FDA Initiatives on Human Factors and Usability for Medical Devices

Molly Follette Story, PhD
FDA /CDRH / ODE

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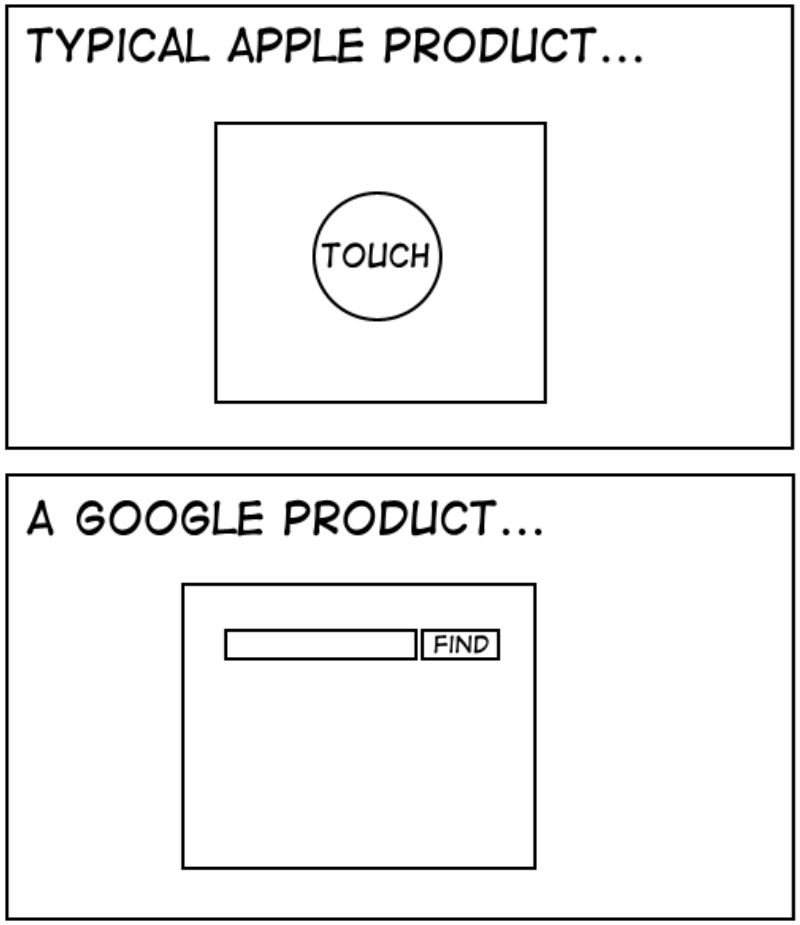
October 21, 2011

Simplicity

March 5th, 2008

What can we learn about usability…



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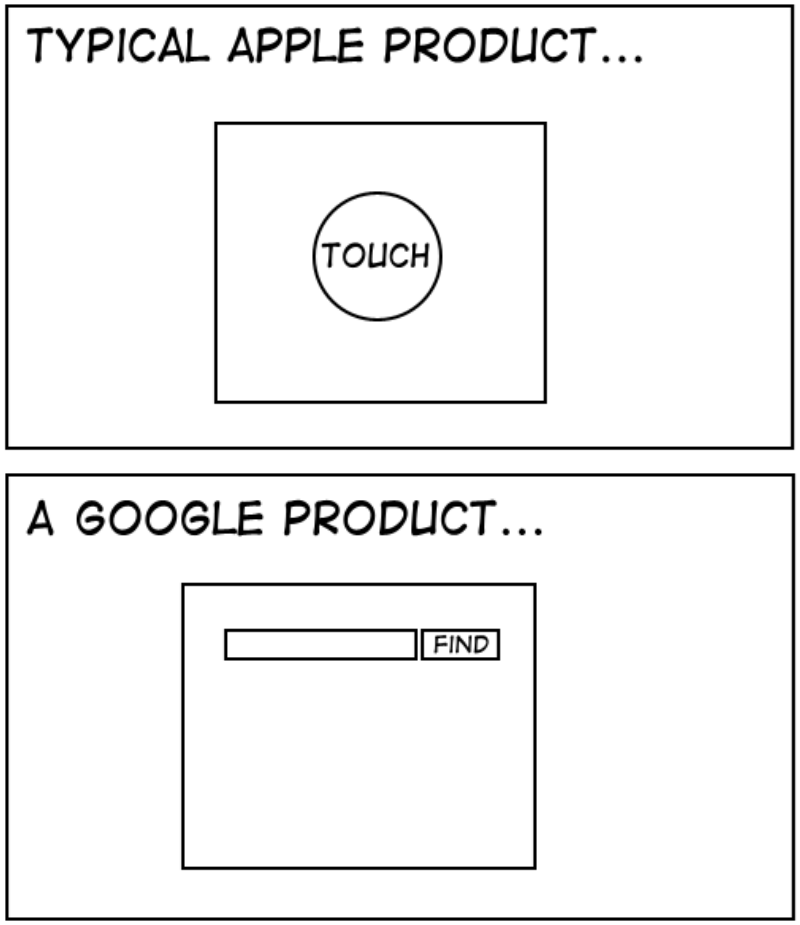

