Human Factors Engineering Series

Poor Interface Design and Lack of Usability Testing Facilitate Medical Error

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Scenario. Joan and Roy are half way through what has been a fairly slow shift in their job as paramedics for City Emergency Medical Services (EMS) when they are dispatched to respond to a priority-1 call. They are to meet up with a rural volunteer rescue squad that is en route toward the city with a patient complaining of chest pain and palpitations. Although the volunteer rescue squad carries advanced life support (ALS) equipment, today it does not have any ALS-qualified emergency medical technician (EMT) staff available; only paramedics are trained to perform ALS skills, such as electrocardiogram (ECG) monitoring and interpretation, defibrillation, intravenous (IV) therapy, drug administration, and endotracheal intubation).

After a 15-minute response, Joan and Roy approach the predetermined rendezvous location at the interstate U-turn. It is dark out, and although traffic is sparse Roy has trouble seeing the U-turn entrance because of the glare of the "battery on" indicator light inside the ambulance. He has always wondered why this light, which seems to be standard on all ambulances, does not dim at night. But, he thinks, at least they finally put the siren speakers down in the ambulance grills. If the speakers were in the light bar on top of the cab as they used to be, his ears would be ringing by now.

Joan gets out of her ambulance and into the rescue-squad ambulance, which then continues on its way toward the hospital. She takes the report from the EMTs inside and immediately recognizes that the patient is unstable. He is a 67-year-old man who says he has "a bad heart." He has been having worsening angina for the past week but now is complaining of

Article-at-a-Glance

Background: A fictional scenario based on a compilation of several real events describes seven medical errors that at first appear to be caused by the paramedics and nurses involved.

Human Factors Engineering (HFE) Analysis: An emergency medical services paramedic attempted to use a debrillator on a 67-year-old man with ventricular tachycardia. Yet nothing happened. The defibrillator displayed an indication that it was in synchronized mode but provided no feedback to tell the user that it was not prepared to shock because of low QRS amplitude.

Usability Testing: A hands-on approach to discovering the difficulties and potential for error that people encounter when trying to use a product, usability testing can help to create medical devices and systems that are not only more "user friendly" and efficient—but safer.

Recommendations: Recommendations are presented to enable health care leaders to apply human factors considerations in their product evaluation and purchasing decisions. Medical device manufacturers should involve human factors engineers in the design process from the outset and should perform usability testing. Health care organizations should expect an optimized and tested user interface in the medical devices they purchase.

Summary: Many adverse events in medicine are the result of poor interface design rather than human error. The HFE concepts of usability and standardization are critical to patient safety.

sustained chest pressure and palpitations. His pulse is 180 so Joan hooks the patient to the cardiac monitor and sees ventricular tachycardia (VT). Like all paramedics, Joan is well versed in the management of this type of patient. She knows to follow the algorithm for unstable wide complex tachycardia, so she starts an IV, sedates the patient, and sets up to perform synchronized cardioversion.

Joan removes the defibrillation paddles and presses the button to select synchronized mode. She is pleased to see the word "SYNC" appear in big letters on the display to confirm her input. Although this is not the same defibrillator model Joan usually uses, she has used this kind in the past so she is fairly familiar with the controls. Joan charges the machine to 100 joules and places the paddles on the patient's chest. She presses and holds the discharge buttons, but nothing happens. Aware that something is not working correctly, Joan checks the machine. Indeed, the display still says "SYNC," which she believes indicates that the device is in synchronized mode and ready to go. But suddenly she realizes that the amplitude on the ECG is too small for the machine to capture, so she tries to turn it up. Initially she turns up the volume of the beeper but realizes her mistake and finds the control that says "QRS size." As soon as she turns this up the familiar marks appear on each QRS complex and the word "SYNC" on the main display starts flashing. Now Joan repeats the procedure and is able to deliver the shock without a problem.

Unfortunately, the patient's VT is refractory to this cardioversion, so Joan turns the energy level up to 200, charges, and delivers the next shock. Joan is surprised to see that the patient goes into ventricular fibrillation (VF). Aware of the gravity of the situation, she immediately charges to 200J and defibrillates the patient. Fortunately, he responds to this intervention and converts to a perfusing sinus rhythm.

