

Human factors: A vital component in product development and launch

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Abstract Concerned about the high incidence of medical errors, The US Food and Drug Administration's Human Factors Engineering Group of the Center for Devices and Radiological Health (CDRH) has begun an aggressive approach to consider the impact of Human Factors (HF) in medical device design and labelling. In Australia and Europe, government activities also include HF in the labelling of pharmaceuticals. The CDRH is encouraging manufacturers to apply HF during design and development. The agency also verifies that HF is being considered when the manufacturer's design validation documentation is reviewed as required by the Quality System Regulation. Including Human Factors throughout the product life-cycle will increase product acceptance, prevent costly post-market 'upgrades' and offer a new competitive advantage. Examples from one HF provider and a medical device developer are provided.

INTRODUCTION

Between 44,000 to 98,000 people die from medical errors each year in US hospitals alone. According to a 1999 report issued by the US National Academy of Sciences, 'To Err is Human',¹ this is more than the number killed in the US by highway accidents, breast cancer or AIDS. Human error is a real problem in medicine. Not all human errors relate to devices or pharmaceuticals, but most do. There are a number of contributing factors involved in medical errors: complexity of medical devices; stressful conditions in which the device is being used; different mind sets of designers compared with users and devices originally designed for use by medical professionals being used in the home by lay people.

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medical errors, The US Food and Drug Administration's Human Factors Engineering Group of the Center for Devices and Radiological Health (CDRH) has begun an aggressive approach to consider the impact of Human Factors (HF) in medical device design and labelling. In Australia and Europe there are government activities to include HF in the labelling of pharmaceuticals. The CDRH is encouraging manufacturers to apply HF during design and development. The agency is also verifying that HF is being considered when the manufacturer's design validation documentation is reviewed as required by the Quality System Regulation. The FDA concurrently provides HF input to manufacturers during development and pre-market guidance.²

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Medical marketers — both device and pharmaceutical — can predict and reduce the incidence of medical errors while increasing competitive advantage. Understanding the importance of HF is a vital component of product development.

HUMAN FACTORS DEFINED

According to the CDRH's Division of Device User Programs and Systems Analysis,³ 'The study of Human Factors is a science devoted to understanding the interaction of people and equipment. The terms 'human factors,' 'human engineering,' 'usability engineering,' and 'ergonomics' are often used interchangeably.' For medical marketers — whether pharmaceutical or device — the product objective is to improve human performance and reduce the likelihood of use error and patient injury. HF can help.

Classical HF emerged during the Second World War, from the work of specialists studying manned weapons systems. Some of these studies involved: systems' performance, problems with information presentation, detection or recognition as well as skills required to perform. Classical HF has since evolved into a more inclusive form. In the late 1970s based on work by Dr Joe Harless, classical HF became integrated into a more holistic study of people, systems and devices called Human Performance Technology (HPT).

HPT extended classical HF by looking at the relationship of devices in the context of the performer — based on what the performer is trying to accomplish. HPT considers four factors that influence people's performance all driven by what the performer is trying to accomplish. Information is the first factor. What information does the performer need and where should that information exist (internal/long term memory, or external to the performer)? Environment is the second factor. How systems, devices and work processes are designed to help or

hinder performance. Selection is the third factor. All things being equal, does the person have the requisite abilities to perform? And, motivation is the fourth factor. Are there clear goals and feedback mechanisms? Is the effort to use the system or device worth it — does it help the users achieve their goals reasonably quickly, easily and safely?

The underlying premise of classical HFs is to look at the device. The underlying premise of the evolved form of HF is to look at desired performance, then identify and clarify that performance in terms of measurable outcomes. Finally, look at how the environment including device design, information, selection and motivation can be engineered to produce the desired result.

The FDA expects this expanded, evolved form of HF will be included in device design and in labelling.

Who cares about human factors and why?

The end-users/customers do not know much about HF, but they know when a product works. They know when they can understand a medication label and when they cannot.

A manufacturer also may not know he cares about HF, but he knows when he has a successful product. He also knows when he has so many customer service calls that profits are reduced. He cares about HF when significant 'upgrades' have to be made to devices already in the field. He certainly knows when he has to initiate a recall.

