Value of human factors to medication and patient safety in the intensive care unit

Matthew C. Scanlon, MD; Ben-Tzion Karsh, PhD

Conventional wisdom suggests that the “human factor” in critical care environments is reason for inadequate medication and patient safety. “Human factors” (or human factors engineering) is also a scientific discipline and practice of improving human performance. Using decades of human factors research, this paper evaluates a range of common beliefs about patient safety through a human factors lens. This evaluation demonstrates that human factors provides a framework for understanding safety failures in critical care settings, offers insights into how to improve medication and patient safety, and reminds us that the “human factor” in critical care units is what allows these time-pressed, information-intense, mentally challenging, interruption-laden, and life-or-death environments to function so safely for so much of the time. (Crit Care Med 2010; 38[Suppl]:S90–S96)

Key Words: medication errors; human factors; human factors engineering; ergonomics; intensive care; safety

“To improve medication and patient safety, we need to deal with the ‘human factor.’”

That quote and similar ones from the critical care world—such as “We invested in this new medication safety technology for the intensive care unit (ICU). Now if only we could fix the human factor so they’d use it correctly”—are all too common. In these quotes, the term “human factor” is used as a synonym for the “baggage” people, such as clinical staff, bring with them to work. This baggage includes memory limitations, <100% compliance with safety rules, misuse or resistance to technology, and general less-than-perfect reliability and accuracy in actions and decisions. Unfortunately, this use of “human factor” puts the blame for patient safety problems squarely on the clinicians, which results in patient safety interventions that implore staff to pay more attention, try harder, stop screwing up, and follow all of the rules, when the focus should be on redesigning the system. That use of the phrase “human factors” is inconsistent with evidence from a scientific discipline and practice known as human factors (also human factors engineering, or ergonomics, or HFE) (1, 2).

HFE is the science and practice of improving human performance (3–6). HFE scientists and practitioners discover and apply information about human cognitive and physical abilities and limitations to the design of tools, machines, systems, tasks, and environments for productive, accurate, safe, and effective human use (5–9). HFE designs and interventions have led to better understandings of, and designs for, operator performance and safety in aviation, manufacturing, nuclear power, process control, surface transportation, rail, air traffic control, service, construction, agriculture, and even health care (3, 10–31). The Institute of Medicine also called for more application of HFE science as a way to improve patient safety (32, 33), although HFE research in health care is actually decades old (34, 35). HFE can be thought of as providing the evidence-based design guidance to support human performance, especially in complex systems like critical care units.

HFE research has demonstrated that performance, efficiency, quality, and safety are the result of the interaction between people and the system in which they work (4, 36). We say, therefore, that phenomena like patient safety or quality are emergent properties of a system. That is, patient safety problems, including human error and violations of safety protocols, are rarely the fault of the clinicians; rather, they emerge from the clinicians working with technologies (which may or may not be well designed), in a particular environment (which may be rushed or dark or filled with interruptions), doing particular tasks (which may require intense concentration), in a particular organization (whose culture may reward shortcuts). This understanding that system interactions produce safety or quality is also known as systems thinking, and solutions that seek to redesign systems are known as systems engineering solutions or systems engineering designs. According to HFE research evidence, improving human performance is not an issue of telling or forcing people to work harder, smarter, or with fewer errors. Instead, performance is improved by designing systems to support the physical and cognitive work of the clinicians. That may involve better designed tools, technologies, policies, tasks, environments, layouts, or teams. HFE scientists and professionals have developed tools, standards, guidelines, and principles for improving human performance (e.g., safety and quality) (5, 37–40) that are increasingly being applied in health care. We argue that trend must continue for there to be patient safety improvements in critical care.

Decades of HFE research have yielded insights into how to improve human performance and, thus, safety and productivity.
ity. These insights are often at odds with “common sense” beliefs that are not evidence based. With this in mind, the goal of this paper is to evaluate a range of common beliefs about patient safety through a human factors lens.

