Attend an (AAMI) Human Factors Committee Meeting

A couple of weeks ago, I attended the Human Factors Committee meeting [1] of the Association for the Advancement of Medical Instrumentation (AAMI) in Nashville, TN. If you aren't already familiar, AAMI [2] is "a nonprofit organization comprised of nearly 6,000 members from around the world with a variety of different backgrounds unified by their commitment to increasing the understanding and beneficial use of medical instrumentation through effective standards and educational programs, and publications."

The Human Factors Committee convenes several times a year, and its members are responsible for writing the Human Factors standards that are adopted by AAMI and ANSI [3] (the American National Standards Institute) and become best practices that the U.S. FDA expects device manufacturers to follow. This committee worked long and hard to develop the forthcoming ANSI/AAMI HE75:2010, "Human Factors Engineering-Design of Medical Devices." This nearly 500-page document will provide detailed Human Factors engineering design guidance, examples, checklists, and case studies. There is a delay in publication due to the fact that the publisher needs to obtain permissions for some of the figures it contains. It should be available for purchase shortly, but because it's so big, you won't be able to download it.

Another important development to be aware of is the FDA has officially endorsed the international standard IEC/ISO 62366:2007, "Medical Devices-Application of Usability Engineering to Medical Devices [4]." IEC/ISO 62366:2007 calls for manufacturers to follow good Human Factors processes when designing medical devices, but does not provide detailed design guidance. Interestingly, Annex D in 62366 is almost a direct replica of ANSI/AAMI HE74, the document developed by this committee.

The meeting ended with discussions of diverse topics, such as post-market surveillance, user interface design for medical software, and guidelines for observational field research. The group is deciding which initiatives to pursue next.

In addition to hearing about these developments, it was a great opportunity to get a behind-the-scenes glimpse at the work that goes into creating, editing, and approving Human Factors standards. It was an insightful experience and a pleasure to finally meet some of the members that make up this influential group of thought leaders. I highly recommend attending if you're interested in Human Factors standards.

Source [5]

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