The FDA definitely cares about HF. The agency is so concerned that it has created new initiatives to encourage manufacturers to include HF in product labelling and design.

CUSTOMERS WANT SAFETY AND EASE OF USE

Customers include the 'man on the street', nurses, physicians, surgeons and all manner of health-care workers. One example of

the customer's view on HF is illustrated in an interview published in Medical Device & Diagnostic Industry (MD&DI).⁴

MD&DI question: Do the people who use medical devices on a daily basis think that there is a usability problem? Do they recognise good human factors design from bad?

'At present, there is much greater recognition of human factors design than there was 5 or 10 years ago by clinicians across the board. However, those clinicians who have been interacting with medical devices in high-stress, rapid-tempo types of environments like the operating room or the emergency room have recognized problems for quite a few years. They have, in fact, played a key role in moving both the standard-making and regulatory processes forward . . . More generally, when clinicians use a device, they may not know about human factors, but most of us know how to cuss at a product when it doesn't make our job easier, but rather makes it more difficult. Or when it makes us more error-prone, prevents us from doing what we want to do or slows us down. As soon as you tell someone what human factors and usability are they say, "Oh, that's the problem with this or that device!" So, they may not know the words, but they certainly know what the problems are.' (Matthew Weinger, MD, Veterans' Administration, San Diego Medical Center)

MANUFACTURERS WANT COMPETITIVE ADVANTAGE

Applying HF early in the development of a product is a new concept for medical manufacturers in the USA. Very few companies are aware or are concerned about the FDA's initiatives regarding HF. Using HF early on may, however, be a key competitive strategy. Those medical marketers who do consider, learn about and include HF all along the development cycle will find a competitive advantage. Consider the new product that better satisfies the customer's goal, provides high error tolerance, produces the desired outcomes while simultaneously causing fewer demands for customer service, no costly upgrades and no recall — that is competitive advantage.

Strategic marketers are including HF early in the product design process. Both medical device marketers and designers want to develop highly reliable successful and therefore, profitable products. To achieve this goal, they are best served when they have a more complete and accurate understanding of how the device is used combined with the limitations and failure modes of users. What are the device failure hazards and use-related hazards and how do they interact? All are functions of Human Factors.

As with physicians and nurses, medical device manufacturers and pharmaceutical companies must 'First Do No Harm'.⁵ Appropriate application of HF early in the design and labelling process can help the analysis of potential use-related hazards. The FDA notes that:

'Use-related hazards occur for some of the following reasons: devices are used in unanticipated ways; devices are used in ways that were anticipated, but were inadequately controlled for; device use requires physical, perceptual or cognitive abilities that exceed those of the user; device use is inconsistent with user's expectations or intuition about the device operation; the use environment effects device operation and this effect is not understood by the user or the user's physical, perceptual, or cognitive capacities are exceeded when using the device in a particular environment.'⁶

Documenting the incorporation of Human Factors in risk management can help demonstrate that a manufacturer has adequately addressed the needs of the intended users. Submission of this documentation can streamline and facilitate that part of the pre-market review process concerned with safe and effective device use. A faster review is another competitive advantage.

THE FDA WANTS FEWER MEDICAL ERRORS

The FDA considers HFs as a discipline that is seeking to improve human performance in

the use of equipment by means of hardware and software design compatible with the abilities of the user population. The FDA includes medical and pharmaceutical labelling and training as HFs.

Hazards related to medical device use should be addressed during device development as part of the risk management process. According to the administration:

‘Potential use-related hazards are best identified and addressed using human factors engineering. Documentation of these efforts demonstrates the work by the manufacturer to control use-related hazards. The user interface includes all parts of a device with which the customer/user interacts while using it, preparing it for use or performing maintenance of cleaning.’⁷

Resident pathogens

Use-related errors can be either active or latent. Active errors have immediate consequences and typically cause some sort of major catastrophe. Examples include the mix-up of two sets of results from a diagnostic test leading to the administration of an incorrect and fatal medication. Could usability testing, a component of HF, produce better labelling and prevent such errors?