“We would not have medication safety problems if people stopped making errors”

This belief, if taken to its logical conclusion, suggests that to improve safety, one needs to get rid of errors. People, however, make errors. Therefore, as long as there are people (patients and providers) in critical care units, there will be errors. From an HFE perspective, efforts to improve patient safety that depend on requiring people to be infallible are misguided and wasteful. The reason goes beyond simply that “people make errors”—HFE research demonstrates that errors often are caused by poorly designed systems, which some have referred to as “design-induced” errors (41). The paper by Fairbanks et al. (15) provides an excellent example of how poor design led experienced emergency medical technicians to err. Therefore, if an error occurs, one should not ask, “Why did the person make the mistake?” but rather, “What caused the mistake to occur?”

Consider an ICU that uses a computer physician order entry (CPOE) system. A typical healthcare approach would focus on education to assure that physicians remember how to correctly order medications. But if an error happened, the physician would be blamed. An HFE approach would instead seek to design systems that make it harder to err in the first place and make errors that do happen more visible so that they can be quickly corrected (39, 42, 43). An example of this is a CPOE system that uses software logic to prevent (that is, a forcing function) physicians from ordering out-of-range doses and warns the physician if an order for a particular drug might create an allergic response or drug–drug interactions. Rather than depending on a potentially tired and distracted intensivist to not make a mistake, the forcing function prevents certain orders, whereas the warning makes other potential errors visible so the physician can correct them immediately.

Another clinical example is the restriction of the availability of high-risk medications. One source of medication errors is the storage of look-alike vials, or medication of differing concentrations in the same area. An incorrect look-alike medication can be given in error and potentially cause harm. A typical “person”-based approach to solving this problem would be to educate the staff to pay more attention to look-alike vials and to make the labels on the medications appear more distinct. The HFE or system-based approach would involve removing the high-risk medications to a different area, making it impossible to confuse medications or concentrations. In other words, by redesigning the system of medication storage and access, the opportunity for error ceases to exist. The HFE solutions in both examples exhibit the characteristic of using system redesign to reduce the risk of errors. This risk-reduction approach is consistent with epidemiologic approaches that seek to identify and reduce risk factors for disease, and it is a standard HFE and safety engineering approach (4, 44, 45).

Other examples of solutions that focus on people instead of system design can be seen by the following “solutions”: warning labels, signs and posters exhorting staff to “be careful” and to “do this” or “do not do that,” repeated educational campaigns, and reliance on policies and procedures. None of these activities are bad per se; they can be part of an effective safety effort. However, they are not sufficient to provide safety. In each of those “solutions,” the goal is to error-proof the people, despite the inherent property of people to err. No amount of rules, education, or warnings will prevent errors from occurring. In contrast, human factors or system-based improvement efforts apply principles of analysis and redesign to make it harder for errors that do occur to reach patients and, when the errors reach a patient, mitigate their harm.

One clinical illustration of applying analysis and redesign to eliminate errors and harm is found in the use of concentrated electrolytes, such as potassium (46). If a nurse inadvertently draws up potassium rather than another medication because of shared storage and “look-alike” labels, then he or she will be viewed as committing an error. Traditional solutions include warning labels or signs. However, identification and analysis of risk reveal that the problem is not the nurse but instead the storage of potassium alongside other medications, creating the potential for error. Redesign would then result in removal of the potassium to a separate, perhaps locked, storage area, reducing the possibility of error. Clinical examples of forcing functions might involve the redesign of intravenous tubing connectors to prevent inadvertent connection of enteral feeds or noninvasive blood pressure tubing to intravenous catheters (47). Similarly, the principle of analysis and redesign is readily seen in newer “smart infusion pump” technology, which essentially introduces constraints or forced limits to the magnitude of programming errors that can reach a patient. In each of these examples, there is an understanding of the work involved that is associated with a perceived risk, which then leads to a careful redesign to eliminate the risk underlying errors and harm.