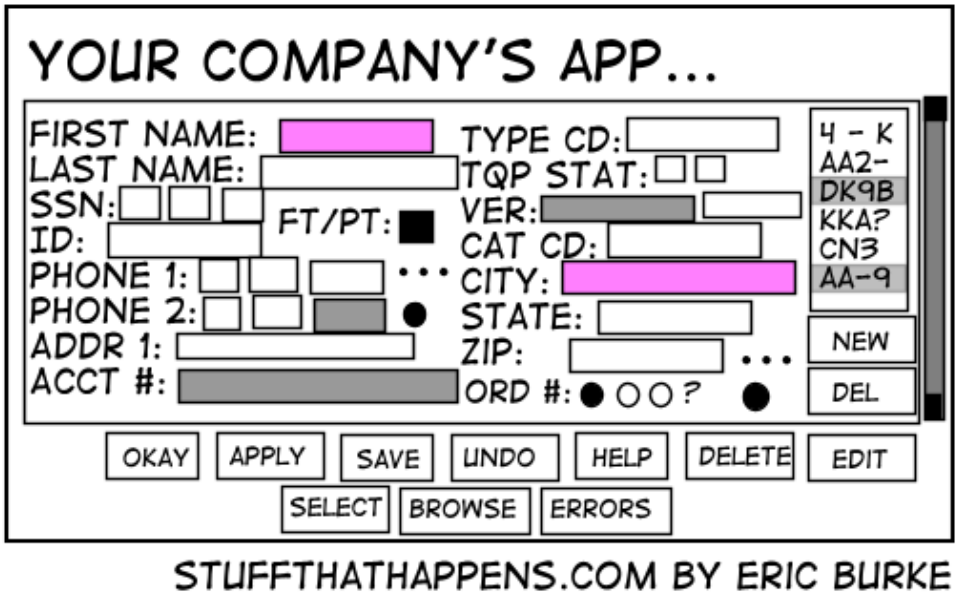

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