how to push buttons in a few minutes but that doesn’t mean they know how to get accurate results every time, or that they know what to do with their results. Using this approach, we were able to determine how long it took a patient to achieve competency on the device and build that into the training program the patient received,” he said.

Aside from analyzing the steps and procedures involved in operating a device, human performance factors analysis also addresses patients. Using this methodology, human factors consultants will observe customer service representatives and talk to actual patients about their goals. The consultants will observe new users and determine how

long it takes them to become proficient at using the device. They will also question experienced patients to gain knowledge about shortcuts that might be useful in labeling. The findings can then be used in creating patient-friendly labeling.

### **Changing Behavior and Attitudes**

Changing their approach to labeling may be a frightening concept for manufacturers. One misperception is that the human performance factors approach takes more preparation time, but it often takes less time. This reproducible process is systematic and based in science, which offers the best empirical data about how people process information.

Manufacturers and their marketing agents often believe that they must first change attitudes toward a product in order to change behavior regarding its usage. This is actually false. By first improving people's performance and experience using a product, their attitudes will shift accordingly. This process is difficult to demonstrate because no one ever really comments about great labeling or thorough training. Rather, they will say that a device is hard to use or does not meet their needs.

### **Saving Manufacturers Time and Money**

Human performance factors research has been tested in numerous fields. Motorola (Asia) cites an example of human factors research in action. The company was experiencing high customer returns, costing it millions of dollars each year. In response, they redesigned their labeling using the human factors approach. After only six months, the company realized a 40% reduction in customer returns, producing annual savings worth more than \$6 million.

LifeScan's Harmony system provides another successful example of this approach in action. Of the 102 patients who participated in the clinical trials submitted to FDA, 68 completed the 36-month study. Measuring the effi-

ciency and effectiveness of the training, which also focused on the use of the Harmony owner's booklet, it was found that with no additional training, patients were able to produce accurate test results that were within  $\pm 0.5$  units of lab results 97% of the time. 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%.

### **Happy Customers Equal Higher Profits**

Any medical device manufacturer concerned with the viability of this approach should ask two key questions: How many customer support calls does the company receive each month? and How much does each call cost? Manufacturers who can analyze their calls should evaluate how appropriate improvements in their labeling instructions could reduce unnecessary calls. One blood glucose meter manufacturer estimates that one unnecessary phone call to customer support consumes one month's profits from that caller's purchase of test strips. This number does not reflect future buying decisions influenced by customer frustration and dissatisfaction—something that better labeling could have avoided altogether.

Sun Microsystems (Santa Clara, CA) used another technique of self-study that most manufacturers can easily duplicate: videotaping a new customer's initial experience with a device. Without any outside help or guidance, simply observe the layperson trying to use the product for the very first time. Are any mistakes made? How long does the process take? Would the customer describe the experience as easy or frustrating? Although this exercise may not reveal why customers are having problems, it will reveal where the major problem spots are in the

learning process.

It is also a good idea to scrutinize the owner's instructions. Some of the problems to look for include:

- Do the graphics match the device? One manufacturer's directions showed a button on the left when, in reality, it was on the right. Remember, customers are using these devices under some degree of stress, and it is best to eliminate confusion whenever possible.
- Are the graphics easy to understand? Too often, symbols, such as items with a line through them, can be difficult to interpret. The safest route is to use words and symbols together.
- Is the purpose of each graphic clear? When used as instructions, simple line drawings actually work better than photos.

Unfortunately, there is no way to calculate the cost of lost customers who could not figure out how to use a device and switched to another brand. However, happy customers can be the best advertising for devices they like. Knowing how to systematically create a patient-friendly device creates such customer satisfaction.

Existing customers can become a de facto sales force with word-of-mouth advertising. Using the human performance factors approach when creating home-use device labeling can play a large part in ensuring that customers are happy, and therefore will continue to purchase consumables, producing measurable results on the bottom line.

### **Conclusion**

By taking the goals of the home user into consideration and applying the scientific human factors approach to those goals, information and labeling become more understandable and helpful. For device manufacturers, this approach leads to fewer customer support phone calls and fewer customers who abandon the device altogether. ■