Human Reliability Analysis Applied to Medical Device Use-Related Hazards

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CERSI CONFERENCE OUTCOMES

CONFERENCE GOALS

a) Understand the critical focus areas for medical device use-related hazards

b) Discuss the main components of Human Reliability Analysis (HRA) applied to medical device use-related hazards

- Human behavior modeling
- Data collection and quantification of human behavioral data
- Risk mitigation strategies and design interventions

c) Understand the barriers to HRA implementation and practical solutions to remove barriers.

ATTENDEES

There were approximately fourteen attendees with an even split between FDA and individuals involved in the medical device design (manufacturers, researchers). The majority of the FDA representation was from CDRH (Office of Science and Engineering Laboratories Human Performance Laboratory and Office of Device Evaluation), with one representative from the DA Office of Minority Health. The medical device design representation was from academics involved in human factors and human reliability analysis, the MedStar Center for Human Factors Engineering in Healthcare, and Siemens. The inter-disciplinary and inter-organizational mix of participants allowed medical device design stakeholders from both sides of the aisle to interact. All breakout groups were instructed to take advantage of the even split between FDA and non-FDA participants in the group composition to insure a diverse discussion. Many of the non-FDA participants were familiar with the methods presented, although most had not used them previously in the healthcare domain or to measure and mitigate use-related hazards. The FDA participants were not familiar with the methods, but were interested in exploring the feasibility of the methods in improving device reliability.

SUMMARY OF DISCUSSIONS AND OUTCOMES

The conference started with a discussion of the concept of human error in healthcare, guided by the 1999 IOM report "To Err is Human," where medical error is defined. This was followed by a discussion of a specific form of medical error, use error, as defined by ANSI/AAMI/IEC 62366 "Application of Usability Engineering to Medical Devices." The systems-based evaluation (human factors, reliability, risk, systems engineering, quality) of human error was introduced with a discussion of how the system complexity necessitated the use of a structured risk assessment tool, such as HRA. An overview of HRA was provided.

Breakout Session 1: For the first breakout session, participants discussed how quality, reliability, human factors, risk, and micro and macro system level risks were currently assessed in their organization and

used for device design, testing and evaluation. Participants listed specific techniques, program directives and organization goals and then presented this information to the entire conference.

Insights from Breakout Session 1 include:

- Many existing methods are available to identify human error, however, these methods are typically missing some element required to perform a thorough analysis. For example, FMEAs provide a method to quantify risk, but do not provide structured guidance to identify the risk, prior to quantification.
- There is great variability in the methods submitted to fulfill usability testing requirements for PMAs.
- The usability testing requirement provide an existing regulatory mechanism to support methods, such as HRA, being implemented.
- Many PMA submissions do not have usability tests included in their submissions, but are still approved. As reported by an FDA participant, this is particularly prevalent for cardiovascular devices. In addition, recent results of a textual mining study funded by the CERSI Innovation Award, "Analyzing Medical Device Recalls and Regulatory Decision Making to Advance Regulatory Science" (PIs: Vaughn-Cooke, Herrmann), found that PMA devices approved by the cardiovascular review panel had the highest rate of recall, which was disproportionate to the number of cardiovascular device PMAs. Further contextual analysis of the defibrillator PMAs (most dominant recalled cardiovascular product) revealed that most were missing usability tests. Further investigation is needed to understand why medical device manufacturers do not comply with usability testing requirements and why ODE review panels approve devices that have not complied with this regulation.

After the first breakout session, guidelines and standards that apply to HRA were discussed. These include the following:

- ANSI/AAMI. (2009). HE75 Human Factors Engineering: Design of Medical Devices.
- ANSI/AAMI/IEC. (2007). 62366 Application of Usability Engineering to Medical Devices.
- CFR - Code of Federal Regulations Title 21
- FDA. (2009). Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design.

An overview of HRA building blocks (task analysis, error classification, causal factor analysis) and their integration in traditional Probabilistic Risk Analysis was provided. The top health tech hazards, as defined by the Emergency Care Research Institute, were discussed, with a more thorough discussion and case study of the top hazard, alarm fatigue. This lead to a debate on where the responsibility lies when a hospital staff (i.e., nurse) turns off an alarm. Barrier to designing less sensitive alarms include potential legal liability for the manufacturer. Through discussion, the group came to the conclusion that partial responsibility lies with the hospital staff and administration to follow safe protocol for use of devices with alarms. The other responsibility lies with the manufacturer to predict these types of behavioral use hazards a priori and design smarter more intuitive device alarm algorithms that remove the motivation to lower the volume or turn off the alarm.

Breakout Session 2: In the second breakout session, there was a discussion of the human reliability issues faced in each participant's organization. In addition, the effectiveness of the tools and practices identified in Breakout Session 1 were evaluated. This lead to a continuation of the prior breakout session conversation on the lack of follow through with guidelines and expectations for regulatory approval.

Next, behavioral modeling, data collection and quantification, and the development of risk mitigation strategies was overviewed to provide participants with an introduction to common methods used in HRA. Resources were provided for participants to investigate each tool in depth after the conference.

Breakout Session 3: The final breakout session discussed barriers and solutions for HRA implementation and served as a discussion of the necessary steps to move forward at the end of the conference. The participants discussed organization inertia, buy-in, HRA analyst training, and resource constraints.

Insights from Breakout Session 3 include:

- There is a need for more transparency into the regulatory process to understand what is currently required for regulatory approval and how much follow through (by the review panel) actually occurs.
- A more structured approach, such as HRA, is needed. However, it must be flexible to account for the specific design and validation needs of each device, while also providing structured expectations.
- There must be buy-in from CDRH to move this process forward, to insure that these expectations meet compliance on each end of the approval process (manufacturer and review panel).
- Standard consultations with the appropriate OSEL expertise should be performed regularly to insure that guideline expectations are being met. For example, a human factors expert could assist in all reviews to insure that the usability guidelines are addressed appropriately.

FUTURE RECOMMENDATIONS

Focused efforts to bring together CDRH, human reliability experts, and representatives from medical device manufacturers can help to address some of the issues raised at the Conference. This could occur in the form of a CERSI sponsored meeting or a breakout session at a future exchange conference. This next meeting should include a goal of understanding the PMA review panel mechanics and the process to insure compliance with guidelines in each review panel. This process must be better understood before addressing the need for more structured regulation. If the existing unstructured regulations are not currently being implemented across the board, any attempts for structured regulations will not be successful. A more throughout investigation of the review panel process can be supported through the CERSI Innovation Awards or other funding mechanics.