Human Factors Engineering Series

Conclusion: You Need Human Factors Engineering Expertise to See Design Hazards That Are Hiding in "Plain Sight!"

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> "I believe that much of the difficulties associated with the nonacceptance (sic) and possible rejection by physicians of this computerized system could have been avoided if human factors specialists had worked more diligently on the physician-computer interface problems… Unless some efforts are undertaken as a matter of routine in the development of future systems, I can assure you that other medical-computer systems will find hard going and, perhaps quick rejection."[1(p. xxiii)]

In 1975, Maurice Rappaport wrote this prescient statement as a practicing physician and human factors engineering (HFE) professional in San Jose, California, after using one of the first hospital computer systems. Five years before, he had written about HFE and medicine.[2] I suspect that he was chagrined that the academics and industry professionals who were creating this computer system that he and his colleagues had to use had not heeded his article. In addition, I think we can all empathize with him about the opportunities for better patient care that might have been realized had the computer system been designed with HFE.

In the introduction to this HFE series in the *Joint Commission Journal on Quality and Safety*, I wrote that the basic ideas and tools from the discipline of HFE are needed to "help organizations go deeper in their analyses of adverse events and develop more effective and lasting remedies."[3(p. 215)] I attempted to show how the understanding of human limitations and capabilities could be applied across a variety of design issues, ranging from labels and

Article-at-a-Glance

Background: The Human Factors Engineering (HFE) series was launched to share the ideas and methods to aid deeper analyses of adverse events and provide tools to ensure more effective and lasting therapies. Articles in the series showed how human limitations and capabilities were important design issues in a variety of areas, ranging from labels and warnings to work place design and complex decision support systems.

Remaining Questions: After reading all the articles, one might ask a number of questions, such as who made all our "puzzle rooms?" How did it happen that so many device components "masquerade" as each other yet perform very distinct functions? What are the procurement systems that gave us medication containers, tubing, and connectors that are hard to see and easy to misconnect? Behind all those questions remains a key query: what stands in the way of developing or hiring the expertise to see and fix these catastrophic design hazards "hiding in plain sight?"

Summary and Conclusion: HFE has already found its way into health care organizations and industry. As with most large changes in professions and industries, many small steps will need to be taken toward applying HFE methods and principles to the large problems of patient safety. But there already ample incentives and tools to start transforming your health care delivery or manufacturing organization.

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After rereading the papers, which describe the application of HFE to computerized order entry systems, cardiac monitors, ambulance design, automatic epinephrine injectors, and other topics, I found that I still had a number of questions—Who made all our "puzzle rooms?" How did it happen that so many device components "masquerade" as each other yet perform very distinct functions? What are the procurement systems that gave us medication containers, tubing, and connectors that are hard to see and easy to misconnect? What was industry trying to do with alarm design, since wildly dissimilar devices provide alerts with similar sounds? What tools have hospitals created in their customized software that make it easy to do the wrong thing? Most importantly, what stands in the way of developing or hiring the expertise to see and fix these catastrophic design hazards "hiding in plain sight?"

Entire books have been devoted to answering questions about incorporating HFE (also known as *usability engineering*) into the computer industry and other domains.[4] Vicente[5] has considered the factors that influence change in the medical device industry, such as pressure by health care organizations purchasing devices and systems and by regulatory authorities. This final article in the series highlights some cases where HFE has already been incorporated into health care organizations and industry. These examples of successes should provide hope and incentive for you to *develop* or *hire* HFE expertise as a necessary component of a patient safety program or a health care system's design team. More broadly, HFE methods should be increasingly tailored to health care settings, including the architecture of such settings, and should be integrated into patient safety education.

