

# The Importance of Utilizing Human Factors Engineering in Developing Biomedical Innovation

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## Introduction

Human Factors Engineering (HFE) is an applied science that coordinates the design of devices, systems, and physical working conditions with the capacities and requirements of the user. The study of human factors engineering has been evident since World War II. Industrial engineers, efficiency experts, and psychologists all worked to increase worker efficiency by streamlining manufacturing equipment and operations. Similarly, human factors were studied and applied to complex systems for military applications such as cockpit and control design.<sup>1</sup>

Though there are vast amounts of information on human factors engineering and its importance to product development, the direct application to biomedical innovation is relatively in its infancy. According to the Institute of Medicine (IOM), about 1.3 million Americans are seriously injured each year by adverse events involving medical products. In fact, more people die in any given year due to medical errors that occur in hospitals (between 44,000 and 98,000) than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).<sup>2</sup> Poor device design and user error are major reasons why these events continue to occur. Utilizing human factors engineering early in the design process will not only mitigate potential use hazards or design flaws, but also save lives. This paper discusses current standards and requirements regarding human factors engineering and provides an overview of human factors engineering and risk management related to biomedical innovation.

## Current Standards & Requirements

The International Organization for Standardization (ISO) is recognized throughout the world as the leader in developing and determining quality systems for various industries including the automotive, defense, and health care industries. Standards are extremely important to govern systems in order to produce safe, efficient, reliable, and quality products or services. ISO standards make a positive impact on not only the engineers and manufacturers who utilize them in their production and distribution processes, but also for society as a whole.<sup>3</sup> Recently, ISO updated their ISO 9001:1994 standards to focus not only on the organization, but on the customer as well. This new standard was introduced in 2000 as ISO 9001:2000 and is used to assess a company's ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction.<sup>4</sup> The push to focus more on the customer was influenced heavily by the Institute of Medicine (IOM) in their 2000 report, *To Err is Human: Building a Safer Health System*.<sup>5</sup>

Traditionally, biomedical device designers focused on military guidelines and standards published by the Association for the Advancement of Medical Instrumentation (AAMI) and a variety of ergonomics and human factors textbooks; however the FDA is increasing their role in standard-setting for biomedical innovation. Past standards in health care did not provide adequate focus on patient safety. The ISO 9001:2000 standard and FDA's human factors guidance documents aim to alleviate this concern. For the FDA, there are two chances to enhance and ensure patient safety: during the approval process for medical devices and through post-marketing surveillance. The FDA approves a product once it concludes that the benefits of using the product clearly outweigh the risks for the intended population and use.<sup>6</sup> Unfortunately, the FDA receives approximately 80,000-85,000 reports annually on device problems.<sup>7</sup>

The FDA now requires each manufacturer to demonstrate how human factors considerations were met during a company's product development process. To assist manufacturers in understanding these regulations, the FDA issued several guidance documents to support its human factors initiative, including, *Do It By Design: An Introduction to Human Factors in Medical Devices* and *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*. Likewise, the FDA mandates that a company's design control

procedure incorporate human factors. These requirements are portrayed in Section 820.30 of the FDA's Quality System Regulation<sup>8</sup> and are shown in Appendix A.

## Human Factors Engineering



Darrell suspected someone had once again slipped him a spoon with the concave side reversed.

In order to minimize potential errors and use-related hazards concerning new product development, it is imperative that a company manages risk effectively. This can be done using human factors engineering and other techniques aimed to examine the interface between a product and its user. When developing medical products in particular, a company should incorporate such approaches into the risk management process early in the design and development stages to recognize use-related hazards. Likewise, integrating human factors engineering into risk analysis helps facilitate the design control process, but more importantly ensures that the product being developed is effective, safe, and easily manageable by the end user. It is important to first understand the principles of use-related hazards, risk management, and of human factors in order for a company to know how to combine these principles into a comprehensive analysis.

