Human Factors and Medical Devices: Overview

A Mamaghani

Topics

- Background Information
- What's Human Factors Engineering?
- Why do it?
- How to apply HFE to Medical Device Design
- Q&A

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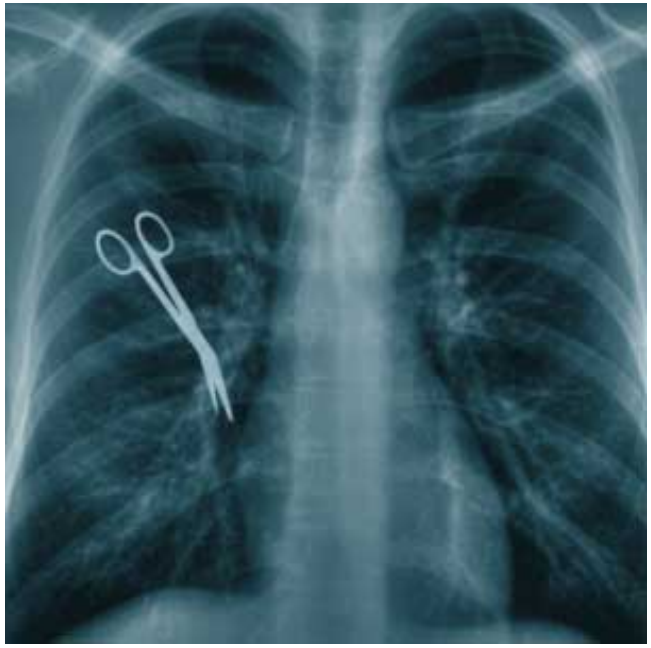
“To err is human”



- To minimize human errors is human factors

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Medical Errors in US each Year Result In:

- Up to ~~98,000~~ 200,000 deaths
- 5th leading case of death: exceeds auto accidents, breast cancer and AIDS
- $29 Billion added cost

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FDA Medical Device Incident Reports:

- 100,000 reports per year
- 44% of medical device recalls due to design problems.
- Use error often linked to design.
- Tip of iceberg.

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Study of Medical Device Recalls (2011)

- 60 medical devices recalled between 2006 and 2011
  - 33 - poor electromechanical UI design (poor ergonomics, unverified alarms, potential for misconnections, etc)
  - 13 – poor GUI design
  - 8 – IFUs did not align well with device use or confusing
  - 5 – labeling not understandable or effective

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Human Factors

- "To understand use-related hazards, it is necessary to have an accurate and complete understanding of *how* a device will be used. Understanding and optimizing how people interact with technology is the subject of human factors engineering (HFE) and usability engineering (UE)…"
- FDA HF Guidance Document

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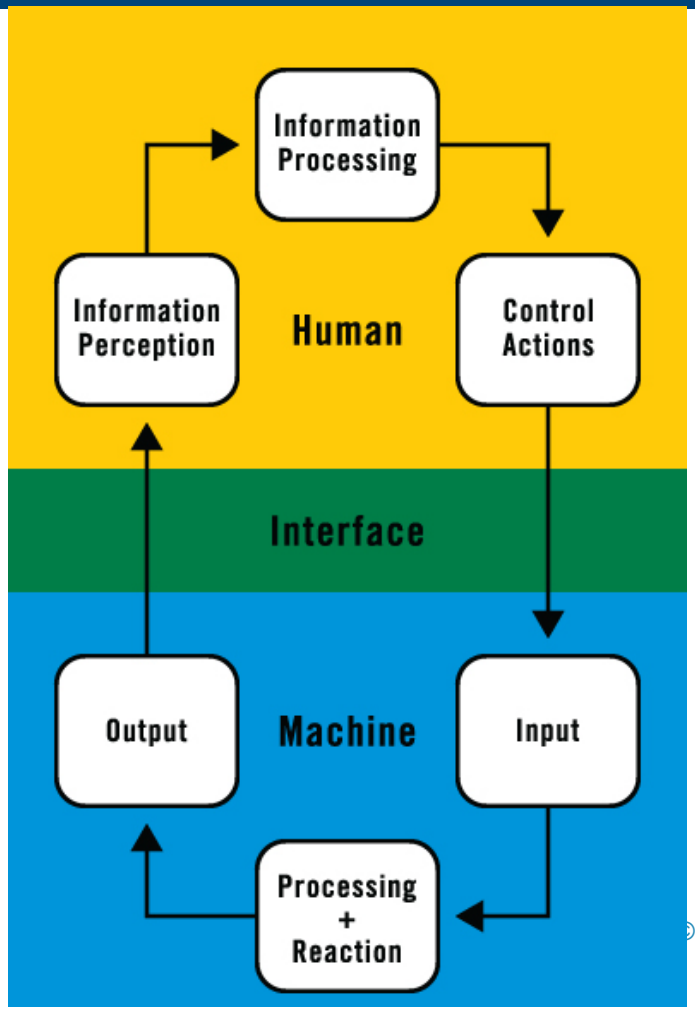
Human-Device Interaction



