



When Age is More
than a State of Mind
The Impact on Medical Device Labeling
By Patricia A. Patterson

Although some people believe in the old adage, “Age is a case of mind over matter—if you don’t mind, it doesn’t matter,” this premise represents a significant misconception when it comes to medical device labeling and instructional materials. Actually, age does matter. That is why professionals responsible for helping to ensure US Food and Drug Administration (FDA) compliance and safe and accurate product use need to understand how the effectiveness of medical and pharmaceutical labeling and instructional information depends upon accounting for the diminished capacities that are among the inevitable effects of aging.

One reason this understanding is critical is the rising market of aging consumers. The first wave of baby boomers began turning 60, 1 January 2006—a trend that will continue at a rate of 8,000 a day. As these numbers grow, it is more important than ever for medical device manufacturers and pharmaceutical companies to pay strict attention to product labeling and instructions to avoid Warning Letters and increase customer satisfaction for this key market segment.

What Is Performance-based Labeling?

Historically, labeling and instructional materials have been viewed as burdensome expenses. Today, FDA considers them part of the device and expects manufacturers to ensure they support safe and accurate device use. FDA’s Human Factors Initiative requires medical manufacturers to “conduct appropriate human factors studies, analyses and tests.”¹ According to FDA’s Center for Devices and Radiological Health (CDRH), human factors (HF) is a science devoted to understanding the interaction of people and equipment. It addresses how humans think, react to stimuli and process information. The agency has placed

a greater share of the responsibility for safe and accurate device use on manufacturers. Given this emphasis, a performance-based rather than the traditional knowledge-based approach to labeling should be examined. **Table 1** summarizes the differences in the two approaches.

Myths of Traditional Labeling Approaches

The traditional, knowledge-based approach produces materials that are inadequate for home use of devices by older individuals. Its perceived efficacy rests upon a number of myths.

Myth #1: Baby boomers are tech savvy

At a recent White House Conference on Aging, Intel Chairman Craig Barrett correctly touted baby boomers as the most tech-savvy generation. However, being tech-savvy about shopping on eBay is not the same as being tech-savvy in using a heart monitor. “Manufacturers don’t always consider the fear factor,” says Mary Brady, CDRH Deputy Division Director. “People who may otherwise be comfortable using technology experience higher levels of stress when using medical devices that can directly impact their health and safety. It’s also important to account for the distractions in the home and the electromagnetic interference caused by devices such as computers and PDAs. The home will never be a sterile environment,” Brady adds.

Myth #2: The more information, the better

The traditional approach subscribes to the notion that if a little information is good, a lot of information must be better. Consumers are subjected to an onslaught of collateral—owner’s manual, quick-start guide, video, audio—with the assumption they will extrapolate from an abundance of content what they need to know and when to use

Table 1: Knowledge-based Labeling vs. Performance-based Labeling

Knowledge-based	Performance-based
Focuses on regulatory requirements and generic information about the device (e.g., how it works, how to maintain it, errors, warnings)	Focuses on regulatory compliance and helping individuals use devices quickly, safely and competently
Product-centric	User-centric
Reliance on expert input and focus groups Reliance upon user performance requirements, analysis, observation and formal usability testing	Reliance upon user performance requirements, analysis, observation and formal usability testing

it. Actual performance tests prove that when it comes to device information, less is more. The performance-based approach points the way to just the right information amount, type, medium and presentation.²

Myth #3: People like graphics and pictures

In a performance-based world, this holds true only if the graphics and pictures are carefully selected to support specific content. Poorly designed graphics and icons only create confusion.

Myth #4: People like learning through videos

On the contrary, research (based upon interviews) indicates that when it comes to medical devices, users prefer print resources.

Myth #5: If people can understand it, they can use it

Traditionally, labeling was submitted to a comprehension test to verify understanding. However, using a medical device is not the same as taking a comprehension test. The question is not, can they understand it, but rather, can they apply it?³ Performance tests ask: Can users perform the actions described in the instructions? For example, will an individual correctly interpret an alarm and know what to do?