## Human Factors

Christopher Wickens, in his book, *An Introduction to Human Factors Engineering*, defines human factors engineering as, "The study of factors and development of tools that facilitate making the human interaction with systems one that reduces error, increases productivity, enhances safety, and enhances comfort."<sup>9</sup> Human factors analysis focuses on the user and exactly how and in what situations a device will be used by that user. As mentioned previously, when developing medical devices, human factors engineering is extremely important to reduce user-related hazards and recognize potential hazards early in the design process. This will reduce development costs and may also add value to a company's intellectual property portfolio. The fact is, clients are interested in costs and profits, but these clients are not the end-user of the device. Once the products enter the market, manufacturers have no further direct interest beyond repair and reliability costs. However, if users reject the device that is on the market, product sales will be affected and manufacturers will therefore be impacted. "The interest in users is becoming more acute, and increasingly, product usability is being explored by product designers."<sup>10</sup>

There are several human factors aspects a company should consider when examining their medical device. These include the device technology and device user interface, the prospective users of the device, and the environment in which the device is used. Figure 1 below shows these human factors considerations and how they can affect a product's outcome.<sup>11</sup>

## Hazard Identification

Hazard identification is the key component of risk management. According to the FDA, a hazard is defined as, "A potential source of harm that may arise in the use of a medical device due to inherent risk of medical treatment, from device failure (or malfunction), and/or from device use."<sup>12</sup> These hazards in biomedical innovation have a profound impact on not only the patients, but the health care providers and patients' families as well. Medical device hazards are a frequently occurring and serious problem. Evidence has shown that the frequency and consequence of medical device use-related hazards far surpass hazards resulting from device failure.<sup>13</sup> It is imperative that companies not only acknowledge that these hazards occur in the device itself, but also recognize potential hazards that may occur due to improper use of the device. The Institute of Medicine (IOM) estimates that, "As many as 98,000 people die in any given year from medical errors that occur in hospitals, which is more than the number who die from motor vehicle accidents, breast cancer, or AIDS."<sup>14</sup> The fact is, a vast number of these errors occur due to medical device use. The following list identifies several reasons why use-related hazards in medical devices occur:

- Devices are used in ways that were not anticipated,
- Devices are used in ways that were anticipated, but 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 device operation,
- The use environment affects 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.<sup>15</sup>

The above is not a comprehensive list of reasons use-related hazards that can occur, but it does provide a company with some insight with regard to recognizing such hazards.

Figure 1. Device Hazard: Green Spigot



Figure 1, above, shows an example of a device hazard that could occur in the healthcare setting. Imagine a nurse telling you to, "Attach the oxygen mask and tubing to the green spigot." The user does what she says, attaching

to tube to the above spigot, but does not notice that what he or she is actually attaching the tube to is air, not oxygen. Figure 2 below highlights this hazard further.

Figure 2. Yellow and Green Spigots



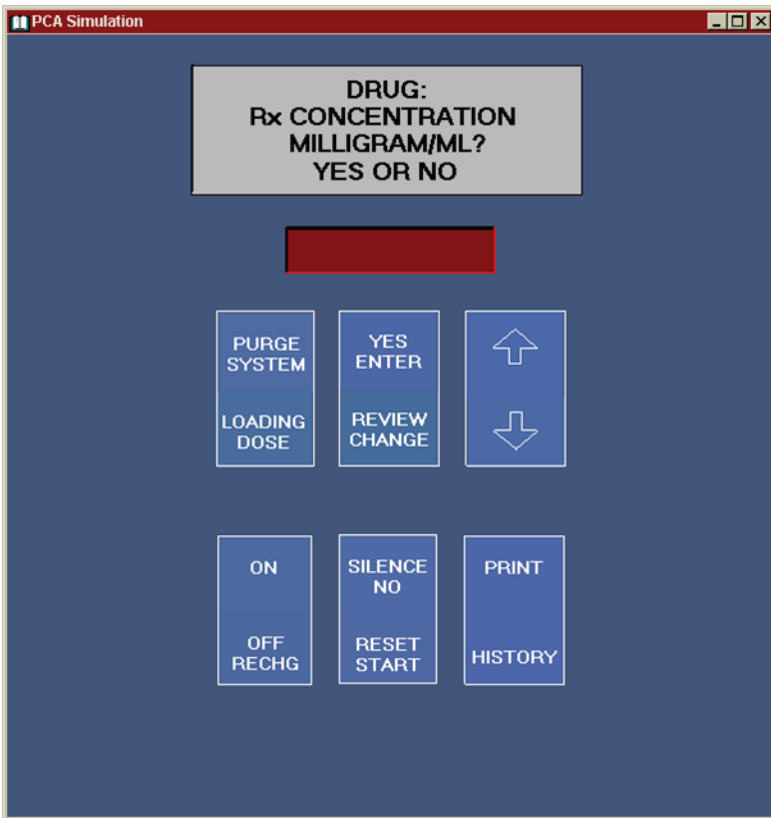
Notice that in Figure 1, someone placed the wrong spigot on the air (should have been yellow). A better design eliminates the potential for this problem to occur by creating a clear spigot and simply allowing the user to correlate air with yellow and oxygen with green (See Figure 3 below).