After the third shock, Joan closely follows her protocol for postVF care and gives the patient a bolus of xylocaine. She is supposed to follow with a 2 mg/minute drip, and she tries to calculate the drip rate but gets confused. She thinks that the rate should be about 30 drops per minute, so Joan uses her watch and tries to adjust the flow to one drop every 2 seconds. But it is a bumpy road and she has a hard time seeing the drops.

On arrival in the ED, Joan gives the report to the doctor and nurses. They notice that the patient is slightly hypotensive so the doctor asks the nurse to start a fluid bolus with normal saline. The nurse opens the IV tubing wide open, but within minutes the patient starts seizing. The nurse realizes that the xylocaine drip instead of the saline had been inadvertently turned up.

The patient is stabilized and Joan starts her paperwork. She prints a code summary from the defibrillator and has a disturbing revelation: It was no coincidence that the patient went into VF. The second shock was not a cardioversion but rather an unsynchronized defibrillation. Joan realizes that unlike the defibrillator she uses every day, this machine resets to nonsynchronized mode after each shock and that the second shock must have been delivered at the wrong time during the cardiac cycle, causing VF.

Background

It is obviously unlikely that so many things could go wrong with one patient. But although this is a fictional case, it is a compilation of true events reported by EMS and emergency medicine providers.[1] Until recently medical error was rarely reported in the medical literature. Even now, although there are studies investigating the nature of error in emergency medicine,[2–4] there is a lack of data exploring the nature of medical error in EMS.[5]

Each component of this scenario is based on an actual event, and all have a common root cause: poor human factors engineering (HFE) resulting in poor interface design. HFE is a discipline that must become as well known to the health care industry as it is to aviation and other industries that involve high risk and complex systems. Previous articles in this series have described HFE in detail.[6]

We will now describe each problem from the scenario from an HFE perspective and show why the cause of the error lies in a poor interface design. In the section that follows, we will describe usability testing, a human factors research tool used to identify interface design problems.

Human Factors Engineering Analysis

Good HFE results in an optimization of the human-machine interface[7] to create medical devices and systems that are not only more "user friendly" and more efficient but also more importantly, safer. In the context

of our fictional case, we can best explain this concept by illustrating each problem from an HFE perspective.

1. Glare in the Ambulance

Glare from the "battery on" indicator light inside the ambulance has been a universal problem of nearly all models of ambulances for years. The problem has recently been recognized and addressed. The newly revised federal ambulance specifications state as follows: "Lighting shall be designed and located so that no glare is reflected into the driver's eyes or his line of vision from switch control panels or other areas that are illuminated while the vehicle is in motion."[8] The concept of optimizing environmental lighting is a core HFE issue, and this example demonstrates a design that failed to account for the different types of environment (night and day) in which a device will be operating.

2. Noise Exposure in the Ambulance

Before a decade ago, siren speakers were located in the light bar on top of the cab and were known to cause sound exposure that exceeded Occupational Safety and Health Administration (OSHA) regulations.[9] However, federal specifications now require siren speakers to be placed in the grill,[8] and a recent report demonstrates no evidence of hearing loss among EMS providers.[10] This example demonstrates a common situation in which a device had been designed to carry out its mission (as an emergency vehicle warning device), without consideration for the human component of the system.

3. Failed Attempt to Shock

Although the defibrillator displayed an indication that it was in synchronized mode, there was no feedback from the device to tell the user that it was not prepared to shock because of low QRS amplitude. Thus, Joan had to figure this out by attempting to deliver the shock. This is a classic interface design problem: the device fails to communicate a status problem with the user, which causes the user to have to go through several unnecessary steps in order to discover the problem.

4. Wrong Button for Amplitude

The QRS amplitude- and beeper-volume control buttons are hard to distinguish from each other. On this particular machine, they are placed together and look the same, which means that even an experienced user may confuse them. The design of this defibrillator has violated the human factors principle for grouping controls. Putting related controls together in a distinct group allows users to perceive relationships and thus imparts additional information beyond the word or symbol that identifies the button: "The perception of grouping depends primarily on spacing but may also involve placement of labels, use of color, or variations in type size."[11(p. 335)] Grouping can be based on such relationships as importance, usage frequency, and function. Groups can be distinguished by putting spacing between them, using different colors, and labeling in different type fonts.