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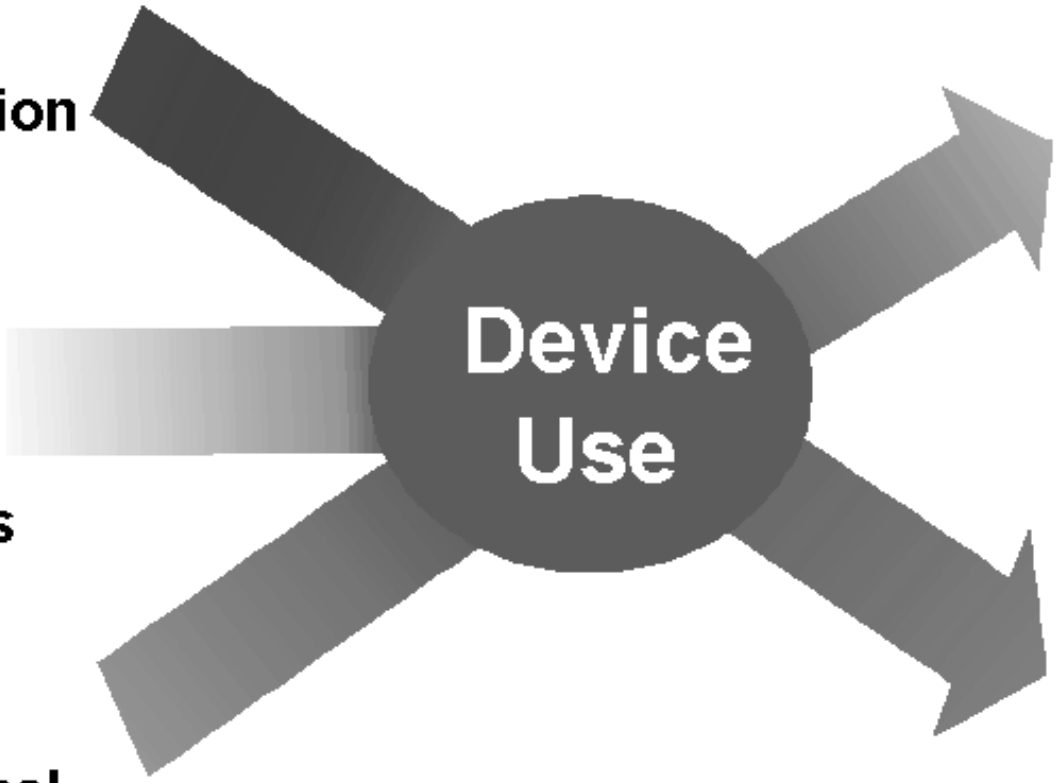
HF Considerations

Use Environment
- Light, Noise
- Distraction
- Motion/Vibration
- Workload

User
- Knowledge
- Abilities
- Expectations
- Limitations

Device
- Operational requirements, procedures
- Device complexity
- Specific user interface characteristics



Outcome

Safe & effective

Unsafe or ineffective ***(Use Error)***

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Regulations

- **Quality System regulation** 21 CFR 820.30, Design Controls
- The need for human factors is implied:
  - **Design input –** includes “needs of the user and patient”
  - **Design verification –** performance criteria met
  - **Design validation –** “… devices conform to **defined user needs and intended uses** and shall include **testing of production units under actual or simulated use conditions.** Design validation shall include **software validation** and **risk analysis**….”

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FDA HF Guidance Document

Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Applying Human Factors and Usability Engineering to Optimize Medical Device Design

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

Makes Good Business Sense

- Well designed devices have:
  - Fewer safety issues (risk of harm to the user/patient)
  - Fewer customer complaints (reduced repair cost)
  - Fewer recalls
  - Well received by customers
  - Sells itself (word of mouth)
  - Makes life easier for the users
  - Pleasure to work with
  - etc ……
  - All this translates to: $$$$$

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FDA's Expectation for Pre-Market Submission

- Focus is on **safe** and **effective** device:
  - Identify and eliminate all potentials **use errors**
    - Device failure hazards
    - Use-related hazards
  - Address issues that cannot be designed out
  - Intuitive user interaction points (GUI, buttons, handles, etc)
  - Easy to understand system notifications and alarms
  - Easy to follow instructions
  - Ergonomic design
  - DOCUMENT YOUR WORK (usability studies, reviews, walkthroughs)
  - Include summary of HF Activities in Pre-Market submissions

