The Complexities of the Human-Medical Device Interface

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Human factors, as a highly interdisciplinary and systems science, has already established the tremendously important role associated with the human-machine interface in ensuring safe, usable, and human-friendly products. For users of medical devices, however, this interface is significantly more complex because the patient is often, quite literally, an extension of the device. Through their direct electrical (e.g., electrocardiogram), fluidic (e.g., arterial blood pressure line), and/or pneumatic (e.g., ventilator) connections to various medical devices, patients become one with the technology.

Not only are the machines capable of altering patient physiology, but the patient is also capable of altering the machine, e.g., through the triggering of alarms. Such an alliance between patient and machine is not only dynamic, it may also be highly fragile and unstable depending on the changing pathology of the patient. This complexity places a significantly increased cognitive burden on the clinical users of medical devices. Correspondingly, designers of medical devices need to be acutely aware of this burden when designing and testing the effectiveness and quality of their product interface. Hospital-based biomedical equipment technicians (BMETs) and clinical engineers will also do well to stay mindful of these complexities during device troubleshooting and, especially, when introducing new technology into the hospital environment.

The focus of this paper is on the subtle, almost subliminal nature associated with many aspects of the human-medical device interface, some of which include the simple use or misuse of color, obscure panel labeling, or switch behavior. Collectively, however, they all may affect how the machine and clinician user will eventually "get along" with each other—and how effectively and safely the device will be used.

The profoundly-instrumented, acutely-ill patient represented in Figure 1 continues to be more the norm rather than the exception in many hospital critical care units. Such patients may have multiple indwelling catheters, be connected to multiple infusion pumps, have direct electrical connections to physiological monitors and/or electrosurgical ground electrodes, and be intubated and connected to a ventilator as well.

Obtaining or delivering clinically useful, real-time information or therapeutics is, in fact, precisely why these patients are instrumented in the first place. These obvious physical connections to and from the patient, however, do not represent the only interface.

As further illustrated in Figure 2, there are additional "connections" between the clinician and the device and between the clinician and patient. These create, in effect, a closed-loop system. The overall safety and effectiveness of this patient-device-clinician system may also be profoundly affected by the environment in which they all reside. It is in this total systems context that the full impact, importance, and complexities of these multiple interfaces become apparent.

Most of the medical errors related to such systems oc-
It is also at these interfaces where the human limitations associated with perception, assumptions made, and communication converge. In particular, it is here where the lessons of human factors engineering are most applicable.

**Issues Affecting the Clinician-Medical Device Interface**

The interface between the clinician and medical device is, in essence, a bi-directional information pathway. In this context, feedback is not limited to that which the device gives its human user through its panel labels, displays, indicator lights, and alarms, but also that which the user gives to the device through proper activation of controls and switches, in the proper sequence and at the proper time.

For humans, meaningful, reliable feedback is crucial to proper learning and the establishment of accurate mental models regarding device behavior. The subtleties associated with these forms of communication can also be profound. Consider, for example, the features of a circa-1970s defibrillator front panel (Figure 3).

For many reasons, the use of this early life support device may have been one of the first that approached the truly "intuitively obvious"—an ideal human factors goal for all device designers. In particular, note the sequential numbering of controls. Upon pressing the number “1” button, the user would also be greeted with two additional forms of tremendously useful feedback: a crisp, positive detent pushbutton which also illuminated upon being properly depressed. Not only does the viscoelastic characteristics associated with such positive detent switches activate tactile receptors in the user’s fingertips, giving the user continuous force and displacement feedback, the abrupt detent further informs the user that they have pushed enough thereby doing the correct thing. Hence, in this single switch, the machine presents three different forms of feedback (multiply-redundant) on both cognitive, tactile, and visual levels. In some switches the detent may be loud enough to be heard, providing a fourth level of redundancy. The raised switch guard surrounding the large pushbutton also provides some protection against accidental activation.

With such feedback, the likelihood of the user doing the correct thing in the correct order increases considerably. Subliminally almost, the device is also rewarding the user for doing the correct thing. Such rewards tend to also build user confidence in using the device.

Secondly, the number “2” on the Energy Select knob instructs the user to select the desired energy level—also following the user-expected convention of functions increasing with clockwise rotation of such knobs. Charging the defibrillator with the number “3”-labeled and color-coded red (implying caution) pushbutton is next. In addition to the same tactile and visual feedback experienced from switch 1, the user is now provided with a frequency and sound level-increasing tone as the defibrillator charges. The horizontal analog meter movement also sends visual feedback on this charging status. Once charging is complete, a steady tone is provided until the defibrillator is discharged.

Additional information about the interrelationship between these three controls and the meter movement is also conveyed through the (calming) pastel blue background surrounding these controls. Essentially this use of color is telling the user—without explicitly telling them—that these device functions work together.

Lastly, a relatively unique concept at the time was to label...
the controls in terms most familiar to the device user, e.g., ECG SIZE. Not uncommon in this era would have been the use of the more cryptic and confusing term GAIN.

Other device panel features that can affect user speed and accuracy in entering information include the concept of spatial congruity, i.e., the placement and behavior of controls in a manner consistent with the user’s expectations. For example, notice the calculator vs. telephone style keypads associated with the two different infusion pumps shown in Figure 4. Not only is the telephone-based style more consistent with what users expect, the buttons on this particular pump are also slightly raised and also possess a positive detent. Such features are often lacking or not as pronounced with conventional membrane switches.

While such design subtleties may at first glance appear

Lessons from the Aviation Industry

In the field of human factors engineering, the healthcare industry is often compared to the aviation industry. Both involve high-tech, high-risk environments. Pilots and physicians have similar authority. And yet, they remain two fundamentally very different entities.