Figure 3. Better Design of Spigot Using Clear Attachment



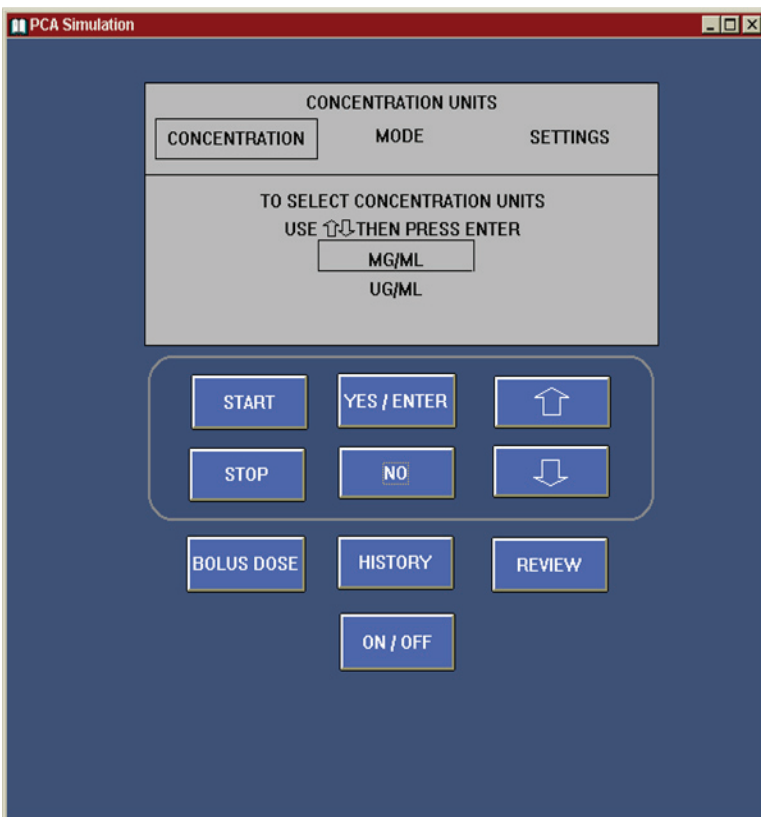
Another common example of a use hazard that often occurs in the healthcare industry, and one device that seems to be prone to these hazards, is the infusion pump. Figure 4 shows a commonly used PCA display screen. Notice the interface between the query and the input response buttons (Yes/No). It seems counterintuitive that a user would push the Silence/No button and then push the Yes/Enter button to accept the input. What if the user changed his or her mind? What if the accepted input is the last step in the sequence and the PCA automatically gives the wrong concentration of the drug? Each of these potential errors could lead to serious consequences for the patient, including overdosing.

Figure 4. PCA Display



A better design to the above PCA display is shown below. The user can toggle between queries and can ensure the input/button represents his or her desired action. Likewise the overall tasks for the system are streamlined and more efficient.

