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HFES Calls for Human Readiness Requirements and Better Human Use Requirements in Healthcare Technology and Systems

The New Policy Statement Provides Recommendations To Leverage Human Factors Science In the Design of Healthcare Technologies And Work Systems To Reduce Preventable Harm During Medical Care

Washington, D.C.—September 21, 2023—The Human Factors and Ergonomics Society (HFES) has released a new Policy Statement, "Supporting the Performance of Healthcare Teams," that provides recommendations on leveraging human use requirements and Human Readiness Levels in healthcare systems and technology such as medical devices.

"One in 20 patients experience preventable harm during medical care, and 12% of those incidents result in severe injury or death," said Mica Endsley, Chair of HFES Government Relations Committee. "Between 22,000 and 25,000 cases of medical error result in preventable deaths each year in the US. These errors are often the outcome of user-interface design flaws and tragedies like these can be significantly avoided or reduced by employing Human Factors science in the design of healthcare technologies and work systems."

The policy statement notes that healthcare costs associated with system training, operations and maintenance can also be significantly reduced when the needs of the human are addressed early and throughout design and development. The FDA provides guidance and regulations on the design and development of medical products and processes for use in a clinical setting. However, usability problems are often encountered by clinicians and patients even though the products meet FDA standards for safety and efficacy. For example, hospital ventilators, which pass FDA human factors regulations, are often used in crowded clinical environments where even 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 errors and slow the process of using the device.

Many healthcare technologies also fall outside of the FDA process, such as electronic health records and healthcare apps. "Improving the ability of patients and healthcare professionals to more easily and accurately use healthcare technologies is one of the simplest methods for significantly improving health care outcomes as well as lowering healthcare costs", said Endsley.

The policy statement highlights the ANSI/HFES Standard 400 *Human Readiness Level Scale in the System Development Process*. This standard outlines the nine levels of the Human Readiness Level (HRL) scale and offers guidance for their use in systems engineering and human systems integration processes. The HRL scale supplements the existing Technology Readiness Level (TRL) scale by assessing the readiness of a technology or system for safe and effective human use. In healthcare, the HRL scale provides visibility to support decision-making in the design, development and procurement of products and systems that aim to enhance healthcare outcomes and reduce costs.

HFES provides two main 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).

For more details and additional information on the recommendations to support the performance of healthcare teams, please see the Human Factors and Ergonomics Society Policy Statements on this and other issues.

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About Human Factors and Ergonomics Society (HFES)

Founded in 1957, HFES is the world's largest scientific association for human factors/ergonomics professionals. HFES serves the needs of members and the public by promoting and advancing the discovery and exchange of knowledge concerning the characteristics of human beings that are applicable to the design of systems, products, tools, and environments of all kinds. The society's more than 3,000 members work in educational institutions, companies, government and military research centers, and independent consultancies in 58 countries. About 15 percent of members are students. For more information, please visit https://www.hfes.org/.