“We would not have medication safety problems if people stopped violating the safety rules”

There is a common belief that risk and harm to patients occur from violations of rules and policies. This perspective stems from the fact that policies are often created to direct care and prevent harm. As a result, it is thought that any violation must decrease safety. HFE research demonstrates that violations, however, are to some extent inevitable in a complex domain like critical care where the exception is the rule (48, 49). Rules are critical for safety, but rules assume a one-size-fits-all mentality. This logic may apply much of the time; however, critical care is a complex domain where multiple rules and goals may always be in conflict. As such, following one rule may require breaking another rule. This puts providers in difficult situations (50, 51).

One example of enhancing safety through violations occurs when a patient requires an emergent medication that is not readily located in the patient’s bedside medication box or the ICU medication-dispensing cabinet. The expected action is to wait for the medication to be sent from the central pharmacy. However, a nurse might recognize that the patient needs the medication immediately and that his/her other patient has the needed medication in the correct dose in the patient’s bedside medication box. Giving one patient another patient’s medication is a clear violation of most hospitals’ medication policies. Despite this, the nurse obtains the medication from the second patient and administers it, treating the critically ill patient. Then,
when the medication finally comes from the pharmacy, the nurse replaces the “borrowed” medication.

Central to the issue of safety and rule violation is the question of whether the rule fits the actual work of clinical care. In the illustration, the intent of the rule is to prevent one patient from receiving another patient’s medication, which may result in harm from incorrect dosing, drug-drug interaction, or an allergic response. Strictly speaking, the nurse has violated an important safety rule. At the same time, the nurse is faced with competing rules and goals: follow the rule not to borrow medications, on the one hand, and treat a patient with an emergent need, on the other hand. The nurse in such a situation must decide which rule to follow based on patient need and safety considerations. In this case, the risk of violating one rule was weighed against the immediate need for medication. Was it the nurse’s fault he/she did not have the needed medication at the time it was needed? No. But it was the nurse who was forced to adapt to this system design problem. This is another important lesson from HFE: When systems or technologies or rules or policies do not fit the situation encountered by the provider, as was the case in the example, the person is forced to adapt and respond (52). Therefore, if an error or accident happens in this situation, it cannot be said to be the person’s fault; after all, this person was just doing what was needed to be done in the face of a system that did not support his/her needs. That is, HFE research demonstrates that more often than not, it is the people in the complex systems that provide resilience (53, 54), or the ability of the system to function safely despite the inherent complexity and the risks. It is the people after all, or the “human factor,” that provides judgment, creativity, problem solving, and context-sensitive solutions. In the case of critical care environments, where providers are always expected to go the extra distance to cope with technologies and systems that do not reliably deliver, efforts should be made to train providers how to respond and react when systems do not work as planned (52).

From an HFE perspective, the concept of rules and violations has three important implications. First, before considering punishment of ICU physicians and providers for violating rules, it is important to understand whether the rules fit the clinical scenario, or whether the violation added to safety (49). After all, a “violation” that everyone agrees is an improvement will be labeled a “best practice” and not a “violation.” Second, the creation of rules and policies must involve front-line staff who truly understand how care is provided under real circumstances. Finally, instead of devoting resources to refining rules that poorly fit complex clinical care, safety might better be achieved through thoughtfully redesigning the systems of care delivery.

The first step in redesigning systems of care delivery (as an alternative to focusing on rules) is to study the nature of work through the application of system analysis methods. We recommend in-depth observations, interviews, and other analytical techniques, such as process mapping. But the key here is the expertise of the person doing the data collection and analysis. A trained human factors engineer observing the exact same clinical encounter as an industrial engineer or physician will see very different things and, therefore, record very different data. A team approach is highly recommended. The goal is not simply to understand the system of care, but specifically to also understand the nature of the work for the clinician—How can redesign help clinicians perform better in light of the true complexities of their work?