Figure 5. Better PCA Display



Two separate populations of nurses were tested on the above displays (twelve novice student nurses and twelve expert recovery room nurses) to determine its effectiveness. Both programming errors and performance were measured. With the old interface, eight drug concentration errors were made, three of which were not detected and left uncorrected. Likewise, eleven mode errors were determined, of which nine were eventually corrected. The new interface, however, provided zero errors in drug concentration and only three mode errors (all of which were corrected). This demonstrated a 55% reduction in PCA errors simply by creating a better display interface and logic process.<sup>16</sup>

The typical response from such a hazard is to fire the clinician or nurse responsible for the error; this may even lead to litigation from the injured party. Fortunately, this response is now being shifted from the operator and user to the device manufacturer. The best way for device designers to minimize the incidence of user errors, and more importantly, the associated hazards to patients and clinicians, is to employ a formal HFE process that focuses on meeting user' needs and requirements. Such an approach will also improve device use efficiency and user satisfaction.<sup>17</sup> A company must also apply effective approaches to manage risk associated with failures of medical devices due to both the device's design and how the device is used. Applying human factors engineering into the risk management process can help accomplish these goals.

## **Device Technology and Device User Interface**

A company must examine the market and need for the technology being developed. This includes a competitive analysis of similar devices on the market. Careful inspection and analysis of existing devices can help a company identify potential hazards. Similarly, many medical devices have pre-existing reports regarding their safety, effectiveness, and errors created by hospitals, other companies, and medical journals or studies. More complex devices, such as ones involving hardware and software utilization, require even more examination into past occurrences of hazards. By analyzing existing devices on the market, a company can recognize immediate risks that need to be mitigated when designing their new technology.

Human factors engineering recognizes the importance of user interface when designing new devices. "Users of devices perceive the problem to be with themselves rather than with the technology. People often blame themselves when failing to comprehend the manufacturer's instructions or when errors occur."<sup>18</sup> In reality, the designer is responsible for creating an interface that corresponds to the user's intentions and desires. The user interface includes all aspects of a device with which a user interacts, including how the user prepares, activates or applies, and maintains the device. The device's buttons, switches, knobs, activation mechanisms, auditory clues, visual clues, alarms, indicator lights, and visual displays are just a few examples of user interfaces. Feedback systems processed internally within many devices are also user interfaces. Specifically, all labeling, operating instructions, and packaging provide feedback to users. All of these systems, information displays, and control tasks must comply with the user's expectations, actions, and expected behaviors in order for the user interfaces to be effective.

## **Prospective Users of the Device**

One of the most difficult things for a company to grasp when developing biomedical innovation is the population of potential users. A medical device that is simple to use for one person may create enormous difficulty for another person. The company must examine all possible users for the device including any limitations these users may have. Examples of the diversity of a user population include the elderly, children, disabled, those who suffer from mental conditions, experts in the industry, and lay persons. The FDA lists several important characteristics of user populations:

- General health and mental state (stressed, relaxed, rested, tired, affected by medication or disease) when using the device,
- Physical size and strength,
- Sensory capabilities (vision, hearing, touch),
- Coordination (manual dexterity),
- Cognitive ability and memory,
- Knowledge about device operation and the associated medical condition,

- Previous experience with devices (particularly similar devices or user interfaces),
- Expectations about how a device will operate,
- Motivation, and
- Ability to adapt to adverse circumstances<sup>19</sup>

Device designers can use human factors engineering throughout the design and development process in order to create a device that compensates for some limitations in user ability. For example, a product may be introduced to the market that has some type of digital visual display. Certain users, such as the ones with poor eyesight, may not be able to see the display readouts clearly. The device designers may then need to redesign the device so that the display can be seen clearly by all users, regardless of their ability to see clearly. Of course, recognizing these potential problems early can help a company save money in the end. Likewise, a company must design a device that meets users' previous experiences and expectations concerning similar devices (i.e., placing a safety cap on a device should mean that the cap is protecting the user from some hazard such as a needle. This is because a user associates the safety cap with protection).

An example of the above may be portrayed when analyzing existing epinephrine auto-injectors on the market (See Figure 6 below). These “pen-like” injectors are used for allergic emergencies and have been widely used for decades. Epinephrine delivery is critical within the first five to ten minutes of a life-threatening anaphylactic reaction. It is thus imperative to have a device that can easily be kept on or near one's body at all times; however, studies have shown that only 30% of individuals requiring an epinephrine injector actually carry with them at all times.<sup>20</sup> This is due to the fact that most epinephrine injectors are simply too bulky to carry around—a design flaw often blamed on the end user, and this flaw is just one of many.