Latent errors set the stage for later accidents. They are often separated by time and space from the loss and injuries they cause. They are more difficult to identify and evaluate than active errors. Latent errors have been called ‘resident pathogens’ because they lie dormant until the conditions are right for them to cause problems. One recent example of a resident pathogen is that part of a flexible bronchoscope design that allowed retention of bacteria inside the scope despite seemingly thorough decontamination procedures. The organisms were passed on to other patients, causing serious infections. Consideration of HF might have prevented this use-related error.

Concern about the use of medical devices in the home

The CDRH notes that sophisticated medical device technology originally tested and labelled for use in health-care facilities under the management of trained healthcare providers has migrated into the home environment over the past several years. Operation and maintenance of these devices has inevitably devolved to patients and caregivers. Many of these devices were never cleared or approved for use in the home, nor were they cleared or approved for use by a person who may not have the training, understanding or physical capabilities to correctly operate the device. ‘There is mounting concern about medical devices used in the home’, notes the agency.⁸

CDRH receives numerous reports under its MDR (Medical Device Reporting) System about breaches of safety with home use devices. For example:

Ventilator: A patient was on a ventilator in the home. The patient’s parent stated a portable ventilator was attached to the wheelchair. It stopped three times. It finally stopped altogether as the wheelchair moved across the small bump created by the threshold strip between the carpet and the tile floor. The patient’s parent had to intervene and start the ventilator again.

AB energizer: A reporter stated the device gave only three good weeks of service. After this, the reporter started experiencing electrical shocks from the device. The reporter stated the shocks were painful.

APPLICATION OF HUMAN FACTORS

Companies who decide to consider HFs early in product design and labelling may use in-house HF experts or seek outside HF consultants. The key is to treat HF as part of the critical path in product design. The processes involved in HF include usability testing, training of users or sales personnel, writing operating manuals and

Table 1 Percentage of people successfully completing tasks in response to questions

What can this medicine be used for?	18%
Who should use this medicine?	14%
How should you keep this medicine?	7%
When should you stop using this medicine?	6%

Source: Communication Research Institute of Australia.

writing labels and package inserts.

Usability testing may include focus groups, one-on-one interviews and laboratory or clinical setting use of the product. Training may include interactive television, Intranet or Internet learning, as well as typical classroom approaches.

Applying HF to manuals, packaging and labels is particularly important. One example comes from a study accomplished by the Communication Research Institute of Australia⁹ (CRIA, www.communication.org.au). A consumer was quoted as saying: ‘They put a lot of effort into designing the package so that I would buy it, but you can tell they don’t really care about the customer when you see the lack of effort they put into designing the instructions’. The CRIA used HF to test labelling efficacy. The results are shown in Table 1. The results proved only 18 per cent of participants in the study knew what the medicine was for and only 6 per cent knew when to stop taking the medication.

In Australia, nearly 30 per cent of hospital admissions are due to incorrect use of medicines. In the UK, nearly 50 per cent of patients surveyed do not take their medicines as prescribed.¹⁰ Studies¹¹ also show that information design preferences and customer opinions are not correlated to performance. Marketers should not ask a customer what they prefer, they should test for it.

IMPLICATIONS FOR MEDICAL DEVICE AND PHARMACEUTICAL MARKETERS

Knowledge of HFs and how they relate to any given product can enhance the

probability of that product’s success. Unit sales, product advocacy, customer loyalty and brand equity are often tied to how well a person can use the product to reach their ultimate goal. Including HF from early development, through launch will add value and decrease cost. Hearing the ‘voice of the customer’ early on can eliminate hours of customer service demands later in the product adoption cycle.

Those marketers working in companies where HF experts are in residence are fortunate. Many others will need to plan to bring in outside HF consultants. In preparing to use HF, marketers might consider what can happen without HF in the Marketing Plan.

LACK OF A DATA-DRIVEN AND SYSTEMATIC INFORMATION DESIGN PROCESS

How long does it take a person to find the right information in the product’s operating manual? Do they ever use the manual to help them with the task? Most marketers would have to answer, ‘No.’ Part of the problem is that information in many manuals is designed using a trial and error method where effectiveness is primarily determined by opinion. In order to cover all the potential bases and all the potential opinions of ‘good information’ more and more information is included. Instead of helping the user, this is often a hindrance. It causes confusion. Soon the customers do not know what to use when. Often, the information is so voluminous, it is ignored.