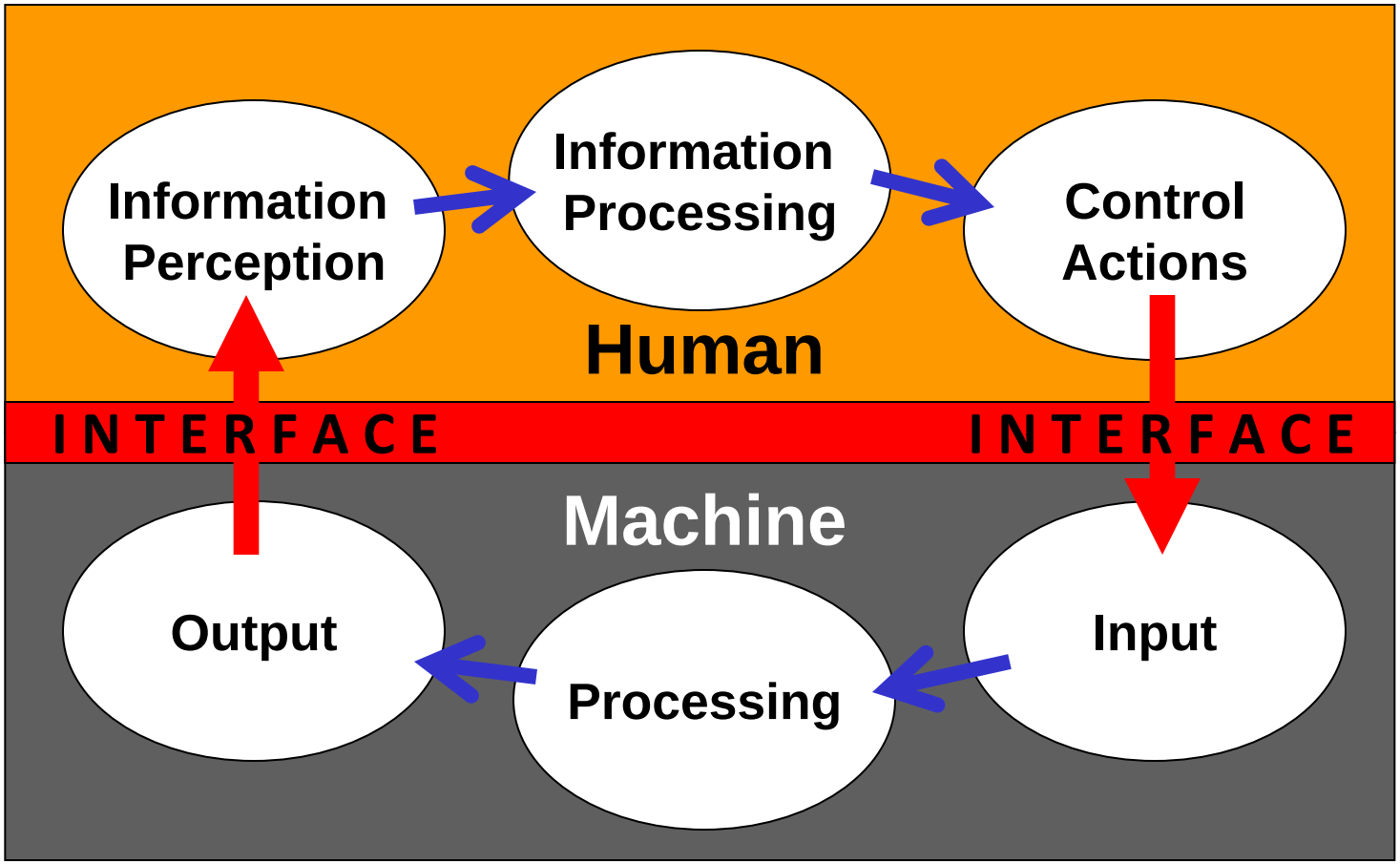
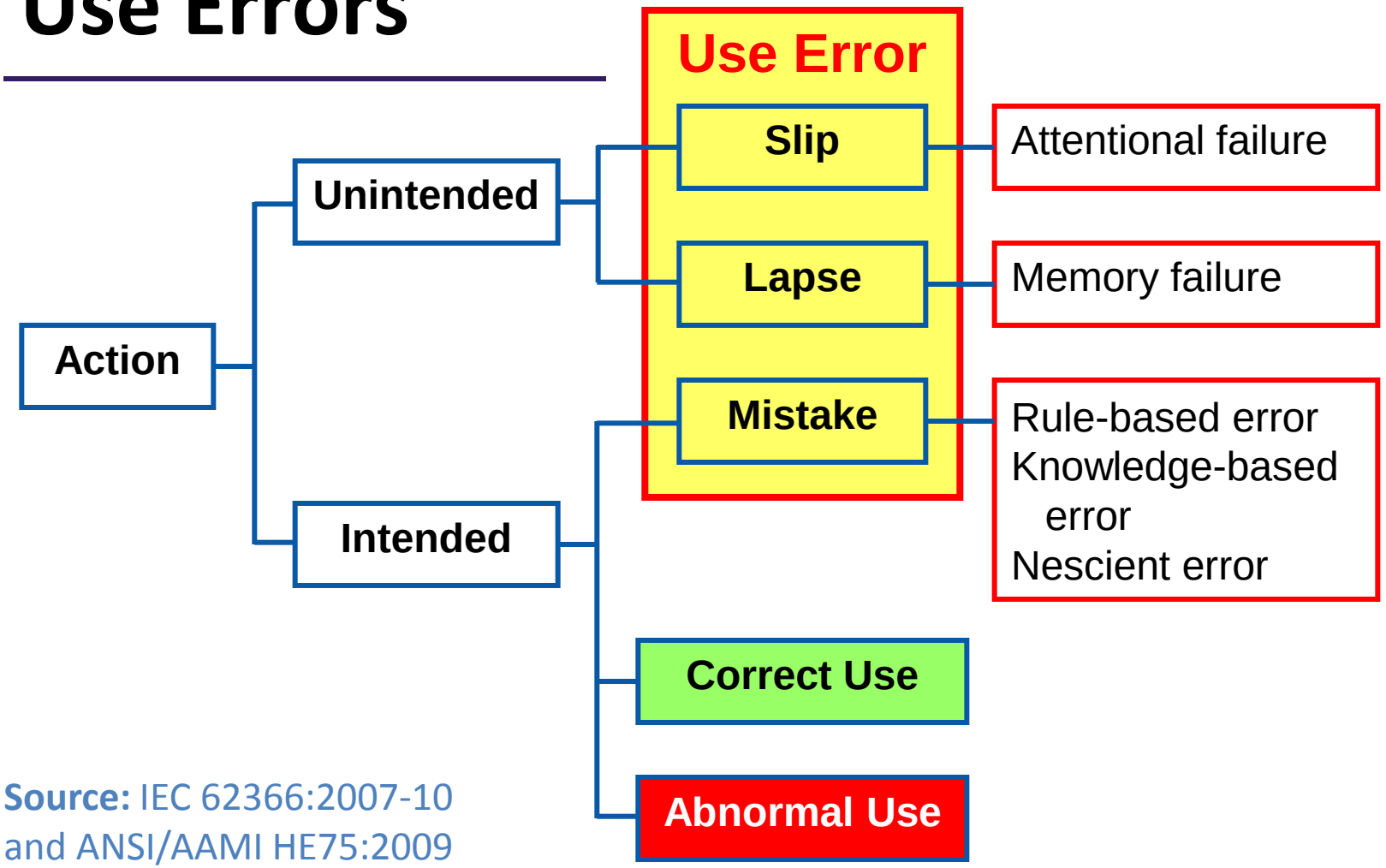
Regulatory Basis for HF at FDA