From those data, safety can be improved in many ways. For example, in high-performing teams, all

### Table 1. Two examples of hierarchies of hazard control

<table>
<thead>
<tr>
<th>Strength of Prevention</th>
<th>Actions to Improve Medication Safety (87)</th>
<th>Occupational Health and Safety Management Systems (88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower</td>
<td>Education/training</td>
<td>Personal protective equipment</td>
</tr>
<tr>
<td>Moderate</td>
<td>Policies/rules</td>
<td>Administrative controls</td>
</tr>
<tr>
<td>Higher</td>
<td>Double checks</td>
<td>Warnings</td>
</tr>
<tr>
<td></td>
<td>Standardization</td>
<td>Engineering controls</td>
</tr>
<tr>
<td></td>
<td>Automation and computerization</td>
<td>Substituting less hazardous material/process/operation/equipment</td>
</tr>
<tr>
<td></td>
<td>Forcing functions/constraints</td>
<td>Eliminate hazard</td>
</tr>
</tbody>
</table>

A recurring theme in patient safety is the need for improved teamwork, and this belief applies to the ICU (55). However, Thomas et al (56) found that critical care physicians and nurses have different perceptions of what is meant by teamwork and how well their team functions. Whereas 73% of physicians rated collaboration and communication high or very high with team members, only 33% of nurses rated collaboration and communication high or very high. Although the authors concluded that these differences might relate to training, gender and role-related culture, another explanation (57–62) may relate to a poor understanding of the science of teams and team performance. Team performance, like individual performance, is a research topic studied in HFE.

In critical care environments, there are a variety of teams. There is the patient’s care team that is composed of the nurses, respiratory therapists, pharmacists, attending physicians, and perhaps trainees, such as residents and fellows. There are also the within-discipline clinical teams, such as the nursing or physician team that cares for a given patient over shifts, days, and weeks. A nurse and his/her nursing assistant might also be a team, as might all of the nurses on a given shift in a given ICU. However, despite that fact that we might call each of those “teams,” HFE evidence demonstrates that does not mean that they function as teams.

Teams are “two or more individuals with specialized roles and responsibilities who must interact dynamically and interdependently and are organized hierarchically to achieve common goals and objectives” (63). But more than that, according to HFE evidence, high-performing teams are those that have been trained to have, and have demonstrated proficiency in, specialized knowledge, skills, and attitudes that support teamwork (64). For example, in high-performing teams, all

---

**Our ICU would be safer if i had a team who would do as i say**

---

Crit Care Med 2010 Vol. 38, No. 6 (Suppl.)
team members have the following knowledge: they share the same mental model of what needs to get done, they all know the team mission, and they all know each others' roles and expectations. Similarly, in high-performing teams, all team members have been trained and have demonstrated proficiency in the following skills: back-up behavior, team leadership, conflict resolution, and closed-loop communication, among others. However, few healthcare organizations train the staff to have that knowledge or those skills. In part, the lack of meaningful team training may reflect that there is no "one-size-fits-all" primer for training teams. As with other processes discussed in this paper, when determining the specific steps or recommendations to training a team in healthcare, the first step should be defining and then understanding the purpose of the team and the work that must be performed by the team to achieve the purpose. Then, team composition must be considered. Only then can specifics of training be entertained, and these specifics will be contingent on the results of these initial steps. Until clinicians and administrators routinely apply this thoughtful and robust approach, HFE research suggests that there will not be high-functioning teams in healthcare (65).

Based on these concepts, it is reasonable to ask, "What is the ideal means to communicate within a team?" However, it is imperative that providers understand there is no "ideal" means of communication. There may be relative ideals that exist for specific types of work in specific contexts but even then, there are multiple dependencies. These include the nature of the work, the available technology, the available team members, and their respective training. In the same vein, questions regarding ideal team size or team composition do not have a standard answer; instead, the correct answer depends on the work being performed by the team and the context in which this work is being done.

