Human Factors Considerations for Medical AI Applications

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Agenda

What is Human Factors?

FDA/CDRH Human Factors Overview

User Interface Design Considerations for AI Applications

An AI-Guided Image Acquisition example: Human Factors Process
Human Factors

Ergonomics and human factors use knowledge of human abilities and limitations to design systems, organizations, jobs, machines, tools, and consumer products for *safe*, *efficient*, and *comfortable* human use.

(Source: http://osha.oregon.gov/edu/grants/wrd/cergos/Pages/ergonomics.aspx)
21 CFR 820.30 Design Controls

(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 user and patient.

(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.

Quality System Regulation Preamble

i.72. “when designing a device, the manufacturer should conduct appropriate human factors studies, analyses, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed..”
FDA/CDRH Human Factors Guidance: Risk-based Approach

"...FDA is primarily concerned that devices are safe and effective for the intended users, uses, and use environments."

"...CDRH believes that for those devices where an analysis of risk indicates that users performing tasks incorrectly or failing to perform tasks could result in serious harm, manufacturers should submit human factors data in premarket submissions (i.e., PMA, 510(k))."

"...where harm is defined to include compromised medical care."
Examples When Use Error in Medical Products Could Cause Serious Harm to Patients Directly
Can the Use Error in Radiology Imaging Devices Leading to Serious Harm to Patients?
Example of Use Error Which May Lead to Wrong Treatment Decision: Continuous Glucose Monitor (CGM)
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User Interface Design for Imaging Devices Containing AI Software
AI/Rosbots in Hollywood Movie are...
Somewhat Concerning...
Many concerns over AI Applications
Seems to be Human Factors-related
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E.g. What is AI's role? What is user's role?

Example: Hands-off process in the ICU
Many concerns over AI Applications
Seems to be Human Factors-related

E.g. What is AI’s role? What is user’s role?

E.g. How does the user tell the context/status of the AI Application?
Example: “Wait, where is the destination again?”
Many concerns over AI Applications
Seems to be Human Factors-related

E.g. What is AI’s role? What is user’s role?

E.g. How does the user tell the context/status of the AI Application?

E.g. How does the user retain the control?
Many concerns over AI Applications
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E.g. What is AI’s role? What is user’s role?

E.g. How does the user tell the context/status of the AI Application?

E.g. How does the user retain the control?

E.g. How does the user verify the result, in particular for lay user/novice user?
   Example: CGM/BGM
Example Design Guideline for Human-AI Interaction (Amershi et al., 2019)

Hypothetical Example AI-Guided Image Acquisition Device
Use, Users, Use Environment, and Use-Related Risks

**Use**: AI-guided image acquisition for early screening deep vein thrombosis

**Users**: Family member, caregivers, lay user

**Use environment**: home environment

**Example Use Error/Use-related Risk**: Failure to follow instruction or labeling may lead to poor quality image, which will miss the opportunity of thrombosis diagnosis, which can potentially cause serious harm to the patient.

(Source: https://g.co/kgs/rw29TU)
Hypothetical Example AI-Guided Image Acquisition Device
Example Finding from Human Factors Study

Does the message make sense to the lay users/home users?
Hypothetical Example AI-Guided Image Acquisition Device Design Modification to Address the Use-related Risk

Inform users with the *language* that they understand,

and,

Present next step *action* that users will take.

Caution:

小微企业 get a low quality image! Please try the test again.
Medical Device Human Factors Engineering Process

- Define Intended users, use environments and user interface
- Identify use-related hazards
- Identify and categorize critical task
- Develop and implement risk mitigation/control measures
- Validate use safety and effectiveness
- Use-related risks Acceptable?
- Document HFE/UE process

(Source: https://www.fda.gov/media/80481/download)
Take Home Message

Integrate the human factors in the design process
The user interface should make sense to the user.
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Understanding the user need and leveraging the design guidelines/best practice in designing the medical AI applications

   Repeating the human factors validation study will not save a flawed design
Take Home Message

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FDA human factors review: Risk-based approach
The goal is to ensure that the device user interface has been optimized to support safe and effective use

We always welcome early discussions via pre-submission program.