HUMAN FACTORS

Human factors engineering and patient safety

J Gosbee

The case study and analyses presented here illustrate the crucial role of human factors engineering (HFE) in patient safety. HFE is a framework for efficient and constructive thinking which includes methods and tools to help healthcare teams perform patient safety analyses, such as root cause analyses. The literature on HFE over several decades contains theories and applied studies to help to solve difficult patient safety problems and design issues. A case study is presented which illustrates the vulnerabilities of human factors design in a transport monitor. The subsequent analysis highlights how to move beyond the more obvious contributing factors like training to design problems and the establishment of informal norms. General advice is offered to address these issues and design issues specific to this case are discussed.

Box 1 Human factors engineering

Human factors engineering (HFE) is a discipline concerned with the design of tools, machines, and systems that take into account human capabilities, limitations, and characteristics. The goals are to design for safe, comfortable, and effective human use. Ergonomics, usability engineering, and user centred design are considered synonymous. HFE is based on design related aspects of several biomedical disciplines, including anthropometrics, biomechanics, sensation and perception anatomy and physiology, and cognitive psychology, which covers models and theories of human performance, memory, and attention.

An HFE process is the foundation of "user centred design". This design process focuses on user needs, user characteristics, and end user testing of the human-machine interface. Another key characteristic of this user centred design approach is the concept of iterative design and testing. Simply put, the design is repeatedly refined throughout the design cycle based on feedback from user testing (or usability testing), which is also repeatedly conducted, starting from the early stages of the design cycle. This helps to ensure that the system being designed meets its intended purpose and operates in its intended manner. Early testing also helps to ensure that design deficiencies are identified and rectified before the system is fielded. The main points of this event come from a real case, but it is not necessarily a case from within the VA healthcare system.

HFE ANALYSIS

Most RCA teams assessing the case in box 2 would not discipline the person who programmed the demo mode or the transport team who did not notice the small "D" on the display. The RCA teams would probably spend their time answering detailed questions about when, where, and how this event happened. Their remedies would probably include adding more detailed policies to double check for demo mode or prohibiting the use of this mode. Some teams might even find out, to their chagrin, that these policies already existed in their hospital. They would reluctantly add additional targeted training on this "hard to see" pitfall to the basic in-service session on the transport monitor.

If an RCA team was applying HFE principles, the team would just be getting started when they found out that there were deviations in policies, that the training was not effective because of the complexity of the device, or that groups of people had devised ways to work around equipment issues.
General issues
Many clinicians were probably doing “work arounds” to use this less than optimally designed transport monitor. Some of them may have confused the fact that the complexity of diagnosing and treating unstable patients does not mean that the operation and interpretation of medical devices are inevitably complex. Without knowledge of the consequence, some managers or peers were probably rewarding those providers who could master this needlessly complex transport monitor. It is also likely that this happened before and was noticed but not reported. Adapting to misbehaving equipment is one aspect of the “culture of low expectations”.

Specific issues
Applying HFE principles of design, there are many specific vulnerabilities in the design of this transport monitor. These design issues exist for both the transport team that used the monitor and the person who set and left the demo mode actuated. The “D” signifying demo mode is too small to be easily noticed. If noticed by the transport team, it still needed to be decoded. Negative transfer of training could have occurred if the transport team had never used monitors capable of displaying anything but real data. There are no clearly marked exits that allowed the person who set the demo mode to navigate the device out of this mode. The person setting the demo mode also encountered inadequate feedback and situational awareness on this rarely used function. Most importantly, there was no interlock method to prevent a confusing mode to be left on permanently.

GENERAL RECOMMENDATIONS
In general, improving the design of this device is a better solution than training or labelling.6 One possible design improvement is to change the programming of this monitor so that...
Biomedical and clinical engineers in hospitals have many roles and responsibilities for dealing with the above issues. Firstly, they have a leadership role in educating other key personnel involved in selecting and implementing transport monitors. They also need to be keen about the design issues if they are members of RCA teams.

Managers in relevant healthcare organizations (for example, emergency medical service, hospitals) who read this case study should communicate it with clinicians and engineers involved in transport, and request confirmation that it was received and acted upon. If some of the HFE concepts are foreign to key members of their staff, training opportunities should be supported with funding and leadership—for example, managers themselves should get trained if needed.

The management of the manufacturers of transport monitors should involve all their engineers, designers, product managers, and human factors engineers in the case and its analysis. Part of any usability testing on new versions of existing products or new products should include lessons from this case and analysis. It is both the right thing to do for business and may be required by FDA regulations.

CONCLUSIONS
HFE must become a core competency of anyone who has significant involvement in patient safety activities. It is not just another set of principles and techniques; HFE provides a “tried and true” framework for building and strengthening that elusive safety culture. The process of HFE can also be applied to many patient safety activities in healthcare organizations, including procurement of medical equipment, RCAs, and patient safety training activities. In some well known healthcare organizations, significant effort has begun.

Key websites on HFE are shown in box 3.

REFERENCES
10 Wiklund M. Eleven keys to designing error-resistant medical devices. MD&D May 2002; 86–90. [Also available at http://www.devicelink.com/mdd/archive/02/05/004.html]

RECOMMENDATIONS TO SPECIFIC GROUPS
Clinicians (nurses, physicians) who use patient monitoring equipment should understand the inherent hazard with demo modes and whenever there are many modes for the same display. It is a very weak defence against future adverse events, but being more aware of this vulnerability and teaching it to others has some utility. They should also keep this in mind if they are members of procurement teams.
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