An alternative is to use a more systematic HF design process. Engineer the

information using structured text design, information visualisation techniques and focus on what the person is trying to accomplish. Then objectively measure if they can quickly and efficiently accomplish those results. Objective data has several additional benefits: decision-making can now be enhanced by the data; marketing claims can be substantiated and users can now base their opinions on clear criteria.

A TENDENCY TO NEGLECT FUNDAMENTAL TRUTHS ABOUT HUMAN PERFORMANCE

Many medical marketers assume there are no hard and fast rules regarding human behaviour. There are, however, some basic truths about human performance that have been research validated and have shown consistency over time. In the information design area some of the truths are:

- There is a stronger link between changes in behaviour leading to changes in attitude than attitude changes leading to behaviour changes.
- When asked their opinion, users tend to want more information which often interferes with their ability to achieve the results.
- User preferences and opinion often do not correlate with their achieving results
- What people say they will do and what they then actually do is not always the same.
- There is a natural tendency to discard external information unless it is immediately useful.

These truths have a clear implication for design and presentation of information. A performance-based approach matters.

Research over the last 20 years validates the superiority of a performance-based approach in information and product design. Some companies, like Ethicon, Inc., a Johnson & Johnson Company (Somerville, NJ, USA) and the US Army have published measurable results from a performance-based HF approach (Table 2).

ANALYTIC AND EMPIRICAL APPROACHES TO PREVENT USE-RELATED HAZARDS

Product teams including medical device marketers and quality assurance personnel should include both analytic and empirical approaches when considering use-related hazards of their products. Analytic HF approaches for a medical device’s risk management concern, involve description, systematic decomposition and analysis of device use. Analytical approaches are particularly valuable when considering in-use situations that might occur only occasionally.

Empirical approaches provide information from real or simulated product use. These steps may provide insight into unexpected use scenarios. Marketers should consider at least the following questions to identify and describe potential scenarios that could result in hazards:

- Why have problems occurred with the use of similar products?
- What are the critical steps in setting up and operating the device?
- Is the user likely to operate the device differently than the instructions indicate?
- Is the user or use environment likely to be different than originally intended?

Examples of analytic HF processes include

Table 2 Performance-based approach: results

81% decrease in the time need to find target information	Ethicon, 1997
54% reduction in errors on task	Schaffer, 1982
2–3.5% reduction in grade level reading requirements	US Army, 1997
A five-fold increase in customer satisfaction	Motorola, 1996
A two-thirds reduction in training time	Motorola, 1997

Source: Agillis Consulting, LLC.

test scenarios, use scenarios, heuristic analysis and expert review. Empirical HF approaches are often ‘use’ studies including walk-through, user testing and consideration of use environments.¹²

Usability testing can range from the very simple to the extremely complex. It should include an overall goal of improving the usability, safety and effectiveness of the product. Tested groups must include intended users and the participants must do real tasks, including those indicating safety and effective use achievement. The testing must include a focus on high-risk possibilities; testers who observe and record important data from participants and collection of data to support the identification of potential use-related hazards and the development of specific recommendations to address them.

A CHALLENGE FOR MEDICAL MARKETERS

Medical marketers already do product testing and usability testing. Focus groups are commonly used. So, what is different about including HF? The name is the same, but a marketing-driven focus group and an HF-driven focus group are very different. An HF expert needs to be involved to ensure a customer-centric focus. Once convinced that HF matters, a medical marketer might consider the following issues before proposing a change to a performance-based HF approach for

medical device design and labelling. There will be challenges to face.

Challenge 1

The systematic data-driven performance-based approach often clashes with the creative, intuitive approach of marketing communications. Both performance and creativity are necessary.

Challenge 2

There is often a clash of different ideologies and value positions between graphic designers (who value style, fashion, innovation, novelty and impact) and the technical writers (who value clarity, legibility, precision, comprehensibility and simplicity).

Marketers can move toward a results-driven approach to product management in an evolutionary manner. Marketers can first help fellow executives and managers understand the difference between a performance-based approach to product design and labelling and traditional approach. Table 3 illustrates this difference.

