HUMAN FACTORS MEDICAL DEVICE CONSORTIUM
(www.hfMEDIC.org)

Mission

The mission of the Human Factors MEdical DevIce Consortium (hfMEDIC) is to engage industry and universities in a partnership to develop safer and more effective medical devices through human-centered design. The hfMEDIC envisions an integrated multidisciplinary team that builds on the strengths and resources of all stakeholders (patients, healthcare providers, industry, academia, government/policy makers, and regulators) to address priorities of the Institute of Medicine which, in 2000, identified an epidemic of medical errors and recognized that the solution must include human factors, a scientific discipline that considers the limitations and capabilities of the people who use the devices.
Although academic researchers have human factors expertise, they have limited access to medical devices and limited time and resources to create systematic research programs on medical devices, and to train and retain research staff and students. Industries are the primary force behind the development of medical devices and combination products, but these may not be based on evidence-based, human-centered design principles due to the challenge of maintaining in-house human factors research and development teams or costly outside consultants. These limitations can be addressed by bringing together the expertise and resources of academia and industry through hfMEDIC.

Organization and Membership

The consortium will form close working relationships with industry, academic, and regulatory partners to ensure that the mission is closely aligned with real-world practices for medical device development and testing. Industry partners will include manufacturers of medical devices and health care service providers (e.g., human factors testing consultants). The Center fits within the human-centered design process advocated by industry and government.

Importance

The global market for medical devices is approximately $228 billion. There are about 7000 medical device companies in the United States, yielding annual sales of over $100 billion. The medical devices market is expected to reach $436 billion in 2020 (Worldwide Medical Devices Forecast to 2020), in part because of the aging global population. In the US alone, individuals aged 65 years and older accounted for 15% of the population in 2016 (US Census Bureau, 2016). The economic impact of medical error is $1 trillion annually when quality-adjusted life years due to preventable medical error are included. In 2008, medical errors in the US cost $19.5B. The estimated cost of human error based on the percentage of errors attributed to human error from the FDA recall and adverse event databases is $48M annually with most due to labeling design, employee error, and software-use environment issues. The hfMEDIC addresses a critical need to reduce errors by using the scientific principles of human-centered design.

List of potential research thrust areas

Possible thrust areas include training for users of medical devices and combinations products; profiling limitations, capabilities and preferences of the users of medical devices; developing systematic and generalizable methodologies for the assessment of medical device design; applications and tools for health literacy; standardization of medical device design; emerging technologies (e.g., smartphones, wearable technologies, implanted chips); telemedicine and remote monitoring; Internet of Things (IOT); augmented/mixed reality (AR/MR).

Academic members

University of Utah (lead), North Carolina State University, Rice University, San Jose State University, University of Maryland.

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