Figure 6. Epinephrine Injector

Since 1980, there have been several case reports of accidental digital injection of adrenaline from an epinephrine auto-injector, with an incidence estimated at one accidental injection per 50,000 devices.<sup>21</sup> These accidental injections into the thumb or digit may occur due to the poor design of such pen injectors. The auto-injectors include a safety tab on one end of the device, yet the needle comes out of the opposite end. In a life-threatening situation, the user may cognitively believe the safety guard should be protecting the needle and therefore remove the safety, flip over the injector, push down, and accidentally inject their thumb or digit. (Figure 8). This could not only cause digital ischemia at the site of injection, but, more critically, eliminate the needed life-saving dose of epinephrine for the patient.



Figure 7. Epinephrine Injector Sharps Hazard & Use Hazard

## Medical Device Use Environments

The environment in which a medical device is used can vary greatly and have a profound effect on the device's use and use-related hazards. Characteristics of an environment, such as workload, visual conditions, auditory conditions, and location influence how effectively a user uses a device. According to Wickens, research has shown that users of a device will perform poorer and cause more errors when confronted with activities that require heavy mental workload.<sup>22</sup> The challenge to product developers is to determine how much workload is simply too much for the user to handle. This is especially true in complex systems or in situations where multiple tasks occur simultaneously. For example, in an operating room there may come a time when multiple auditory warning signals on different devices activate and the doctor may have trouble distinguishing between them. Heavy mental workload corresponds to high stress levels. A user under high stress may not be able to perform efficiently or correctly due to distractions caused by this high stress. It is extremely important that a company analyze all potential situations in which high stress may occur when designing a new device, especially since many medical devices are used for emergency purposes.

Visual and auditory conditions within an environment also affect the user's ability to use a device correctly. The product development team should recognize the conditions in which a person will use the device, such as during the day or night. Likewise, auditory feedback should be clear and effective enough to be heard in noisy environments where applicable or soft enough in environments where noise is unfavorable. If the devices are not designed to accommodate for these conditions, errors and use-related hazards are likely to occur. Environments where motion and vibration are evident should be examined as well when designing the device. For instance, if a device is used in an ambulance at high speeds, the vibration may cause use-related error.

Designing the device to adapt to many environments can mitigate risk associated with use-related hazards. A company should evaluate all locations where the device will be used and determine how to appropriately address all potential hazards concerning these locations in the design of the device.

## Conclusion

Incorporating human factors engineering principles and methods into a company's risk management program is essential in order to produce safe and effective biomedical innovations. With the FDA and other institutions increasingly emphasizing the need for human factors programs and creating related standards, a company needs to focus on utilizing HFE within their research and development process. There are increasingly more resources and guidance available in order to create such valuable programs within the biomedical companies. Once implemented, they will optimize the medical device's design, mitigate unforeseen costs in the development process, reduce potential hazards that may occur, and ensure that the technology created meets the end user's needs; most importantly, it could save lives. Likewise, effectively managed human factors and risk management programs will provide a competitive advantage to the company once the innovation is commercialized.

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## **Appendix A**

### FDA Design Control Requirements relating to Human Factors Engineering

(c) Design Input: “Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the users and patient.”

The FDA’s goal is to ensure that manufacturers make a systematic assessment of who will be using the device, the conditions under which it will be used, how it will be used, and whether any use-related hazards could occur. Human factors activities for generating design inputs include user research studies such as focus groups, task analysis, and initial usability testing of design concepts.

(f) Design Verification: “Each manufacturer shall establish and maintain procedures for verifying the design input. Design verification shall confirm that the design output meets the design input requirements.”

Verification pertains to examination and testing of the company’s device against requirements and specifications. Human factors techniques for verification include reliability and safety testing as well as usability testing.

(g) Design Validation: “Design validation shall ensure that devices conform to defined user needs and intended uses, and shall include testing of production units under actual or simulated use conditions.”

Validation includes confirmation of the product’s design by analyzing the device and how it functions, meets all specifications or requirements, and conforms to user needs. The FDA expects the company to perform usability testing with actual users under simulated conditions, using production or pre-production prototypes.

By incorporating the new ISO 9001:2000 standards, FDA’s human factors engineering guidance documents, and FDA’s Quality System Regulations into the innovation development process, a user-centered approach is addressed and device error is decreased.