Thank you for joining us! We will begin at 12:00 p.m. Central.
Your phone line is currently muted.
Human Factors Considerations for Medical Devices

May 23, 2012

Mary Beth Henderson, Ph.D.
Senior Principal Advisor, Regulatory Affairs And Quality Systems

Your phone line has been muted.
At any time, type questions in the Questions box.
We will answer questions at the end of the presentation.
For technical difficulties, please call 952-746-8080.
Overview

• What is meant by “Human Factors”?  
• Why has HFE become so critical for medical devices?  
• HFE considerations in medical device design and development.  
• HFE evaluation and testing  
• Conclusion  
• Resources
Human Factors Engineering (HFE), also known as usability engineering or ergonomics is the study of how humans interact with machines and complex systems.

HFE entails overt consideration for all aspects of user interaction with the device and is assessed continuously through usability testing.
Medical devices are becoming more complex – due, in part, to available technology and the sophisticated tasks asked of them.

More devices are being used directly by patients.

Medical applications are being developed for mobile devices.

Advent of “Personal Health Devices.”

Use and user error is increasing and unacceptably high.

Need to ensure patients and health care providers can safely and effectively use medical devices.
Regulatory Considerations

- CDRH receives over 100,000 MDRs per year and roughly one-third of these mentions something about user error.
- Between 1993 and 1998, the U. S. Food and Drug Administration became increasingly interested in reducing errors/injuries that arise due to questionable human factors designs.
- FDA has initiated several regulatory mechanisms to ensure consideration of HFE in device design. Some of the mechanisms include site inspections of manufacturers, review and approvals of medical devices and review of medical device incident reports (MDRs, complaints).
Regulatory Considerations

• The extent to which human factors is considered both by the manufacturer and ODE for any device should be governed by the complexity of the device and the risks associated with its use.

• FDA can audit your design control procedures and activities to ensure adequate human factors were considered in the development process.

• FDA now has a human factors team working within ODE.
Regulatory Considerations

• What do we, as a regulated industry, need to do?
  – Risk Management
  – Mitigate risk
  – Ensure safe and effective use
  – Demonstrate usability to regulatory agencies (for approvals)

• Use and User error is the manufacturer’s responsibility and can be considered a design flaw.
Regulatory considerations: cGMP/QSR

- 820.31(c) Design Inputs: Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.

- 820.30(g): Design Validation: Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.
820.100(a)(1) Corrective and preventive action: Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

Patient death or injury caused by “user error” is an unacceptably high risk and nonconformity “...because human factors and other similar tools should have been considered during the design phase of the device” Kim Trautman, The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, 1997
Cost Considerations

• An investment in Human Factors Engineering...
  – Will lower the number of use and user errors.
  – Will reduce risk associated with use of your device.
  – Will lower training costs.
  – Can reduce costly and unnecessary service and support.

• Health care facilities often consider results of HFE evaluations when deciding which products to purchase. (Mayo)
Cost Considerations

- Device firms can contribute to the health care cost-containment aims of the current healthcare debate by making devices less prone to human error according to medical device industry representatives.

- The device trade association, AdvaMed, was among six national organizations that, in May of 2009, collectively pledged to help slow the growth in health care costs over the next 10 years by 1.5%, for savings of $2 trillion or more, which is one of the Obama administrations goals for comprehensive health reform.

- The device industry's focus on product design issues to help reduce medical errors is one of the two commitments from AdvaMed outlined in a letter to the President from the six trade groups following the meeting and human factors was identified as a major target for member companies.
Considerations in Design & Product Development

• When errors involving medical devices recur repeatedly, people typically blame the users instead of the real culprit, which is often a poorly designed interface between the medical device and user.

• Need to consider in design:
  – the user (patient, family, prescriber of the device, etc.) characteristics, including the persons’ abilities and training and their expectations of the device,
  – device design considerations, which focus on the device-user interface including instructions for use, and;
  – the environment in which the device is used (noise, lighting, workload, movement/vibration, etc.).
Considerations in Design & Product Development

- Hazards due to human factors should be addressed during device development as part of the risk management process.
- Human factors should be considered early in product development and tested throughout the stages of development with “hands-on” testing using the end user population.
- Testing should also consider the environment where the device will be used (noisy, poor lighting, confusing, competing attentions, motion, vibration)
Considerations in Design & Product Development

Assessing risk due to human factors

• Device users, (e.g., patient, family member, physician, nurse, professional caregiver)
• Typical and atypical device use,
• Device characteristics,
• Characteristics of the environments in which the device will be used, and;
• The interaction between users, devices, and use environments.
Considerations in Design & Product Development

Human Factors and Risk Management

- Analytic approach: Operational Analysis, Analysis of Similar Systems, Failure Modes Effects Analysis (FMEA), Fault Tree Analysis (FTA), Critical Incident Technique, Hazard and Operability Studies (HAZOP)
- Empirical approach: Use Studies – Walk Through, Usability Studies
• Manufacturers are required not only to use human factors principles to repeatedly test the product in all phases of design, but also to validate the ultimate device design.