Educate product managers, marketing and team leaders about performance-based approaches by illustrating how performance-based HF approaches can be critical for product success. Start small. Implement the concept on several projects and measure the success in terms of business issues (eg, helps increase

Table 3 Traditional vs performance-based design

Traditional	Performance-based
Regulatory	Regulatory and competitive advantage
Product-centric	Customer-centric
Reliance on interviews, focus groups, opinions and perceptions	Reliance on observation, performance descriptions and pilot tests.
Evaluation based on opinion	Evaluation based on opinion and the customer's ability to quickly, safely and easily meet specific performance results.
Concern with explanation of errors	Concern with avoiding errors or minimising their effects.
Give people as much information as possible in many different formats. Maximise options	Target who needs what information and how — based on the desired performance outcomes.

Source: Agilis Consulting Group, LLC.

satisfaction, quicker time to proficiency, less user errors, etc.). Use that information to educate others. Then begin to transition from a traditional approach.

OUTCOMES: HUMAN FACTORS OF A HIGHER ORDER

One US-based consulting group decided to take HFs to a higher level. Agilis Consulting, LLC (www.agilisconsulting.com) does not focus entirely on how humans perform with products or labels. Instead, the company concerns itself with the desired medical outcomes — what the patient or the physician or the nurse wants.

When presenting the HFs approach to a medical manufacturing client, Agilis' first priority is fulfilling the client's business objectives and the customer's/enduser's desired goals. First, what are the business and marketing goals for this device? Who is the target customer? What is his desired goal? The customer's goal is very often not the same as that of the marketer. The first focus is on describing desirable and valuable medical outcomes — results and goals. Then, why is task performance important? What is its purpose? The first focus is not on tasks.

The traditional approach is to load the device with features. This can cause 'feature glut' unless there is a clear picture of either the business or customer goal. The temptation is to 'Build it and they will come.' They may, but at what cost?

Improving a person's ability to execute certain behaviours can be expensive in terms of usability testing and training. Unless that training and testing enables the client company to measurably improve the product and get the desired results — the investment was wasted. Improving results produces value. Improving behaviour may only produce cost.

A clear definition of the desired result described in measurable terms results in fixing this or that task and influencing the achievement of the desired result.

Agilis describes this process as $W = V - C$, where the worth (W) of any intervention or remedy is determined by the value (V) it produces minus the cost to produce it. In order to ensure appropriate worth, Agilis creates a Customer Performance Profile to guide decisions regarding product design, information, labelling and training.

According to Pat Patterson, President of Agilis:

'We create a Customer Performance Profile based on what the actual user does NOW. We interview and observe real people doing real stuff. We look at data from call centers and error logs. Our goal is to ensure that devices, labeling and training meet the customer's desired medical outcomes because it is the behavior that will influence their opinions, not the other way around. A customer will never say, 'Gee, the technology in this device is brilliant' but it's hard to use and I don't like the Owner's Booklet.' No, they'll just say, 'I don't like it' and go to another brand'.

A Customer Performance Profile is defined as a description of a performance based on actual and/or targeted customers. It includes the customer's desired medical outcome using their language; the criteria for producing desired outcome including accuracy, quantity, quality and time; the key behaviours required to produce that result including frequency, complexity, speed, consequences of error and psychosocial issues and finally the performance desired under normal conditions, off-normal circumstance and emergency situations.

For instance, when seconds count, speed can have a dramatic impact in both product design and labelling. As an example of using the customer's language, some medical marketers of insulin pumps talk in terms of 'control.' Customers talk in terms of lifestyle, 'I can eat when I'm hungry, not when I have to'. When considering the outcome's accuracy and time, some marketers will claim only minutes are required to learn to use their product, but the customers say otherwise

— months. Most marketers are product-centric and task-focused. Customers are not.

Agilis believes that the next big breakthrough for making devices easier to use or learn will be ‘on-board performance guides’ that comply with sound HF principles. This is sometimes called electronic performance support systems (EPSS). In the interim, Patterson says, ‘Manufacturers are often under-using their device interfaces in the same way they have underused and undervalued labeling. If a marketer tracked the customer call volume from a typical product versus a HF designed product, they would see a real difference.’