5. Defibrillation Performed When Cardioversion Intended

This example allows us to illustrate two human factors principles: standardization and consideration of user resources. The defibrillator model that Joan used in the case study resets to unsynchronized mode after each discharge, whereas the model she usually uses persists in synchronized mode during repeated shocks. As a result, Joan was unaware that her second shock was unsynchronized. Indeed, when the defibrillator reset out of synchronized mode the display indicating "SYNC" mode disappeared, so a product designer might assert that the device did attempt to communicate the change. However, it is not reasonable to expect that Joan would notice the absence of this visual display during a stressful time. In this case, defibrillator designers failed to heed a principle called "consideration of user resources," which is defined as "designing a product so that its method of operation takes into account the demands placed on the users' resources during interaction."[12(p. 28)] A better design might include an audible alert to capture Joan's attention and tell her that the mode had changed from synchronized to unsynchronized mode. Standardization of functions between defibrillator models would have averted this problem altogether.

6. Trouble with Setting the Xylocaine Drip

We expect paramedics to calculate drip rates considering the desired dose, patient's weight, concentration of the preparation, and the drops/ml rating of the drip chamber. This complex calculation has been shown to

be difficult for even the most experienced paramedics to perform.[13] At most hospitals in the United States, nurses routinely use "drip charts," which can be referenced in lieu of performing a calculation. Furthermore, infusion pumps are used in hospitals to automate the flow rate, a process that is otherwise prone to human error. Automation is a human factors solution for tasks that exceed human capabilities; it has long been used in the aviation industry (such as the use of autopilot during times of high task load).

7. Xylocaine-Overdose-Causing Seizures

In the absence of infusion pumps, IV medication infusions are routinely prepared by using the same tubing and drip chambers that are used to prepare unmedicated IV solutions. As a result, there is no visual cue beyond the IV bag to indicate the presence or absence of a medicated solution. This is important because the roller-clamp used to control the flow rate is remote to the IV bag. The tubing could be color coded to indicate there is a medication in the line. In this respect, the IV tubing is treated as part of the human-machine interface, as it displays a message. Redundancy is a human factors principle used in many contexts (such as space flight) to make systems error resistant.

How to Identify Interface Design Problems

Each of the seven components of the scenarios showed a mismatch between demands and/or expectations imposed on the provider and the ability of the provider to "respond" to those demands and expectations. As a human being, the health care provider brings visual, auditory, motor, and cognitive capabilities and limitations to the performance of the task. The consequences of neglecting these factors when designing a device or a task can be seen in daily living experiences[14] and in both medical and nonmedical systems involving high-technology hardware and software.[15] Several methodologies can be employed during the product development process to optimize and test for a design's usability. One of the most widely used evaluation methods is usability testing, a hands-on approach to discovering the difficulties and potential for error that people encounter when trying to use a product (See Sidebar 1, right).

Sidebar. Usability Testing

Usability testing evaluates the user interface by focusing on user interactions and perceptions. When possible, usability testing is done in an environment similar to the actual product usage venue. More often, testing sessions are done in a room with a one-way mirror and are videotaped. Observational data and user feedback are collected and become the basis of the subsequent improvements.

The testing procedure is as follows:

1. Recruit participants who represent the type of people who will use the product
2. Identify real tasks that exercise the interface you want to test
3. Administer the tasks in the actual or simulated environment in which the device will be used
4. Observe the participants' performance (sessions are often video-recorded)
5. To enhance data collection, encourage the participants to "think aloud" while performing tasks and by soliciting feedback after the tasks
6. Analyze data to (1) find interactions that caused difficulties or errors for most participants and (2) identify the causes of the difficulties and errors
7. Modify the interface design to remove causes of the difficulties

A Usability Study of Defibrillators

Usability testing is an important HFE methodology for the health care industry to understand and expect in the design of medical devices. A usability study of manual defibrillators used by EMS and hospital personnel[16] illustrates usability testing's potential to contribute to safer, more easily used medical products. Twelve experienced paramedics tested two defibrillator models with very different user interfaces. The testing was done in a simulated living room and using a computer-driven patient simulator. Each subject performed four typical tasks that exercised various functions on the defibrillator. Through close observation of their performance, confusion and difficulties operating the defibrillators were noted and recorded. Subject perceptions were obtained through

think-aloud feedback and interview responses. Analysis of the performance and perception data showed a multitude of design deficiencies that complicated the subjects' ability to easily, quickly, and reliably complete the tasks. Problems 3, 4, and 5 in the fictional scenario cited earlier are based on the results of this study. Other findings include the following:

- Too many buttons on the face of the defibrillator caused an overload of information that required the subjects to search for the "right" button to perform the task.
- Flat, pressure-sensitive buttons did not give adequate tactile feedback to the subject, which was exacerbated by the fact that the subjects wore gloves (as they would in actual practice). When the absence of feedback on the screen is also considered, subjects sometimes reported that they had not pressed the button hard enough and repeatedly pressed it before realizing that it was the wrong button to be pressing at the time.
- Paper rolls were placed incorrectly into the paper well because the defibrillator design "accepted" rolls in the wrong orientation. Trying to retrieve the roll from the well to correct the mistake was difficult because there was inadequate space for fingers to grasp a full roll.

These findings and others from the usability study can be translated into guidelines for defibrillator design that manufacturers could use to bring more error-resistant designs to market. Ideally, usability testing should be conducted very early in the development stages of product design. The results from usability tests that are conducted after a product has been brought to market are much less likely to affect current or future designs. However, it is useful for purchasers of defibrillators to use the guidelines to evaluate the usability of devices under consideration. This article was intended to begin sensitizing health care providers and managers to the importance of device and system usability testing.

Recommendations

Health care decision makers cannot be expected to conduct usability tests on every device under consideration for purchase to determine the extent of usability problems. How, then, can knowledge of this process help us improve patient safety? The key is to expect this level of refinement from medical device manufacturers. Although usability is a critical factor in patient safety, it is rarely given much attention in the purchasing process. Just as you request efficacy or cost-analysis data from a vender, you should request usability-testing data. Manufacturers that conduct usability tests during the design process should be happy to share the results with their customers and show how they integrate usability into their design process. This request would reveal a telling difference between companies because, unfortunately, some companies consider human factors to be an expensive luxury.

Involve a human factors engineer in the evaluation process at a local level. The Human Factors and Ergonomics Society maintains a directory of human factors consultants who can work with your organization.[17] These professionals can help apply usability principles and guidelines to assessment of medical products and processes.

Integrate human factors engineers into your safety program. For example, a human factors engineer could attend safety rounds, sit on the quality committee, participate as a member of root cause analysis teams, and be involved in purchasing and medical device evaluation decisions. Smaller institutions might use a consultant, whereas larger institutions would benefit from hiring a staff member with human factors expertise. Many human factors engineers also have backgrounds in industrial safety engineering or cognitive psychology and might be able to fill dual roles within an institution. In addition, hospitals that are associated with a university may be able to find human factors experts within the industrial engineering or psychology faculties.

Use a proactive approach such as a walkthrough with a human factors specialist. A "heuristic review" can be performed, which is an expert inspection of processes and environments to discover opportunities for adverse events.

Raise the level of front-line providers' awareness about interface design and other HFE issues. This should increase your organization's ability to identify some of the more obvious problems, to make informed decisions when selecting new equipment, and to more effectively work with human factors specialists when the need arises.

Finally, strive for standardization. Ideally, every defibrillator in an EMS or hospital system should be the same make and model. When this is difficult to achieve

and different models must be purchased, make sure that they have user interfaces that are similar to those of the other defibrillators, especially for critical functions. Also, take the time to recognize the differences in the interface design (such as in the sync modes described above) so that staff awareness can be raised by training. Health care administrators should look critically at the infrastructure that underlies purchasing decisions within their institutions. For example, different departments may be independent cost centers within the institution and as a result make independent purchasing decisions, which can result in a lack of standardization.

Summary

Many adverse events in medicine are the result of poor interface design rather than human error. The HFE concepts of usability and standardization are critical to patient safety. Manufacturers should involve HFE in the design process from the beginning and should perform usability testing to discover unanticipated sources of error and evaluate the devices' ability to protect from human error. Health care organizations can involve human factors engineers in their product evaluation process and should expect and demand an optimized and tested user interface in the medical devices they purchase.

Key Points

- Poor design of the human-machine interface is the root cause of many medical errors.
- Human factors engineering principles can be applied to system and medical device design to decrease the likelihood of adverse events.
- Usability testing is a research tool that helps designers of consumer, commercial, and military products and systems discover design problems and the potential for error.
- Usability testing can also help designers of medical products and systems create designs that are error resistant, error defeating, and error forgiving.
- It is important for leaders in the health care industry to understand and expect this type of human factors engineering input into the design process of medical devices. J

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