Myth #6: Age makes no difference

The most common and potentially deadly myth is that people process information the same way, regardless of age. Specifically, there are five physical conditions that affect the aging population:³

- Declining eyesight. “Older individuals have difficulty reading labels and instructional materials because the print is too small or too fine or in a color of ink that provides insufficient contrast against background, for example black writing on a gray device or light blue writing on beige paper,” says Fran Marinaro, Administrator of St. Cabrini Senior Sisters Residence in Philadelphia, PA. “In some cases, a label covers other writing. People then become discouraged and don’t read the material at all.” Marinaro recommends a white background with black, bold writing in an easy-to-read font.
- Diminishing memory. “Don’t give too much information,” says Marinaro. “Keep each step brief, simple and to the point.”
- Declining ability to draw inferences. Research has conclusively demonstrated that people in their 60s process informa-

tion differently from people half their age. “Always include an 800-number for people to call,” Marinaro suggests.

- Declining ability to decipher symbols. “Pictures and graphics help visually oriented individuals as long as they are simple, large and clearly show the relevant area,” says Marinaro.
- Slower response time. For example, when a glucose meter was subjected to a usability test, it showed that the device’s internal timer timed out unless the user entered information within 12 seconds. The typical user was an older individual whose slower response time made this impossible.

Performance research tests the user’s ability to apply the information given in labeling and instructional materials and to perform as desired.

Human Factors Principles in Labeling

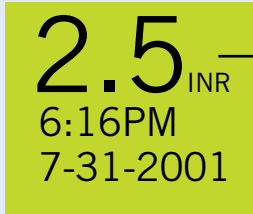
The basic principle of human-centric labeling is that it must support how, when, by whom and under what conditions individuals are using the device to accomplish a specific outcome. The following additional principles follow from this basic premise:

- The information must be derived not merely from expected device performance, but from the relevant aspects of human performance using the device—what users will see, hear, feel, etc., when using the device under both ideal conditions and in predictable, but less than ideal scenarios. These data are not captured in the typical systems engineering block diagrams that focus on the system and not the human.
- The information must be formatted so that it is easily read, understood and applied. Specifically, it must:
 - be designed to be used when the person is actually using the device
 - clearly state when and how to use the device
 - be written at a level of detail that minimizes trial and error
 - use appropriate graphics that support specific tasks and content and are positioned correctly, relevant to the content

Figure 1: An example of performance-based labeling⁴

Figure 7: Harmony's Owner's Booklet

When you see this: Do this:



This could be any number from 0.8 to 8.0, ID, HI or even error (ER) message.

12. In your logbook, write the test result displayed on your monitor. Also record the time and date on the display.

13. Compare the IANR test result with your therapeutic INR range. This range is given to you by your doctor or healthcare professional

If the test result is:	THEN
Outside your therapeutic range (Above or Below)	Call your doctor or healthcare professional to report a result outside of your therapeutic range.
Within your therapeutic range	1. Do as directed by your doctor healthcare professional 2. Continue with step 14

OBTAINING/APPLYING SAMPLE

Source: LifeScan, a Johnson & Johnson company

Performance-based labeling and training materials shorten the time it takes people to perform the required device usage functions. They also improve accuracy and increase the retention of performance over time.⁴ In addition, they lower after-sale delivery costs and increase consumer satisfaction because they leave people self-sufficient, reducing their need to rely on costly customer service.

For both devices and documentation, the maxim of performance-based research is: early and often. This ensures labeling will be ready when the device is, rather than holding up a release at the last minute because of poorly designed documentation.⁵ It also facilitates compliance, since FDA now requires evidence of systematic human factors analysis throughout the product development process.

It's Good Business, Too

The number of home-use medical devices will only increase in the years ahead, creating new consumer safety benefits and challenges, according to CDRH Director Daniel Schultz, MD. Since the primary market for these devices, aging baby boomers, will also continue to grow, it is critical for regulatory affairs professionals to understand the needs

of this expanding market, both to obtain FDA clearance and to support the business of providing what people look for in medical devices—products that are both safe and easy to use.

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5. Patterson PA, North RA. 2006. Fitting Human Factors into the Product Development Process. *Medical Device & Diagnostic Industry*; January 2006, Volume 28 pp. 124-133; The Sensys case study in this article demonstrates how performance research of both a device and its accompanying materials can be carried out throughout the design and development process.

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