Enlisting the "Front Line" to Report HFE Events and Issues

An anesthesiology resident recently thanked me for arranging the sessions because they "really changed the way I think." This resident went on to describe being more aware of the environment in which we work…

These quotes are excerpts from a June 2004 e-mail to me from Kathy Rosen, M.D., faculty for the anesthesiology residency program, West Virginia University. This feedback from residents came after I worked with her on several presentations and small-group exercises related to HFE and patient safety. These sessions are part of a patient safety curriculum, with a purposefully heavy emphasis on HFE, that is being launched across 100 of the 163 facilities in the Veterans Health Administration (VHA). The HFE curriculum-related activities at VHA and university-affiliate hospitals serves the following three purposes:

- It is the foundation for many patient safety activities and concepts
- It provides a conceptual structure to explain the many human-machine and human-computer glitches that residents see every day
- Learning and engaging in HFE methods helps turn residents' brains around "180 degrees"[7,8]

Neilson, another series author,[9] has continued her HFE in-house training efforts as the safety professional in her health care organization. The initial work in training and working with biomedical and clinical engineers has expanded. Stakeholders from pharmacy, purchasing, education, and front-line nursing have been added to the HFE and "no problem found" task force. Nielsen and her colleagues are proposing expanding HFE training to their entire health care system within a year.

Small, describing the need for HFE training approaches in health care,[10] cites numerous problems with the existing systems to find and analyze medical device adverse events, many of which involve HFE components. Surveillance using event reports, clinical software data, or administrative data (for example, International Classification of Diseases-9th revision [ICD-9] codes), is limited, whereas clinical engineering logbooks, which enable deeper analysis of usability issues and case-based training about device-associated issues, have "great potential to enhance the safety of medical devices."[p. 369]

HFE Methods and the Procurement Process

Many HFE methods, such as those described in the introductory article to this series, can be used to assist in proactive risk assessment efforts during procurement or in-house development of devices, software, and other clinical systems.[3] For example, one HFE-related facility can be found at The Centre for Global eHealth Innovation, which

was developed as a joint initiative of University Health Network (Toronto, Canada) and the affiliated University of Toronto. At the heart of The Centre is a usability testing facility, which is designed to test and develop electronic health innovations. This facility has enabled University Health Network to build on earlier usability work done to aid in evaluating medical devices. Whereas the earlier HFE work was conducted in informally assembled laboratories, the new facility, which features a multitasking simulation laboratory capable of being transformed into many health-related environments, allows for more sophisticated data collection. The laboratory is equipped with numerous cameras and microphones to capture fine level of detail, including key presses, facial expressions, and task sequences from multiple viewpoints, such as in the simulated use of an infusion pump.[11] Another usability lab for patient safety and improved medical device design, a Healthcare Product Usability Lab at the Miami Center for Patient Safety (Miami), is designed to evaluate devices regarding patient safety and work with companies to refine or fix products. As the Web site states:

> Usability Testing is a powerful analytical procedure that lets us look at whether or not a typical user will make errors when using a given product, when that product is put into actual use. With the Usability Testing tool we can predict behavior. This is an important building block in the development of safer medical products.[12]

Matthew Scanlon, the patient safety officer for Children's Hospital of Wisconsin and author of the third HFE series article,[6] has worked with colleagues, especially biomedical engineering and hospital information systems department personnel, to make a business case for evaluating devices with various proactive risk assessment techniques, especially usability testing. Along with colleagues in the outcomes research group, he is planning another approach to incorporating HFE and usability testing methods—by starting much more informally and trying to make a business case by integrating the process into overall technology assessment.