PERFORMANCE-BASED LABELLING

Today’s consumer is being swept away by a tidal wave of information. The sheer volume swamps consumers at all levels. This forces them to filter or ignore most information. In recent years, the FDA has resourced several projects under the auspices of its HFs initiative. This includes labelling, such as package inserts, owner’s booklets and instructional documentation. Based on actual data, the FDA concludes that human error is a significant problem and suggests re-examination of the approach to product labelling and how it communicates information to customers.

When HF is to be applied to drug labelling, Agilis considers how to ensure users of information can achieve their goals quickly, efficiently with increased satisfaction. As Table 4 illustrates, there is

agreement that the fundamental purpose of labelling is to help people use the product and a number of organisations are concerned.

So, if the purpose is clear, why are the results still so poor? The problem rests with the process used in designing the labelling information. Specifically, the issues are: product-centric versus user-centric information; a focus on comprehension versus performance; lack of a data-driven and systematic information design process and a tendency to neglect fundamental truths about human performance.

PRODUCT-CENTRIC VERSUS USER-CENTRIC INFORMATION

Agilis promotes a focus on user-centric information. In some cases, organisations confuse information about the product with information from the perspective of a user. Product-based information focuses on generic topics about the product itself: what it does, how it functions, what it looks like and so on. It also includes information on how to use it, but the focus remains on the product, not the user.

According to Best Practices, LLC — the provider of benchmarking reports for corporate improvement — ‘Building a customer-centric organisation provides benefits of sales and revenue growth, reduced cycle time, increased customer satisfaction, improved customer targeting and ultimately growth in shareholder value’.¹³

Customer/User-centered information is an HF process that looks through a customer’s eyes and focuses on how the

Table 4 Organisations concerned about labels

Adequate directions for use under which the layman can use a device safely and for the purposes intended	US Food and Drug Administration Center for Devices and Radiological Health
Information the user can read, understand and act upon	The US Pharmacopoeia
Information they can use easily and appropriately	Communications Research Institute of Australia — Labeling Dialogue Group

Source: *Designing Better Medicine Labels: Report to Pharm, 1995* Communication Research Institute of Australia

Table 5 Owner booklet chapter headings

A	B
Product-centric Insulin boluses — why and how Meter operation Troubleshooting	Customer-centric When and how to bolus at mealtimes How to test your blood How to interpret your test results

Source: Agilis Consulting, LLC.

user thinks about using the product to produce specific results such as better control and seamless integration with their life-style. Table 5 shows an actual owner booklet chapter headings in column A. Column B shows how those heading could be seen in a customer-centric manual, highlighting the differences between the two approaches.

FOCUS ON COMPREHENSION OR PERFORMANCE

Information must be understood. People need to understand not just information, but in many cases all the information. They then take what they need and apply it to their unique circumstances. Using the chapter headings noted in Table 5, it appears clear to the product-centric designer that once people understand Meter operation, they will be able to translate that into testing their blood.

Unfortunately, this is not always the case. Research data from educational psychology proves people often have a very difficult time taking general concepts and translating them into specific applications.¹⁴

Ensuring comprehension is an important first step, but it will not suffice. Helping people apply that information, ensuring that they can perform the tasks to achieve specific results must also be included. This can be done by clearly articulating what a user needs to accomplish and in what context. Understanding the tasks a person needs to perform to achieve that result and providing easy to use information to help people accomplish those tasks as quickly as possible is the goal.

The goal is to integrate the device into the customer's life, so it seamlessly and easily helps them achieve their desired medical outcomes, while keeping them self sufficient, satisfied and continuing to use the product.

HUMAN FACTOR IMPACT ON A PRODUCT

LifeScan, Inc., a Johnson & Johnson company, (www.LifeScan.com) received product clearance for its new Harmony INR Monitoring System by the US Food & Drug Administration in September 2001. INR is an International Normalized Ratio, a standardized and accepted method for reporting prothrombin time results. The new anticoagulation blood monitoring system could help the 2.5 million US patients on the blood-thinning medication warfarin. It helps the patients keep their blood coagulation time in a safe or 'therapeutic' range. The monitoring system allows patients to self-test anywhere, at any time, facilitating the benefits of frequent testing while reducing the cost and hassle associated with repetitive clinic visits.