- Less concerned about look and feel unless it affects safety

- Not at all concerned about marketability

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Human Factors activities throughout design

Development Cycle	Concept and Feasibility	Design Input	Design Output	Verification	Validation
Design Activities	Initial studies and concepts	Customer and product requirements	Design and build engineering units	Test output against design input	Test against users needs
HF Activities	• Market research • Literature review • Complaints • Contextual Inqueries	• Use environment • User profiles • Task analysis • Risk analysis • HF Requirements	• Prototyping/ simulation • Iterative design • Formative tests • Risk Analysis • Cognitive walkthrough	• Cognitive walkthrough • Expert Review • Usability tests • Risk analysis	Summative usability testing: 1. Using production units 2. Actual or simulated use environment 3. Formal protocols 4. Summaries

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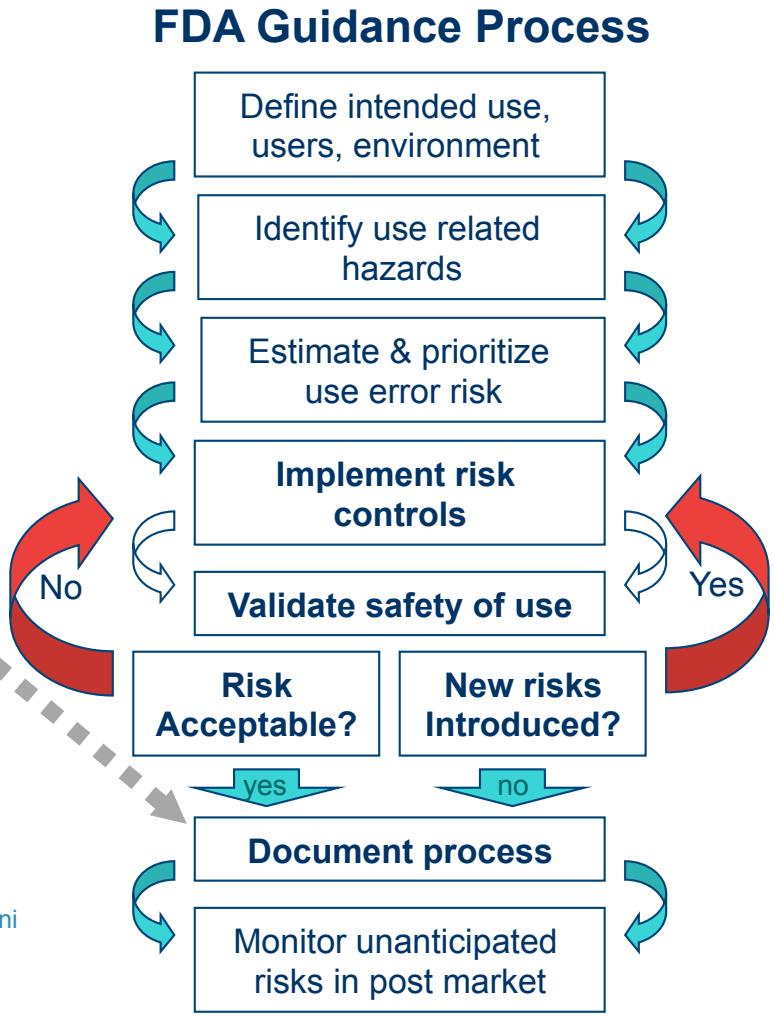
Human Factors Process

- Human Factors Report "Documentation" of human factors efforts consistent with FDA Guidance and recognized HF Standards



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Concept and Feasibility

- Understand
  - User Demographics
  - Use environment
  - Work habits and workflow
  - Knowledge
  - Stress level
  - Errors and mistakes
  - Consequences of errors

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Concept and Feasibility

- Document Findings
  - Customer requirements
  - Human factors requirements
  - Detailed risk analysis

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Development

- Develop Initial Concepts and Prototypes
  - Drawings
  - Storyboards
  - Rough prototypes
- Conduct expert reviews (stakeholders, internal users)
- Develop tasks and test with actual users
  - Initial (formative) usability testing
  - 5-10 participants
  - Test for
    - Common workflow
    - Potential errors
    - Daily tasks
  - Utilize actual users
  - Using internal users (company employees) may mislead you

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Development

- Refine and Finalize Design
  - Fix issue and address failures
  - Address design aspects contributing to errors and mistakes
  - Address usability issues
  - Repeat usability tests if necessary
- Develop formal usability tests
  - Based on human factors requirements
  - Comprehensive workflow involving user interface
  - Formal acceptance criteria

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HF - Validation

- Perform Validation
  - Use final design
  - Larger number of participants (15-25)
  - Run in actual of simulated use environment
  - Create a formal summary
  - Address/Explain all observations
  - Include in pre-Market submission

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