Increased HFE Activity in Medical Device Industry

It is beyond the scope of this article to address whether HFE activity and the number of HFE jobs in the medical device industry have increased, but it is of interest that a recent job posting from "a leader in developing, manufacturing, and distributing medical devices for the global cardiovascular market" lists the following responsibilities for the human factors engineer:

- Create interaction design solutions for life-saving medical products
- Document, communicate, and advocate for design solutions
- Plan and conduct field research as well as usability benchmarking with customers
- Develop graphical user interface (GUI)
- Designs and interactive prototypes for usability testing
- Conduct usability tests and apply customer feedback toward improved concepts

In the HFE series in the *Journal*, more than one author has highlighted HFE issues with infusion (IV) pumps.[13] Another author (Ed Israelski, Abbott Laboratories, Abbott Park, Illinois) has worked with AdvaMed, a medical technology association, and IV pump manufacturers to create universal IV pump usability requirements.[14] For example, their draft document might state that 95% of all nurse end-users can power on the IV pump with no training in less than 5 minutes or that 90% of all nurse end-users can program the main functions with no training in 15 minutes. The final document, which will likely be published by a national medical devices standards group, is likely to not only be a groundbreaking step for the IV pump industry but also provide a model for all medical device companies. For example, perhaps the work with defibrillators noted in this series by Fairbanks[15] will jumpstart activity in this area.

The Future of HFE and Patient Safety

> In 2010, a 14-year old girl is being brought into the magnetic resonance imaging (MRI) room for minimally invasive surgery. All her cardiovascular monitoring wires and IV tubes need to be moved over to special, nonferromagnetic medical devices, and these medical devices have to be programmed anew. Her anesthesiologist and surgeon are working with many specialized technicians to arrange the video screens, gas lines, surgical instruments, and other equipment. Because of the invisible magnetic and electrical fields, and the space constraints of the MRI equipment and room, everything and everyone needs to be in a particular place.

Today, you are the HFE officer. What kinds of things should you have done to ensure that multiple things would not go wrong? What are the optimal HFE methods to procure the best MRI-compatible devices? What about the hundreds of "little" devices, hand tools, and maintenance items that are nearly anonymous—and for which the vendor is switched every two years? How have you addressed the intractable problem of line and tubing management to avoid cross connections and misconnections? Where were you when the architects and builders developed the new MRI floor plans? Finally, should you be nervous that your education was provided by professors who research HFE in aviation and that your master's degree did not require an internship?

Fortunately, many professionals and organizations are working on these issues. Some are adapting HFE methods for use in health care settings. Series authors developed HFE methods to apply to the health care safety issues of wrong site surgery[16] and adverse drug events.[17] A group has applied and evaluated the use of usability testing of home medical care information technologies.[18] Other professionals are looking at cost effectiveness of HFE methods such as heuristic (expert) evaluations of IV pumps.[19] Professional societies and patient safety experts have provided recommendations for HFE and health care architecture[20] in general and for specialized areas, such as MRI.[21] Most importantly, there is definitive movement to create innovation in HFE and patient safety education. For example, at the University of Wisconsin, professionals from health care schools and engineering schools work together to develop the cross-disciplinary expertise[22] needed to answer the difficult rhetorical questions posed to the HFE officer.

Summary and Conclusion

As with most large changes in professions and industries, many small steps will need to be taken toward applying HFE methods and principles to the large problems of patient safety. The series authors have used case studies to provide examples of the problems HFE can help solve. Some of the analyses were conceptual, where other articles described the HFE solutions that were actually put into place. Other cases illustrate where progress is being made and where challenges remain to adapt the HFE methods to health care and build a workforce capable of their effective application. But there are already ample incentives and tools to start transforming your health care delivery or manufacturing organization.

Key Points

- A brief summary of various aspects of the HFE series reveals that it demonstrated the breadth and depth of HFE and patient safety
- Progress can be shown in many areas inside health care organizations and companies, including the following:
  - — Usability testing and procurement
  - — Improving analysis and reporting by teaching HFE to front-line practitioners and students
  - — More HFE activity and nationwide guidance for the medical device industry
- The future of HFE and patient safety lies mainly within the following
  - — Adapting existing HFE methods and providing better practical data about them (for example, cost/benefit)
  - — HFE and architecture of rooms, units, and the entire health care building
  - — Innovation in education to create true cross-disciplinary expertise to help us "see" design hazards hiding in plain sight . . . and for sustainable progress J

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