But, long before final clearance was sought from the FDA although not at the beginning of the development cycle, the marketers responsible for Harmony recognized they needed to be sure the patient could use the device properly. Enter Human Factors. Using the Customer Performance Profile approach, the *Harmony Owner's Booklet* was written using HF.

Brian Earp, then Senior Manager of Clinical Research at LifeScan comments:

Table 6 Pre-design analysis


Stimulus	Response
INR result on meter display	Write result in your logbook
INR result in your logbook	Compare result to your therapeutic range
INR is over the therapeutic range	Call the doctor or healthcare professional
INR is under the therapeutic range	Call the doctor of healthcare professional
INR within the therapeutic range	'Think OK to proceed'

Source: Agilis Consulting, LLC.

'In the development phase of the project patient training was thought of as a "necessary evil" that we would need to contend with through labeling and creation of guides for use. In determining the path for clinical evaluation of the product, we met early with the CDRH branch of the FDA. In our meetings, the FDA was very clear on the inclusion of human factor analysis as part of the design and that training is part of the product evaluation. We engaged Agilis in the development of a human performance model for the product after the design was completed. The program that evolved tied all of our components together in a logical fashion and actually eliminated additional pieces we previously thought necessary. The program focused on 'where does the patient find information when he needs it.'

A pre-design use analysis measured what performance was desired for using the Harmony. Table 6 illustrates how a stimulus should cause a response. When the patient tests for INR, a result is shown by the device. That should cause a response of writing in their logbook, for example.

After this use analysis, the product development team's Owner's Booklet (User's Guide) looked like the illustration in Figure 1. The reader stays focused on the task to be done because the booklet is organised by task and the necessary steps in performance sequence.

When you see this:	Do this:						
 <p>Example</p> <p>This could be any number from 0.8 to 8.0, LO, HI, or an error (ER) message.</p>	<ol style="list-style-type: none"> In your logbook, write the test result displayed on your monitor. Also record the time and date on the display. Compare the INR test result with your therapeutic INR range. This range is given to you by your doctor or healthcare professional. <table border="1"> <thead> <tr> <th>IF the test result is</th> <th>THEN</th> </tr> </thead> <tbody> <tr> <td>Outside your therapeutic range (Above or Below)</td> <td>Call your doctor or healthcare professional to report a result outside of your therapeutic range.</td> </tr> <tr> <td>Within your therapeutic range</td> <td> <ol style="list-style-type: none"> Do as directed by your doctor or healthcare professional. Continue with Step 14. </td> </tr> </tbody> </table>	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	<ol style="list-style-type: none"> Do as directed by your doctor or healthcare professional. Continue with Step 14.
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Within your therapeutic range	<ol style="list-style-type: none"> Do as directed by your doctor or healthcare professional. Continue with Step 14. 						

OBTAINING/APPLYING SAMPLE

Figure 1 Harmony's Owner's Booklet
Source: LifeScan, a Johnson & Johnson company

Table 7 Was the patient able to perform the finger stick correctly?

Response	Number	(%)
Yes	262	97.8%
No	6	2.2%

Source: Agilis Consulting, LLC

HUMAN FACTOR MADE A DIFFERENCE

With product instructions now HF-oriented, the development team conducted a clinical test of 268 patients over a 12-week period and again after one year and two-year periods. During the trial the patient had to learn how to successfully use the Harmony monitoring system. Teaching of the patients in the trial focused on patient *performance*, not patient training. At the end of the 12-week period, the patients were observed by nurses as they did independent blood testing using the Harmony device.

Nurse observers found excellent results when they watched how the patients stuck their fingers to obtain a blood sample (Table 7), and, again when the patients used the device to get their test results (Table 8).

Not satisfied that the patients did so well

on their initial performance, Harmony's development team wanted to know if the patients would retain this information over time. When statistical analysis was performed at one year and again at two years post-instruction, the results compared favorably with the initial results (Table 9). With minimal — but HF-guided — customer-centric training, a high degree of skill and knowledge retention was accomplished.

'PST' is 'patient self test,' where the Harmony INR Monitoring System (PST) is compared with the Laboratory Reference Method (LAB) and to Healthcare Professionals (HCP).