• Validation entails testing the device, either in an actual clinical situation or a simulation and documenting that the device conforms to the individual user’s needs.

• Medical device designers and manufacturers should take a lesson from the consumer products industry (Apple’s iPhone, iPod, etc...).

• This will require that manufacturers have in place a process that ensures adequate consideration of human factors in the design and development of medical devices.
Examples of HFE issues...

• Employ labels and displays that can be easily read and interpreted (consider environment).
• Use colors and contrasts that minimize ambiguity and add information redundancy when possible, e.g., red alarm lights to further convey a dangerous condition.
• Recognize the implications for visually impaired users.
• Evaluate, in advance, to learn if viewing angle limitations, such as those associated with LCD or LED displays, are likely to be problematic under expected use conditions.
Examples of HFE Issues

• Manage the tones, intensities and types of audible alarms, avoid the same combination of tones and intensities for differing alarm conditions, ensure that device alarms are distinct from the many other devices that are likely to be in use in the immediate working environment, and never provide the user the ability to permanently silence audible alarms or turn alarm volumes to less than ambient noise levels, i.e., 55-65 dB.

• Seek to make the alarm compatible with the level of the threat. Humans tend to equate both the volume and character of an alarm with its severity. In other words, do not assign an ear-splitting klaxon for a relatively minor alarm condition.
Examples of HFE Issues

• Provide the user with tactile feedback whenever possible and appropriate. Humans possess touch receptors that are sensitive to both displacement and viscoelastic resistance. Positive detent push buttons and keypads communicate to users that their actions were sufficient. However, today there are new technologies, such as proximity capacitive sensing, that do not require positive detent push buttons. Users may lose the tactile response of pushing a button, but audio or visual (lights or LEDs) feedback can be programmed into the system to return a satisfactory response. These interfaces are also easier to clean and maintain, since users don’t have direct contact with the circuits inside the device.
Usability Studies

Confirming safe and intuitive medical device use
HFE Evaluation and Testing

• Types of Usability Testing
  – **Formative:** design input early in the development process – exploratory product definition. May be interactive and use very rough depictions of product concept.
  – **Summative:** assessment of design or components early/middle/end of the development process, after the high level design is established – usability of components. Should be less interactive.
  – **Validation:** evaluation of device/system at the end of the development process against a performance standard; may be an assessment of the mitigation measures identified in the risk assessment. Not interactive.
Rationales for a Usability Study

• Safety: Are patients/clinicians likely to use/misuse the device in a way that could increase safety risks?
• Design validation: Are patients/clinicians able to use the device as intended?
• Labeling: Are patients/clinicians able to find information needed to perform required tasks?
• Marketing claims: Is the device easy to use, i.e. how quickly can patients/clinicians use the device to perform specified tasks; what are patients/clinicians perceptions regarding device use?
Study Design and Implementation

• Understand the device indications, use, and risks.
• Define study objectives and pass/fail criteria, study design, sample size, user eligibility criteria, procedures, device components, and study assessments.
• Define site(s) for testing (office, clinic, other setting).
• Prepare the protocol, consent, case report forms, training materials (if applicable), instructions, and obtain IRB approval.
• Enroll users, perform testing, analyze data, summarize.
Consent

• Mindset: The medical device is the subject to be tested.
• Reality: Humans will be asked to use the device. As the users they must understand what will be asked of them and freely consent to participate.
  – General user activities:
    • Provide demographic and other background data.
    • Follow testing instructions that may or may not involve risk or discomfort.
    • Receive compensation for participation.
Institutional Review Board approval

- Even if the study is exempt from IDE regulations, if it is “...being conducted to collect data to support either a clinical investigation or a marketing application, then the study must comply with 21 CFR Part 50 [protection of human subjects], and should comply with 21 CFR Part 56 [Institutional Review Boards]. 21 CFR Parts 50.1(a), 50.20, 56.101(a), and 56.103.” (Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors).

- When directly asked, FDA has replied that “...All human subject research, even sociology and educational studies, require IRB approval....”
Common Challenges

• Device availability
  – Functional devices may not be available until late in the development process.
  – Pre-production devices may not look or feel exactly like the production version.

