Larry Fennigkoh and Diego Haro

Human Factors and the Control of Medical Device-Related Error

Introduction

Hospitals have become extremely complex, high-technology environments where the use of intrinsically dangerous equipment and procedures is routine. While the benefits associated with this technology have been tremendous, the additional complexity carries a human cost, namely, the disturbing increase in the number of patient deaths that are attributed to medical error. As concluded in the 2004 Health Grades report, Patient Safety in American Hospitals, “over 575,000 preventable deaths occurred as a direct result of the 2.5 million patient safety incidents that occurred in U.S. hospitals from 2000 through 2002.”[1] The estimated average of 191,000 deaths per year is nearly double the 98,000 annual deaths cited in the pivotal 1999 Institute of Medicine report, “To Err is Human: Building a Safer Health System.”[2]

The authors of these two major studies should be credited for waking up the government and health care community to the problem of medical error. As a result, the medical literature today includes more case studies and calls for action. Despite this growing awareness, the magnitude and seriousness of medical error remains largely obscured. The mingling of these accidental deaths with those from natural causes, combined with a gross underreporting of such accidents, makes obtaining accurate figures extremely difficult.

A major conclusion within the 1999 Institute of Medicine report, and the prevailing consensus within this community, is that most of this error is due to faulty systems and processes embedded within the health care system. It is these flawed delivery systems, not the health care worker, that tend to be directly or indirectly associated with medical errors. Systems problems require systems solutions. It is here where the interdisciplinary and systems science associated with the field of human factors offers the greatest promise.

While the full scope of medical error is much too broad to adequately address here, those errors caused or aggravated by less than optimal medical device design will be targeted. Specifically, it is through the use of established human factors principles that many common device-related errors can be mitigated if not completely eliminated. As such, the primary purpose of this article is to encourage medical device designers and manufacturers to fully embrace many of these well-established human factors principles. These same principles have been successfully integrated throughout much of the aerospace industry, including the military, NASA and other high-risk, high-technology enterprises.[3] Human factors, as a scientific, systems-focused discipline, is poised to identify and solve many of the medical systems’ problems in general and device-related shortcomings in particular.

Human factors as a systems science

The study of human factors is a highly interdisciplinary systems science.[4][5] From its interdisciplinary perspective, it is heavily rooted in the principles obtained through experimental and cognitive psychology research. Such principles include, but are not limited to, how people communicate, perceive and process information, how they interact with machines and their environment (i.e., user interfaces) and how they make mistakes. The design and optimization of tools, work places and processes also borrows heavily from industrial engineering, biomechanics and anthropometry. Here, reducing work-related errors and their associated injuries and maximizing worker efficiencies are often the primary objectives. It is, however, human factors’ foundation and emphasis on systems science

Simple Diagram of a Medical System

- Noise Levels
- Lighting
- Facility Design
- Air Quality

Figure 1

Human Factors and the Control of Medical Device-Related Error
that offers the greatest opportunity for improved medical device design. In this context, and also as defined by Alphonse Chapanis, widely regarded as one of the fathers of ergonomics, a system is “an interacting combination, at any level of complexity, of people, materials, tools, machines, software, facilities and procedures designed to work together for some common purpose.”[6] For both the medical device designer and its clinical user, the essence of such a system is illustrated in Figure 1.

While most designers are understandably focused on developing device functionality, its ultimate performance, safety and effectiveness can be strongly influenced by the human user and the particular environment in which it is used. This is precisely why interdisciplinary design teams are so essential, not only internal to the organization but external as well. Such teams can recognize and integrate the unique skills and specialized components of their trusted suppliers. Good human factors in design are not just about user-friendly, cosmetically appealing front panels. They extend all the way through a device, from components, to firmware, to network connectivity. In the context of Figure 1, consider how these individual elements often interact in subtle yet complex ways.

Hospital environment

Noise levels

Hospital ambient noise levels can affect safe and proper device operation in two critical ways:

- They can severely mask life-critical equipment alarms. Ventilator-dependent patients, for example, have died when such alarms cannot be heard.
- Excessive and persistent ambient noise may contribute to increased stress levels in patients and hospital staff. Persistent exposure to noise levels of 65–70 dB, while not known to cause hearing damage, has been shown to degrade task performance and cause temporary hearing threshold shifts. A variety of physiological changes also occur at such noise levels.[6]

A 2005 hospital noise study from Johns Hopkins University also concluded that “hospital noise levels have internationally grown steadily over the past five decades, disturbing patients and staff members, raising the risk of medical errors and hindering efforts to modernize hospitals with speech recognition systems.”[7]

