HUMAN FACTORS and ERGONOMICS SOCIETY

HFES Policy Statement:

Supporting the Performance of Healthcare Teams

Background

One in 20 patients experiences preventable harm during medical care, with 12 percent of those incidents leading to severe injury or death (Panagioti, 2019). Patient harm includes unanticipated patient injuries, care complications, or death, which are the direct result of failures in patient care stemming from insufficiencies in the healthcare system (Nabhan, Elraiyah, & Brown, 2012).

Tragedies like these can be significantly avoided or reduced by using Human Factors science in the design of healthcare technologies and work systems. Human Factors is the scientific approach of studying how humans interact with complex systems, with the objective of improving human safety and overall system performance. For example, the FDA now requires medical device companies to perform Human Factors testing to ensure that their devices are understandable and meet usability requirements. Human Factors teams in healthcare settings work to identify and reduce hazards that can lead to medication or surgical errors, or problems with post-operative care. Human Factors also has been used to identify inadequacies in electronic health record systems and provide improved interfaces to support medical decision-making. The ability to better deliver patient care will significantly reduce preventable patient harm and improve health outcomes in general, and even more so during future pandemics and health emergencies which tend to stretch healthcare provider resources and increase factors such as fatigue, which further increase risks to patients.

The FDA provides guidance and regulations on the design and development of medical products and processes that focuses on the safety and effectiveness of product use in the clinical environment (FDA, 2020). However, once in use in the marketplace, clinicians and patients often encounter usability problems with approved products despite the fact that they met FDA standards for safety and efficacy. System development programs for these products fail to address human factors considerations, which results in suboptimal systems that degrade human performance (Pew & Mavor, 2007). For example, while all hospital ventilators pass FDA human factors regulations, they are often used in crowded clinical environments where when small usability features, such as the color of a button on the user interface that is not optimized to match the user's expectations, can cause an increased cognitive load for the user and slow the process of using the device. User interface details such as this can lead to significant errors in using the device that can lead to patient injury or death (Schraagen and Verhoeven, 2013). Third party organizations, such as ECRI, have shown that the ease of use of medical products is not equivalent across all devices, even when all devices are approved by the FDA (ECRI, 2023).

Human error is cited in 60 to 80% of accidents and incidents across a wide range of systems including healthcare. Though often viewed as a cause of these events, human error is primarily an outcome of design flaws and is largely preventable with proper attention to Human Factors design during system development. (Bogner, 2018; Gawron, Drury, Fairbanks, & Berger, 2006). In addition, healthcare costs associated with system training, operations, and maintenance can be significantly reduced when the needs of the human are addressed early and throughout design and development (Carayon & Gurses, 2008; Karsh, Holden, Alper, & Or, 2006).

The ANSI/HFES Standard 400 *Human Readiness Level Scale in the System Development Process* (ANSI/HFES, 2021) provides an overview of the user interface process and a means of quantifying the degree to which Human Factors has been addressed within the system development process. The Human Readiness Level (HRL) scale was developed to evaluate, track, and communicate the readiness of technologies for safe and effective human use at each stage of their design and development (ANSI/HFES, 2021). The HRL scale provides a rating (ranging from 1 to 9) of the level of maturity of a technology with respect to its readiness for human use and implementation of needed Human Factors processes and standards. HRLs provide an approach for communicating to managers, regulators, and others to what degree and stage Human Factors considerations and processes have been addressed in development and testing. The HRL scale provides visibility to support decision-making with respect to the design, development, and procurement of products and systems that are intended to optimize healthcare outcomes and reduce costs.

Providing attention to HRLs offers a systematic method of ensuring that user needs are met during product development. HRLs can communicate gaps with Technology Readiness Levels (TRLs) by addressing and mapping to the human-related aspects of technology (Salazar et al., 2020). TRLs have a long history of use for studying and evaluating the capabilities and limitations of technological systems during development and are frequently used in the development of medical products. TRLs help developers and decision makers understand the level of maturity of a technology (Mankins, 2009). However, TRLs do not address whether the technology considers the needs of the end user (Salazar & Russi-Vigoya, 2021). The aim of HRLs is to address the gap between what a technology is intended to do and whether the technologies have been designed to improve system usability and reduce negative outcomes such as unnecessary patient injuries.

Recommendations

(1) The FDA should track the development of medical device design in meeting human use requirements per ANSI/HFES 400 Standard (*Human Readiness Level Scale in the System Development Process*) as a part of their review of technologies for healthcare.

(2) Human Readiness Levels should be included as a requirement in the procurement, design and development of government healthcare systems (e.g., Veteran's Administration (VA), Defense Health Agency (DHA)) per ANSI/HFES 400 Standard (*Human Readiness Level Scale in the System Development Process*).

About the Human Factors and Ergonomics Society (HFES)

With more than 3,000 members, HFES is the world's largest nonprofit association for human factors and ergonomics professionals. HFES members include psychologists, engineers and other professionals who have a common interest in working to develop technology, tools, environments, and systems for safe and effective human use, including use in challenging conditions.

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