As Mr Earp of LifeScan summarised,

'If I had the opportunity to do this over again, I would have engaged a human performance professional with human factors background in the initial product design and throughout the clinical evaluation process.'

Table 8 Was the patient able to obtain an accurate test result with NO help?

Response	Number	(%)
Yes, with no problems	188	70.1%
Yes, but with some difficulty	56	20.9%
Yes, but with a lot of difficulty	6	2.2%
No, not able to get a result	18*	6.7%

Source: Agilis Consulting, LLC. *Of the 18 unable to obtain a result, 15 stopped testing after receiving an error message or other similar problem. Three of the 18 were judged to be performing the procedure incorrectly by the nurse observer

Table 9 Statistical performance results, regression statistics

Conducted	Comparison	n	Slope	Intercept	Correlation coefficient	Sy.x
During clinical trials	PST vs Lab	1,041	1.04	-0.11	0.94	0.22
During clinical trials	PST vs HCP	1,042	1.01	-0.04	0.95	0.20
1 year later	PST vs HCP	546	1.01	-0.04	0.97	0.14
2 years later	PST vs HCP	1,120	1.04	-0.10	0.96	0.17

Source: Agilis Consulting, LLC.

CONCLUSIONS

Medical device and pharmaceutical marketers survive in a highly competitive marketplace. Adopting a strategic use of Human Factors (HFs) in product design, development and in labelling can make a major impact on a product's successful use and speed of adoption.

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References

- 1 Kohn, L., Corrigan, J. and Donaldson, M (2000) *To Err is Human: Building a Safer Health System*, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, DC.
- 2 Center for Devices and Radiological Health, Division of Device User Programs and Systems Analysis, Office of Health and Industry Programs (1997) *Human Factors Points to Consider for IDE Devices*. (www.fda.gov/cdrh)
- 3 Division of Device User Programs and Systems Analysis (DDUPSA) (2001) *What is Human Factors?*, Human Factors Engineering Group, Center for Devices and Radiological Health, US Food and Drug Administration, www.fda.gov/cdrh/humfac/hfbrochure.html.
- 4 Wiklund, M E, *Human Factors Roundtable Part 1: The Regulatory Imperative*, Medical Device & Diagnostic Industry, January 2002. www.devicelink.com/mddi/archive/01/01/006.html
- 5 Hippocrates (420 BC) *Epidemics*, Bk.1, Sect. XI.
- 6 Guidance for Industry and FDA Premarket and Design Control Reviewers (2000) *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*, Center for Devices and Radiological Health, Division of Device User Programs and Systems Analysis, Office of Health and Industry Programs. (<http://www.fda.gov/cdrh/humfac/1497.pdf>)
- 7 *Ibid.*
- 8 CDRH (2002) personal communication, May.
- 9 Rogers, D., Shulman, A., Sless, D. and Beach, R (2001) *Designing Better Medicine Labels*, Communication Research Institute of Australia. www.communication.org.au.
- 10 *Ibid.*
- 11 Ley, P. (1991) *Guidelines For Warning Labels: A Report to the Preventative Strategies Panel of the Public Health Committee*, Department of Health and Housing, Canberra, Australia.
- 12 Sawyer, D. (1996) *Do It by Design: An Introduction to Human Factors in Medical Devices*. www.fda.gov/cdrh/humfac/doiit.html.
- 13 *Empowering Corporate Marketing: Building a Customer-Centric Organization* (2002). www.benchmarkingreports.com.
- 14 Broad, Mary L. and Newstrom, J. W. (1992) *Transfer of Training*, Addison-Wesley, Reading, MA.

Further reading

- Safe, Comfortable, Attractive and Easy to Use: Improving the Usability of Home Medical Devices* from Committee on Human Factors, National Research Council, 2101 Constitution Avenue NW, Washington, DC 20418.
- Human Factors in Medical Devices, Design, Regulation and Patient Safety*, AAMI/FDA Conference Report, from AAMI, 3330 Washington Boulevard, No. 400, Arlington, Virginia 22210. Tel: 703.525.4890.
- Human Factors and Ergonomics Society (HFES)* Santa Monica, California. www.hfes.org.