Facility design

Hospital patients are routinely moved throughout the facility, often connected to a variety of monitoring devices with their associated cables and fluid-filled catheters and tubes. Transporting patients connected to multiple devices through long, tortuous hallways and up and down elevators, crossing a number of flooring transitions and thresholds in the process, creates a variety of opportunities for accidental cable and tubing disconnects. What’s more, during these patient transports the connected medical devices need to continue to function reliably on their internal batteries. Combined, these facility-related issues may contribute significantly to mishaps and mistakes. The physical environment has been implicated as the root cause of approximately 15 percent of the sentinel events reported to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[8]

Air quality

Electronic medical devices, patients and their caregivers may also be adversely affected by:

- Temperatures that are either too hot or too cool, or temperature control that is widely fluctuating.
- Insufficient or excessive humidity and humidity control.
- Inadequate air filtering, surgical smoke evacuation or air exchanges.

Here, designers are encouraged to use the embedded intelligence and processing capacity within their products to monitor critical internal device temperatures and other factors, such as pressure differentials across air inlet filters, and alert the user to take appropriate action if necessary.

Lighting levels

Glare from overhead or inappropriately placed task lighting can obscure instrument displays and can elevate worker stress levels.

Human factors

When developing a new medical device, it is essential that the designer view the end product from the human user perspective. Namely, what human characteristics does the device need to cater to in order to be operated correctly and safely? In this regard, it is essential for medical device designers to consider human factors, such as the perceptual abilities associated with sight, hearing and touch, early in the design process. They should:

- Employ labels and displays that can be easily read and interpreted.
- Use colors and contrasts that minimize ambiguity and add information redundancy when possible, e.g., red alarm lights to further convey a dangerous condition.
- Recognize the implications for visually impaired users.
- Evaluate, in advance, to learn if viewing angle limitations, such as those associated with LCD or LED displays, are likely to be problematic under expected use conditions.
- Manage the tones, intensities and types of audible alarms, avoid the same combination of tones and intensities for differing alarm conditions, ensure that device alarms are distinct from the many other devices that are likely to be in use in the immediate working environment, and never provide the user the ability to permanently silence audible alarms or turn alarm volumes to less than ambient noise levels, i.e., 55–65 dB.

Freescale.com/beyondbits
• Seek to make the alarm compatible with the level of the threat. Humans tend to equate both the volume and character of an alarm with its severity. In other words, do not assign an ear-splitting klaxon for a relatively minor alarm condition.

• Provide the user with tactile feedback whenever possible and appropriate. Humans possess touch receptors that are sensitive to both displacement and viscoelastic resistance. Positive detent push buttons and keypads communicate to users that their actions were sufficient. However, today there are new technologies, such as proximity capacitive sensing, that do not require positive detent push buttons. Users may lose the tactile response of pushing a button, but audio or visual (lights or LEDs) feedback can be programmed into the system to return a satisfactory response. These interfaces are also easier to clean and maintain, since users don’t have direct contact with the circuits inside the device.

Many of these human perceptual design elements, for example, were incorporated into a (circa 1970’s) cardiac defibrillator panel shown in Figure 2.

In particular, note the user-appropriate label “ECG SIZE” (as opposed to the then-popular term “Gain”), the numeric numbering of the positive detent, illuminated controls and the effective use of a single background color that indicates that all of the controls within this area are related even though there is no label that specifically points this out. Additional effective elements in this design include the use of redundant feedback mechanisms associated with many of the controls. The power on/off switch, for example, sends three different messages to users to indicate that they did something correctly when turning this device on. First, the “1” on the button says “press me first.” Second, the crisp detent of the switch provides tactile and audible feedback that this was done correctly. Third, the switch illuminates, indicating that the device is indeed on.

User training

Inadequate training, or the lack of user training, has often been used to explain why clinicians make mistakes. Doing so, however, can often deflect users from uncovering device- or systems-related factors that may be the real culprit. Granted, proper education and training are important and vital to ensure that devices are used properly and safely. However, user training is rarely an effective substitute for user-friendly, intuitively obvious equipment design. Any medical device that requires hours of instruction and a voluminous operator’s manual is not user-friendly. To continually promote training as a solution to the problem of medical error obscures larger system issues. An over-emphasis on training also tends to insult the intelligence of the device user.

Machine

Poor medical device design and the lack of usability testing have been repeatedly discussed as being key factors in many device-related incidents.[9][10][11][12] While the FDA and many medical device manufactures have made considerable progress in addressing the importance of human factors in device design, pre-market and pre-purchase usability studies continue to be under-utilized. Consider, for example, the differences in the front panel design of two infusion pumps shown in Figure 3. In particular, note the conventional (and familiar) telephone keypad layout in the pump on the right in contrast to the less familiar layout pattern used with the pump on the left. Such subtle differences can affect the speed and accuracy of data entry, and the lack of standardization also invites user mistakes.

