Human Factors in Medical Device Design

Methods, Principles, and Guidelines

Russell J. Branaghan, PhD

KEYWORDS

• Intensive care unit • Human factors • Adverse events • Medical devices • Usability

KEY POINTS

- A total of 400,000 to 500,000 patients die in intensive care units (ICUs) each year, largely because ICUs care for the sickest patients.
- On the other hand, factors such as workload, shift changes, handoffs, alarm fatigue, inadequate team communication, and difficult-to-use medical devices contribute to the problem.
- This article focuses on the human factors of those medical devices, a significant cause of adverse events in the ICU.

INTRODUCTION

There are approximately 6000 intensive care units (ICUs) across the United States,[1] caring for nearly 55,000 patients every day.[2] This accounts for approximately 10% of all hospital beds and 1.5% of US gross national product,[3] numbers that will only increase as the population ages.

More important, 400,000 to 500,000 patients die in ICUs each year,[1] largely because ICUs care for the sickest patients. On the other hand, factors such as workload, shift changes, handoffs, alarm fatigue, inadequate team communication, and difficult-to-use medical devices contribute to the problem. For example, Donchin and colleagues[4] estimate 1.7 errors per patient per day in ICUs, with 29% of these errors having potential to cause significant harm or death. This article focuses on the human factors (HF) of those medical devices, a significant cause of adverse events in the ICU.[5]

HUMAN FACTORS

The most complex part of any medical device is the person using it. Unless the device operates entirely on its own, the user's behavior, capabilities, and limitations

Disclosure Statement: The author has nothing to disclose.
Human Systems Engineering Program, Ira A. Fulton Schools of Engineering, Arizona State University, 7271 East Sonoran Arroyo Mall, 150 J Santa Catalina Hall, Mesa, AZ 88001, USA
E-mail address: Russell.Branaghan@asu.edu

Crit Care Nurs Clin N Am ■ (2018) ■–■
https://doi.org/10.1016/j.cnc.2018.02.005 ccnursing.theclinics.com

are key to its effectiveness and safety. HF applies scientific knowledge about human behavior, capabilities, and limitations to design.[6] By understanding how humans think, decide, and act under stress, we can engineer products that humans can use safely, correctly, and reliably.[7] Because people are complex and multifaceted, HF includes practitioners from cognitive psychology, sociology, anthropology, industrial engineering, industrial design, medicine and related health sciences, biomechanics, and more. The common denominator is that each focuses on human behavior, capabilities, and limitations. This focus not only improves the performance and satisfaction of health care providers, but also improves patient safety.

It is also important to describe what HF is not, articulated by Lee and colleagues[6] who point out that HF is not simply applying a checklist to determine if a product is easy to use. The variability of people, situations, tasks, technologies, and environments make creation of such a checklist impossible. Second, HF is not simply using oneself as a model of the end user. There are sizable person-to-person variations in size, strength, reading ability, stress, exhaustion, technical sophistication, and so on. This requires design for a wide range of users, rather than just one "type." Unfortunately, organizations may believe that good HF is easy or "common sense," but if that were true, the world would be chock full of easy-to-use medical devices. Personal experiences of health care providers, as well as numerous product recalls and adverse events, suggest quite the opposite.

USABILITY

Usability[8] is a term so closely related to HF that it is often treated as a synonym. Rubin and Chisnell[9] argue that "a usable product enables users to do what they want to do, in the way they expect to be able to do it, without hindrance or questions." Usability is defined along 5 dimensions.

- *Learnability* refers to users' ability to begin using a new system quickly and correctly, and to develop proficiency within a reasonable time frame.
- *Efficiency* refers to whether the system allows users to complete tasks more easily than working without the product.
- *Memorability* refers to how easily users can return to the system after a period of inactivity and recall important functions, features, and interactions.
- *Error resistance and remediation* refers to how well a system prevents errors or handles errors when they occur.
- S*atisfaction* refers to how pleasant the system is to use. Users desire products that are not merely functional, and systems that cause individuals to be miserable are less usable.[10,11]

Two approaches to improving medical device HF are described in the following sections. The first is a design philosophy called human-centered design. The second is a set of design principles, derived from research in cognitive and biological sciences, such as perception, attention, memory, learning, and emotion. These approaches should be used in tandem.

USER-CENTERED DESIGN

The International Organization for Standardization states that user-centered design involves the active involvement of users, clear understanding of user and task requirements, correct allocation of functions between users and technologies, iterative