Mitigating Medical Device Risk through **Human Factors**

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A profound statistic

“one-third of medical device incidents involve user error and more than half of device recalls for design problems involve the user interface”

_FDA spokesperson 2005_

Who wants to have a product on the market that is used correctly 60% of the time?
So, what is Human Factors?

A multidisciplinary field including:

- Learning & Behavior
- Cognitive Psychology
- Sensation & Perception
- Statistics
- Experimental Design
- Anthropometrics & Biomechanics
- Industrial Design
- Human Computer Interaction

**Ultimate Goal of Human Factors** is to understand user interactions with product and systems to optimize the user experience and overall system performance.
How is Human Factors Unique?

Beyond perceptions and attitudes.

Multiple scientific-driven methodologies

Analysis at multiple stages in the design process.

Providing concrete and actionable design inputs.
Where else is Human Factors leveraged?

Government and consumer sectors of industry have been incorporating human factors for many years:

- Aviation
- Transportation
- Telecommunication

Continues to be the trend, in other industries to take a retroactive approach to Human Factors.

- Validation Testing after Tooling
- Focus groups after Tooling

**Risk Mitigation** is best accomplished when involved Human Factors early and iteratively.
Movement of HF in Medical Devices

Human Factors has received more attention from the medical community with the release of AAMI’s standard: HE75

Good resource for Pharma Equipment developers.

Key point is the importance of risk mitigation and the involvement of human factors early in the design process.

Many industries can benefit from this standard.
Standards for HF are not completely new

Code of Federal Regulations (Section 820.30)

(c) Design input

• 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 users and patient.

(d) Design output

• Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

(g) Design validation

• …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.
But the product works…

Technical functionality does not guarantee user functionality.

Technical functionality does not prevent use errors.

Users will do things with your product you never expected.

Predicate devices don’t guarantee risk mitigation.

Instructions for use don’t guarantee risk mitigation.
Mitigating Risk One Step at a Time
The old way of "mitigating risk.

The user-centered way of mitigating risk.
Design Controls (no HF integration)
Putting this into Action
Develop a plan

**Human Factors Integration Plan:**

Defining a path for various human factors activities and evaluations with the ultimate goal of mitigating risk one step at a time.

**Human Factors File:**

Design History File should include a human factors file. Human Factors file includes all the human factors activities, design inputs, formative and summative reports.

**What submissions need HF?**

510K
PMA
NDA…is your drug in a device? Will it be a part of a system?
Who are your users?

This is KEY!

What is the primary condition?

What are associated comorbidities?

Who are the users?
  • Age
  • Abilities
  • Limitations (modality-specific)

Will users be trained on your device?
  • Training documentation?
  • Health care professionals?
  • Environment?
Identify risks early and continue to evaluate

Human Error Safety Risk Assessment/uFMEA:

The primary goal of a HESRA/uFMEA is to proactively identify elements of a product, system or process that present high risk of human errors that might lead to serious consequences which can be a product of perception, behavior, potential interactions, etc.

Knowing your user makes this possible
Expert-based Heuristic Analysis:

Experts in human factors and usability can provide early feedback on medical device designs using:
- Human factors design principles
- Compliance with standards and guidelines
- Setup, use, breakdown
- Labeling and instructions
Conduct Formative Research

Per AAMI’s standard, HE75:

3.39 – “Formative usability testing is usability testing that is performed early with simulation and the earliest working prototypes and that explores whether usability objectives are attainable, but without strict acceptance criteria”

• Know your user

• Know where your product will be used

• Know the user-associated risks

• Know your open questions and/or concerns (i.e. size, force, intuitiveness)
Formative research should be iterative

Iteration allows a company to focus on different topics:

- Instructions for use
- User limitations and abilities
- Labeling
- Overall ease of use
- Early validation of claims

5 – 8 participants per Unique user group
Conduct Summative Testing

*Per AAMI’s standard, HE75:*

9.3.1.2 – “Summative usability testing is performed late in design as part of a formal verification and validation and should have formal acceptance criteria (e.g., usability objectives for human performance).”

- Instructions for use should be final
- Medical device should be production-like or ready
- Training materials should be established
- Critical and non-critical use-errors should be identified

15 – 20 participants per Unique user group
Conduct Summative Testing (continued)

**Explain the Errors**

What kind of use-errors?
- Critical failure
- Non-critical failure
- Close call
- Unanticipated error or action

*Example:*
2 Patients and 1 Caregivers recorded a non-critical partial dose failure:

Reasons for Partial Dose:
- Wet Dose resulting from holding the button
- Didn’t wait 15 seconds after injection
Risk Mitigation through Human Factors

Human Factors is best when leveraged proactively and iteratively

- Identify your risk and opportunities early on.
- Make informed decisions throughout and be accountable for them.
- Validate your product/systems and decisions.

Mitigate risk one step at a time!
Thank you