Human-machine interface

The human-machine interface is perhaps the most dynamic and complex element within the device/user environment. It is the point of engagement between the human and the machine. As the device is attempting to communicate with its user through visual and audible displays, indicator lights, color-coded

Cardiac Defibrillator Panel

![Cardiac Defibrillator Panel](freescale.com/beyondbits)

Traditional vs. Non-Traditional Keypad Layouts

![Traditional vs. Non-Traditional Keypad Layouts](freescale.com/beyondbits)
controls, icons, control panel design, function and labeling, the user attempts to perceive, interpret and respond to these stimuli in a timely and appropriate manner. In this regard, the human-machine interface is effectively its own closed-loop stimulus-response system. It is also here where much of what is conveniently but inappropriately labeled “user error” occurs. To blame the user, however, for device designs that allow, invite or encourage the user to make inappropriate responses, while convenient, is often not warranted. It is also at this human-machine interface where users express much of their frustration, which can be violent, damaging the device or even the user. While this might result in a missed movie or broken DVD player at home, the same conflict, when attempting to use an infusion pump, ventilator or defibrillator, may result in compromised patient care.

Applicable codes and standards

After reviewing some of the factors that may affect the intended use of a device, it is important to mention that standards have been defined, some of them being relatively new. They include key features and strategies that suggest how to design better and more efficient medical devices in order to reduce or even eliminate mistakes. The U.S. Food and Drug Administration (FDA) has increasingly recognized the value of human factors in medical device design and encourages manufacturers and designers to adopt appropriate sections from the following available standards.

ANSI/AAMI HE74:2001

Human factors design process for medical devices

The AAMI Human Factors Engineering Committee developed this process-oriented standard to provide manufacturers with a structured approach to user interface design, helping them develop safe and usable medical devices. It also helps them respond to the increasing number of national and international human factors standards in the medical field and the promulgation of new governmental regulations (based on ISO 9001) pertaining to medical device user interface design [13]. This standard includes an overview of the human factors engineering (HFE) discipline, a discussion on the benefits of HFE, a review of the HFE process and associated analysis and design techniques and a discussion on implementation issues and relevant national and international standards and regulations.

Improving usability

Medical device users (e.g., physicians, nurses, therapists, technologists, patients and service personnel) regard usability as one of the most important design considerations. They understand that a highly usable medical device is likely to reduce the amount of end-user training time and will help clinicians be more productive. With devices intended for unsupervised patient use, such as home glucose monitors for diabetics, ease-of-use can affect whether the patient will be able to use the device at all. Medical device manufacturers will be well served by investing the necessary resources to improve usability. From a business standpoint, the potential payoffs from this investment may include:

- Faster time to market (by avoiding user interface problems late in the development cycle)
- Simpler user manuals and related learning tools
- Improved marketing through credible claims about a device’s usability and associated gains in user productivity
- Increased sales (attributable to enhanced user interface quality)
- Reduced customer training and support requirements
- Extended market life
- Clearer compliance with regulatory requirements
- Reduced exposure to liability claims
- Increased user satisfaction

IEC 62366:2007 Medical devices—application of usability engineering to medical devices

This standard was developed to help manufacturers improve the usability and safety of medical devices. The standard recognizes that the use of all medical devices has associated risks and provides an engineering process for identifying, assessing and mitigating those risks.

IEC 62366 describes a process that addresses medical device use errors and divides those errors into categories to guide their analysis. This process can be used to assess and mitigate risks caused by the usability problems associated with the normal and abnormal use of a medical device. As shown in Figure 4, use errors can be first separated by whether there were intended or unintended user actions or inactions [14]. All unintended actions, as well as intended actions that are categorized as either mistakes or correct use, are considered to be part of normal, and thus foreseeable, use. The manufacturer can only be responsible for normal use. Abnormal use errors are outside the scope of manufacturer responsibility, and they need to be controlled by the hospital.

If the designer complies with the usability engineering process detailed in this standard, the residual risk associated with device usability is presumed to be acceptable. Patient safety will improve as future medical devices are designed to comply with this standard.
Conclusions

The safe and proper use of medical devices can be dramatically improved when established human factors concepts are integrated early and applied throughout the design process. The incremental costs to do so are often negligible, but the payback can be tremendous. Improved user satisfaction, reduced use-related errors and a reduction in adverse patient outcomes are often the results. Freescale is helping make the medical world a smarter and safer place with a new generation of powerful, high-quality medical semiconductor products. With its wide product portfolio and support ecosystem, Freescale can help developers find the perfect fit for their next medical device product design. Simply put, a human factors approach to medical product design plus advanced semiconductor technology makes for better, intrinsically safer products—and a safer health care environment.

References