Aircraft, despite their complexities and dependency on human pilots, are still machines—and typically do not have an often compromised and acutely ill human being in the control loop. The highly-regulated airline industry has also had a considerable headstart over healthcare in its use of established human factors concepts and practices.

Nonetheless, there are at least three fundamental concepts that have been successfully embraced by the aviation industry, parallels to which continue to be seriously lacking within healthcare. Most notably healthcare continues to lack the following:

Standardized equipment and accessories. Despite the progress and tireless effort of many within the standards industry, medical devices and their associated accessories continue to exhibit a host of troubling incompatibilities across device manufacturers. Non-interchangeable patient cables, blood pressure cuffs, finger plethysmograph sensors, infusion pump tubing sets, defibrillator electrodes, batteries, etc., continue to be more the norm than the exception. It is also not uncommon for hospitals to have different electro-surgical units throughout their operating rooms, different defibrillators, and anesthesia machines. Such inconsistencies—especially among the more intrinsically dangerous therapeutic devices—simply invite more use errors, treatment delays, and potential patient harm. As with all things, familiarity and repetition breeds comfort and competency, especially in times of stress. Standardized equipment encourages competency.

Structured, consistent, and competent investigation of all equipment-related injuries or accidental deaths and the formal reporting and follow-up of such incidents. Regrettably, it is often only after equipment or systems fail and people are injured or killed that engineering really learns anything. Only after accidents are reconstructed and failure modes identified can the often latent hazards be addressed, minimized, or designed out completely. The tremendous safety record within the aviation industry is due, in part, to what it has learned from crashes and component failures. As an industry, healthcare has no such authoritative incident investigative mechanism. As a result, the healthcare industry has been very slow not only to learn from its mistakes but more importantly to identify the latent flaws within its delivery systems.

Communication and team work. Specifically, the concepts embedded in an aviation crew’s resource management training and techniques include the freedom and expectation of all members of the team to be able to challenge anything that they perceive to be a problem or threat to the mission. As also offered by Nance, the communication problems that result when such techniques are not used are the major root cause of many medical errors. Although many hospitals are making progress in this area—especially those within the U.S. Department of Veterans Affairs system—it is still virtually unconscionable for many operating room nurses to freely and safely challenge a surgeon or a catheterization laboratory technician to challenge a cardiologist. In this regard, healthcare and medical school education have considerable catching up to do.

quite insignificant, much of the related human factors research would suggest otherwise. In essence, when device appearance and behavior matches what the intended user expects, frustration and errors tend to be reduced.

Identifying these often hidden user-device mismatches is precisely what structured usability studies hope to accomplish, preferably before the product is introduced to the market. Problems with device use are often best identified by the prospective user. Obscure or cryptic labels, complex programming steps, or indecipherable alarms are all device features that usability studies can capture and correct before the product is introduced.

Well-designed pre-purchase evaluations performed within the clinician’s actual environment still remain one of the best techniques for identifying these often subtle but profound human use issues. The actual user community, in their particular patient care environment, with their particular mix of patients and practice needs, can best evaluate issues of device usability. Additionally, the simple act of staff inclusion in the purchasing process tends to improve device acceptance. All too often however, this vital input is not solicited or valued. This fact is emphasized by the Agency for Healthcare Research and Quality as follows:

“Device purchasers should strongly consider institution-specific human factors testing. Usability testing at the institutional level establishes built-in redundancies to capture any design problems missed by manufacturers. Furthermore, the users and environments at individual institutions will differ, possibly in important ways, from the users and environments in which the device or pro-

gram was initially designed and tested. It is important for an institution to be aware of who the intended users of the device or software will be, as well as where and when they plan to use the device.”

Environmental influences

Also represented in Figure 2, a variety of environmental factors can have a direct and potentially detrimental effect on how well the clinician and device interact.

High Ambient Noise Levels

High ambient noise levels have repeatedly been cited as sources of psychological and physiological stress for both patients and clinicians. While such noise levels may not result in permanent hearing loss, temporary threshold shifts that may interfere with hearing alarms and make communication difficult are a concern. Tijunelis, et al. reported that time-weighted average sound levels measured in a large urban emergency department over both 12- and 8-hour shifts exceeded 52 dB with measured peak noise levels of 94-117 dB occurring each minute during their measurement period.

It is in this context of hospital noise pollution that the many issues and problems surrounding medical device alarms need to be examined. Ironically, as hospital ambient noise levels increase, so too must the sound levels of medical device alarms in order that they be heard, which only increases ambient noise even more.

Facilities Design

Facilities design includes the physical layout and placement of devices relative to the patient. The often cramped and crowded critical care environment may contain a variety of tangled cables and lines, reach problems, and tripping hazards. Similarly, the often lengthy distances, multiple thresholds and elevators along which patients are often moved while precariously tethered to multiple infusion pumps only adds to the potential risk of harm. The influence of such environmental factors on the patient-device interface is another compelling reason for hospitals to do extensive pre-purchase usability testing.

Lighting

The intensity, position, and color temperature of available lighting are also key. Such lighting factors may contribute to glare on monitors and instrument panels, artificially alter skin tones, and increase annoyance for both the patient and clinician.
Conclusion
As an established scientific discipline, human factors offers healthcare a tremendous wealth of knowledge, principles, and solutions associated with the problems and complexities of the patient-clinician-medical device interface. It is only when these complexities are acknowledged and understood that the accompanying latent threats to patient safety can be identified and removed. Such an approach continues to work exceedingly well within the aviation industry. Healthcare only needs to embrace and apply these concepts.

References