Another twist on team composition is whether families or even patients should be included as part of the team. Continuing the theme identified above, asking whether teams should include families should be supplanted by asking, "What is the purpose of the team?" If the purpose of the team is providing care and the involvement of the family helps achieve this purpose through provision of important information or participating in critical decision-making, then involvement of the family would enhance team performance. That said, the next question is: "How do we effectively include a family member?" Drawing from the points on team communication, if the clinical team strictly speaks in medical language and the family member cannot understand the discussions, then the family member is essentially excluded from the team by virtue of the performance of the team.

For critical care providers who are faced with managing multidisciplinary rounds, performing together to resuscitate patients, or managing mass-casualty situations, there is a rich source of HFE literature on team design and training that can improve language. Applying the science to team performance will yield improved safety, not the expectation that a "team" blindly follows orders (61).

**"Our ICU would be safer if there was less focus on workload/number of hours worked"**

The topic of work hours and work hour restrictions in healthcare has gained increasing attention over the last decade, particularly in light of the standards implemented by the Accreditation Council for Graduate Medical Education (66). Rather than attempting to summarize the literature related to the effects of sleep deprivation and prolonged work hours, there are some additional lessons from the HFE literature that are germane to issues of workload. First, workload is multidimensional (30, 67). Unit-level workload can be viewed as staffing ratios in a nursing unit (or duty assignments for trainees). However, other important types of workloads exist. Job-level workload "refers to general and specific demands of the job, including the general amount of work to be done in the day, the difficulty of the work, and the amount of concentration or attention required to do it" (66). A third type of workload can be thought of as task-level—those resources and demands associated with a specific task. In the ICU, this can be understood in the context of placing a central venous catheter. Task-level workload encompasses the concentration required by the clinician to place the catheter in the face of competing demands for concentration, as well as the training of the clinician, his/her cognitive capacity, and the available resources such as monitoring technology and staff to assist with the catheter placement.

The concept of multidimensional workload is essential to understanding the issues of work hour and workload restriction. First, efforts to reduce one type of workload will likely have implications for the other types of workloads. That is, reducing the unit-level workload by shortening shifts without increasing the number of staff may unintentionally (but predictably) increase the job-level and task-level work for the clinicians remaining in the work environment. Although the number of hours worked definitely is an issue and can lead to fatigue and then mistakes, even with a reasonable number of hours, the workload can be excessive, exceeding the capacity of well-intentioned clinicians, and leading to errors and workarounds. Workload is a matter of design and a choice by an organization. Sadly, if someone is identified as having made a mistake because of excessive workload, it is unlikely that "workload" will be blamed.

**"Medication delivery would be much safer if we only had [blank] technology"**

ICUs are technology-rich environments. Not surprisingly, there is a perception that additional technologies may enhance safety. Specific technologies attributed with improving safety include electronic health records, clinical decision support, CPOE, bar-coded medication administration, and "smart" infusion pumps. These technologies have been linked to reduction in errors, even though there is little evidence that they reduce harm to patients. There is also evidence that these technologies can introduce new types of errors, violations, and harm (68–73).

Although it might seem paradoxical that technologies designed to improve safety can actually lead to errors and violations, it is not paradoxical when seen through an HFE lens. For instance, CPOE does not exist in a vacuum within the ICU. Instead, people (physicians, nurses, pharmacists) must use the CPOE system to perform tasks (ordering, modifying, and managing medications) within a busy and often distracting ICU environment. Independent of whether the CPOE system works as intended, the interactions between technology and people, tasks and environment, not to mention how the technology was implemented and supported, will ultimately determine whether the CPOE improves or sometimes worsens medication safety (74). Health information technologies intended to improve
safety may have usability problems (75–81) that increase the likelihood of user errors, provide misleading feedback, lead to high rates of false alarms, or difficulties interpreting data. If such usability problems exist, it can lead to “design-induced” errors (41).

