

GUIDELINE FOR APPLYING HUMAN FACTORS ENGINEERING TO PROCUREMENT AND PROBLEM INVESTIGATION

Published: 6/16/07

PREAMBLE

Clinical Engineers are often called upon to help with procurement of new devices or new models of existing devices; and to investigate problems that users have with devices. Human factors engineering (HFE) principles and methods are applicable to both of these types of activities. Clinical engineers have been identified as key healthcare personnel to apply HFE in a healthcare organization.

Suitable HFE is primarily of interest as a method of reducing human errors (HE) or preventing human errors from resulting in patient injuries or patient discomfort. In this context, HFE and HE are opposite sides of the same coin. For each human factors feature associated with a device or within a health care system, there is the potential for an error. We recognize that many human errors are trivial and learning experiences, while others can be injurious or deadly.

Clinical engineers encounter HFE designs during the procurement process, during accident investigations, and following maintenance reports of no-problem-found (NPF). Acquiring education and training related to HFE and HE is mandatory if we are to make professional level recommendations for improvements to health care systems, in general, or health care technologies, specifically.

QUALIFICATIONS

- The Clinical Engineer (CE) applying HFE or HE theory should attend at least one human factors engineering course (3-credit) or week-long workshop where the fundamentals of HFE and HE principles, guidelines, and methods are taught. Preferably, the teaching should focus on healthcare or medical device examples.
- The CE applying human factors engineering to their major roles should obtain education and training in the techniques of human factors design, and human error theory, including, at minimum:
 - Heuristic (HFE checklist) evaluation
 - Usability testing
- To apply HFE, the CE should have used the HFE techniques of heuristic evaluation and usability testing in five procurement or problem investigation projects.

GUIDELINES

- As appropriate and as a minimum, the Clinical Engineer should follow the guidelines established by recognized standard-setting bodies such as AAMI (ANSI-AAMI HE74) and FDA (Quality System Regulations).

- The CE must be aware of pertinent literature on the relative strength and applicability of HFE tools for procurement and problem investigation.
- The CE should apply user-centered and “redesign-first” mindset to all their roles.
- To enhance practical knowledge of optimal HFE tool usage and promote best practices by healthcare organizations, the Clinical Engineer should share case studies at conferences or in literature.
- For procurement:
 - Specific conclusions should be:
 - a) organized and communicated to support the decision making group/person;
 - b) stratified based on best estimates of severity and likelihood of adverse event arising from a feature of the device; and
 - c) developed within context of likely usage and end-users (e.g., once per year by novice doctors).
 - General conclusions about any HFE shortcoming for that class of device (e.g., mode error for infusion pump) should be shared with the healthcare industry so lessons can be learned without adverse events having to recur.
- For problem investigation:
 - Specific conclusions should focus on how the organization can implement modifications to design (e.g., labeling), training and trouble-shooting tools.
 - General conclusions about the type of HFE shortcoming for that class of device (e.g., mode error for infusion pump) should be shared with other healthcare providers so lessons can be learned without adverse events having to recur.
 - When HFE related shortcomings are identified, attempts to collaborate and share these possible hazards with the device manufacturer should be a primary goal.
- For No Problems Found:
 - When a device or technology meets the manufacture’s specification, the Clinical Engineer should pursue the cause of the NPF through the HFE designs of the other components of the system to determine if they contributed to the failure to deliver a clinical benefit.

REFERENCES

- American National Standards Institute, Association for the Advancement of Medical Instrumentation. *Human Factors Design Process for Medical Devices* (ANSI/AAMI HE74:2001), Association for the Advancement of Medical Instrumentation, Arlington, VA, 2001
- Gosbee JW, Gosbee LL. *Using Human Factors Engineering to Improve Patient Safety*, Joint Commission Resources, Oakbrook Terrace, IL, 2005
- Hyman WA, Wanglor V. Human Factors: Environment, 353-355, *Clinical Engineering Guidebook*, Elsevier Academic Press, Burlington, MA, 2004
- United States Food and Drug Administration. Human Factors Implications of the New GMP Rule: New Quality System Regulation that Apply to Human Factors. U. S. Food and Drug Administration, Washington, D.C., 1998.

- Welch DL. Human factors in the health care facility. *Biomed Instrum Technol.* 1998 May-Jun;32(3):311-6.
- Reason, J. Human error, Publ. Cambridge Univ Press, Cambridge, UK, 1998
- Norman, D. The design of everyday things, Publ: Doubleday, NY, 1988
- Senders, J. Moray, N. Human error; Cause, prediction and reduction, Pub. LEA, Hillsdale, NJ, 1991

APPROVAL DATE (ACCE board): 6/16/07

REVIEW DATE