Human Factors/Usability for Medical Devices: An Historical Perspective

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Milestones

• 1974
  Bureau of Medical Devices

• 1976
  Medical device amendments to the Pure Food and Drug Act – the most comprehensive legislation for medical devices ever passed by U.S. Congress

• 1978
  Anesthesia Gas Machine Standard
    – 80% of the standard addressed use error
    – Led to the establishment of a Human Engineering Committee within the Association for the Advancement of Medical Instrumentation (AAMI)
Milestones, cont.

• 1984
  Congressional Hearings
  Focus on anesthesia-related death rate
  Record number of TV cameras
  Al Gore presided
  FDA praised and manufacturers castigated

• 1995
  AAMI/FDA HF Conference

• 1996
  Quality System Regulation: Design Controls
Milestones, cont.

• 1999
  IOM’s “To Err is Human”
    – Up to 98,000 deaths in U.S. Hospitals resulting from medical error
    – 5th leading cause of death; exceeding auto accidents, breast cancer and AIDS
    – Cost to society: $29 Billion

• 2000
  CDRH released Human Factors guidance where “use error” was implicated as a necessary consideration within Risk Analysis
    – Human Factors techniques recommended to reduce use error risk
Milestones, cont.

• 2001
  – ANSIAAMI HE74 – Human Factors Design Process for Medical Devices

• 2006
  – IEC 60601-1-6, Collateral Standards: Usability of Medical Electrical Devices

• 2007
  – HF Team relocates to Office of Device Evaluation
  – IEC 62366, Application of usability to medical devices

• 2010
  – HF pre-market review team increases in size
Center Effort on HF/Usability and Industry Response

- Agency Focus/Effort on HF
- Frequency of device manufacturers doing HF
- Quality of HF Submitted by manufacturers
Key Factors that have influenced HF/Usability in industry

• Review of HF/Usability in pre-market submissions for new devices
• Outreach to industry
Outreach to industry

• Presentations at conferences, workshops
  – Message: FDA believes that medical device use error impacts the health and well-being of the public and therefore looks closely at HF/Usability
  – Relevant guidance, national and international standards
  – Premarket review priorities and processes
  – Opportunity to receive anecdotal feedback on HF/Usability efforts in industry
Outreach Cont.

• AAMI sponsored course “Human Factors and Medical Devices”
  – Observation: Increasingly more medical device manufacturers with staff doing HF/Usability work for medical devices than in the past

• Participation on committees integrating HF content into national and international standards

• Informational “pre-submission” meetings with industry
Anecdotal Feedback from Medical Device Industry Professionals

• “We have better, safer, medical devices now that we have HF/Usability input”

• Impact and progress is assisted by Agency efforts in outreach and premarket review

• Sales increase along with satisfaction of clientele for devices that receive HF/Usability attention
HF/Usability pre-market review of medical device submissions

- HF/Usability evaluations, test methods and results
- Meetings with industry representatives
- Requests for additional information, disapproval can result from inadequate HF/Usability
- Priority on HF/Usability influenced by post-market reports and analyses
Most common HF/Usability review concerns

• HF/Usability work is needed and not provided in submission
• Lack of focus on priority of performance success for high priority tasks in validation testing
• Inadequate or absent descriptions or characterizations of errors
• Not obtaining test participant descriptions of difficulties or problems they experienced
• Not testing with representative users of the intended population of users (e.g., not U.S. residents or non-employees)
• Checklist or rating scale approach to validation rather than systematic assessment of user performance and experience
Summary

• Consideration of HF/Usability for medical devices at FDA has increased
  – From focusing only on anesthesia machines in the 80s and small beginnings in the 90s with a limited number of other devices
  – Several major milestones while addressing HF/Usability more directly are reflected in corresponding efforts in industry
  – Agency performs reviews of HF/Usability in new device submissions and conducts various outreach activities to industry

• Results
  – Increasingly manufacturers are doing good quality HF/Usability
  – Better, safer, medical devices
  – More medical device manufacturers with HF staff and doing HF/Usability work for medical devices than in the past
  – Sales increase along with satisfaction of clientele for devices that receive HF/Usability attention