• User selection – not part of device development, and likely to use the commercialized device.

• Simulating the environment – noise, light, temperature, movement/vibration, work load of user.
A Few More Challenges...

• Obtaining negative feedback from users: Users want to succeed to seem smart and have the device work well to please the tester.

• Moderating without bias: Avoid the temptation to help a user struggling to complete a protocol task.

• Capturing the nuances of the user experiences.

• Interpreting negative feedback – It is hard for developers to believe that the users had difficulty and that changes might be necessary. Test often and early to avoid surprises during validation testing, or worse, after market introduction.
RCRI has the experience to understand your device, design a study that will meet your requirements and goals, and closely manage it to completion of the results report.
Conclusion

• Human Factors Engineering is a “hot button issue” at the FDA particularly for devices intended to be used by patients.

• Risk Management is already integral to both premarket and postmarket responsibilities of medical device manufacturers and a significant part of risk can be mitigated through proper HFE methods.

• Cost containment is a requirement of the health care debate and all stakeholders will be asked to contribute. AdvaMed has committed to reducing errors though promoting HFE with its membership.
RCRI can help medical device manufacturers establish a human factors program and assist in usability testing.

RCRI can help you at all levels of Usability Testing, human factors assessments, submission documentation, and general counsel on human factors issues.
Sawyer, C., *Do It By Design: An Introduction to Human Factors in Medical Devices*. FDA; 1997. This is FDA’s “primer” on Human Factors and can be found among the CDRH guidance documents on the FDA website. It provides an overview of HF issues and checklists to help manufacturers consider HF issues in medical device design.

Callan, J.R., & Gwynne, J.W. (1993). Human factors principles for medical device labeling. San Diego, CA: Pacific Sciences & Engineering Group. This report was commissioned by FDA and can be found among the CDRH guidance documents online.

Other Resources: Guidances +

Applying Human Factors and Usability Engineering to Optimize Medical Device Design. DRAFT GUIDANCE, June 22, 2011. Available on FDA website. (will supersede previous FDA Guidance)
Other Resources: Books


Other Resources: Online Resources

http://www.upassoc.org/

http://www.usabilitynet.org/home.htm
UsabilityNet was a project funded by the European Union to provide resources and networking for usability practitioners, managers and EU projects.

This standard is based on the military specification MIL-STD-1472D, a standard for the US Department of Defense for the human factors of weapons and military control system and is hardware-oriented. Provides ergonomic information and human factors engineering guidance so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in medical device design. Specifically, the recommended practice deals with the controls, displays, consoles, size, weight, and general user interface design of medical devices and is extensively illustrated. User instructions, manuals, software, and algorithms associated with medical devices are also discussed briefly.
AAMI HE75\Ed.3, Human factors engineering – Design of medical devices.

This is an encyclopedic document containing more than a thousand human factors guidelines for the design of safe, effective, and user-friendly medical devices. This document tells you how to make a patient monitor’s digital readouts legible, what features enhance a portable CT scanner’s mobility, how to design alarms that draw attention in noisy environments, and myriad other ways to improve medical device safety, effectiveness, and usability.
Other Resources: Standards


The AAMI Human Factors Engineering Committee developed this process–oriented standard to provide manufacturers with a structured approach to user interface design, helping them develop safe and usable medical devices. It also helps them respond to the increasing number of national and international human factors standards in the medical field and the promulgation of new governmental regulations (based on ISO 9001) pertaining to medical device user interface design. This standard includes an overview of the human factors engineering (HFE) discipline, a discussion on the benefits of HFE, a review of the HFE process and associated analysis and design techniques and a discussion on implementation issues and relevant national and international standards and regulations.
Other Resources: Standards


This standard was developed to help manufacturers improve the usability and safety of medical devices. The standard recognizes that the use of all medical devices has associated risks and provides an engineering process for identifying, assessing and mitigating those risks. If the designer complies with the usability engineering process detailed in this standard, the residual risk associated with device usability is presumed to be acceptable. Patient safety will improve as future medical devices are designed to comply with this standard.

This International Standard specifies a PROCESS for a MANUFACTURER to analyze, specify, design, VERIFY and VALIDATE USABILITY, as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT. This USABILITY ENGINEERING PROCESS assesses and mitigates RISKS caused by USABILITY problems associated with CORRECT USE and USE ERRORS, i.e., NORMAL USE. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.
Mary Beth Henderson, Ph.D.
Senior Principal Advisor, Regulatory Affairs and Quality Systems
mbhenderson@rcri-inc.com