As with team training, there is a rich body of nonhealthcare literature and a growing body of healthcare-specific literature that can guide the design, selection, and implementation of technologies to yield the best results (3, 74, 82–84). Without leveraging this knowledge, ICU providers risk the unintended but foreseeable consequences of suboptimal technology adoption.

“Things would be safer if we could standardize everything in the ICU”

Standardization, like technology, has been identified as a potential solution for both medication and patient safety. However, HFE research suggests that this perspective is overly simplistic and potentially hazardous, especially in complex environments like ICUs. It is clear that standardization of processes, such as the central catheter insertion bundle, reduces unwanted and potentially dangerous variation. What is not as obvious is the need to standardize the right processes to the right standard.

For core processes, such as preparing and dispensing a medication, handoff communications or placing a central venous catheter, standardization will reduce unwanted variation and potentially reduce waste while improving quality and safety. At the same time, the practice of standardization can be overused. Standardizing the ordering, dispensing, and administration processes of aminoglycosides in septic ICU patients would be beneficial; standardizing to a single dose of aminoglycosides regardless of patient gender, age, weight, or renal function would be potentially dangerous. The distinct between standardizing processes of care and “one size fits all” will likely be more important with the emerging science of pharmacogenetics and individualized medicine. The key HFE point on standardization is this: If the standardization of a process will support the needs of the ICU providers in all or nearly all cases, then use standardization but allow exceptions for the few cases that do not apply. If, on the other hand, standardization will only support the needs of the providers some of the time, then standardization may be problematic. After all, if a standardized process does not fit many typical situations, then standardizing will simply create more “violators.”

“I never make that mistake, so I do not need a checklist”

A specific type of standardization that has gained greater visibility in the ICU setting is the use of checklists. Physicians may be asked to use a checklist for placing a central venous catheter, ICU nurses use checklists for assuring the resuscitation cart is prepared for the next emergency, and ICU pharmacists may use a checklist while preparing a group of medications necessary for cannulation for extracorporeal life support. Despite this, it is possible to hear resistance to checklists by such comments as: “We would never make that mistake, so we do not need a checklist” and “We do not want to be forced into cookbook practice or cookbook medicine.” These sentiments stem from a misunderstanding of checklists. From an HFE perspective, checklists are not an attempt to force “cookbook” care. Instead, they are an effective solution to the limitations of human memory and the time-pressured and interruptive nature of critical care environments. For instance, work has identified that omissions in a sequence of events occur at a rate of 1 per 100 (85). This failure rate is multiplied three times by poor procedures, six times by information overload, ten times by poor communication, and 11 times by shortage of time (86). These data suggest a reliance on memory, for safety is fraught with risk.

Checklists, whether for placing a central venous catheter, decreasing risk factors for ventilator-associated pneumonia, communicating transfers of patient care, or initiating hemodialysis, are simply tools to minimize overlooking essential information or process steps. Rather than viewing them as an unnecessary crutch, they should be viewed as a tool to assure good outcomes. They free clinicians to focus on care, instead of trying to remember what was done or what still needs to be done.

Conclusions

Human factors, or HFE, is a science that is invaluable to improving the safety of critically ill patients. First, it provides a framework to understand why things do not go as planned or desired without resorting to laying blame on the many providers working in ICUs. Second, HFE offers insights into how both medication safety and the larger issue of patient safety might be improved. By understanding that critical care providers are people with strengths and limitations that interact with a system comprised of tools and technology, tasks, environment, and organizations, efforts can be redirected to redesign systems to reduce unnecessary risk and harm in the ICU. Finally, the science of human factors reminds us that the “human factor” in critical care units is what allows these time-pressed, information-intensive, mentally challenging, interruption-laden, and life-or-death environments to function so safely so much of the time.

Acknowledgment

We thank Richard Holden, PhD, for his assistance in preparing this manuscript.

References