- **Quality System regulation: 21 CFR 820.30, Design Controls – Implies HF in design and evaluation**
  - **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**…."
- **Use errors and failures are specific types of risk**

Device-User Interface



Use Errors



Source: IEC 62366:2007-10 and ANSI/AAMI HE75:2009

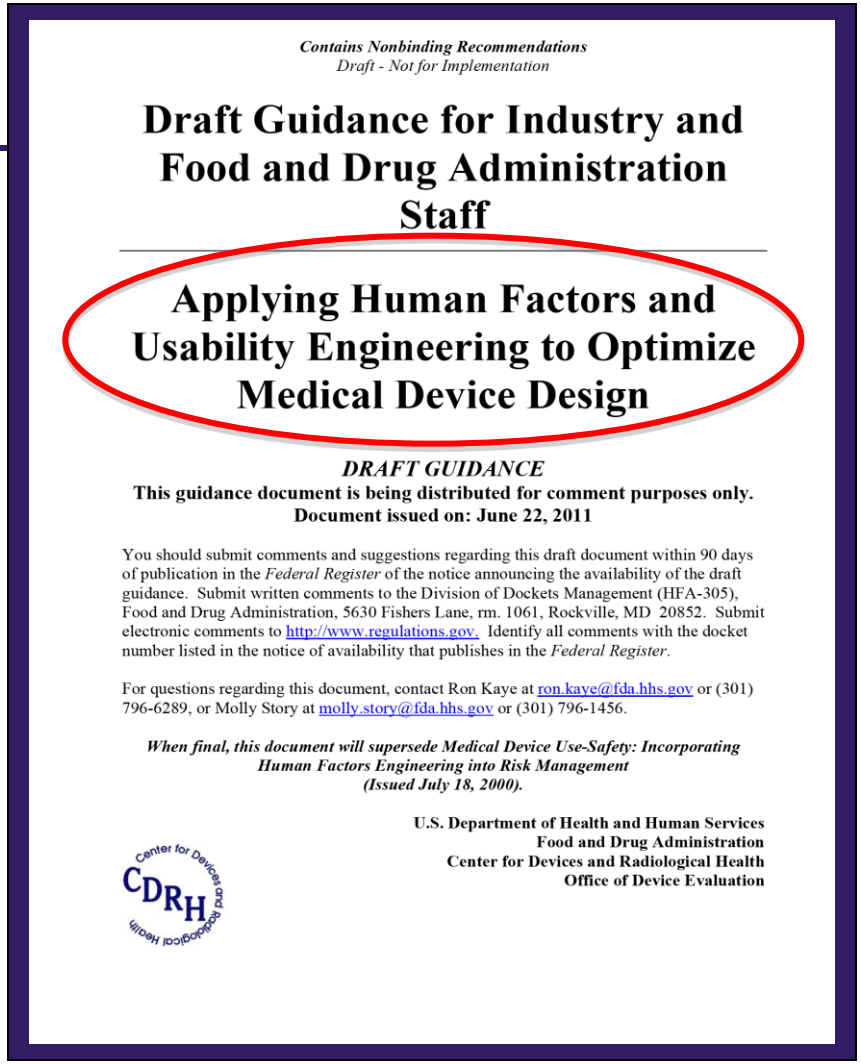
Reasons for Use Errors

- Device use exceeds user's capabilities;
- Use environment has negative effects;
- Device use is inconsistent with user's expectations or intuition;
- Device is used in unexpected ways;
- Device is used in inappropriate ways for which adequate controls were not applied.

FDA Guidance

fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm

- *NOTE: This guidance is not yet in effect but it reflects FDA-CDRH's current thinking and approach to human factors.*



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

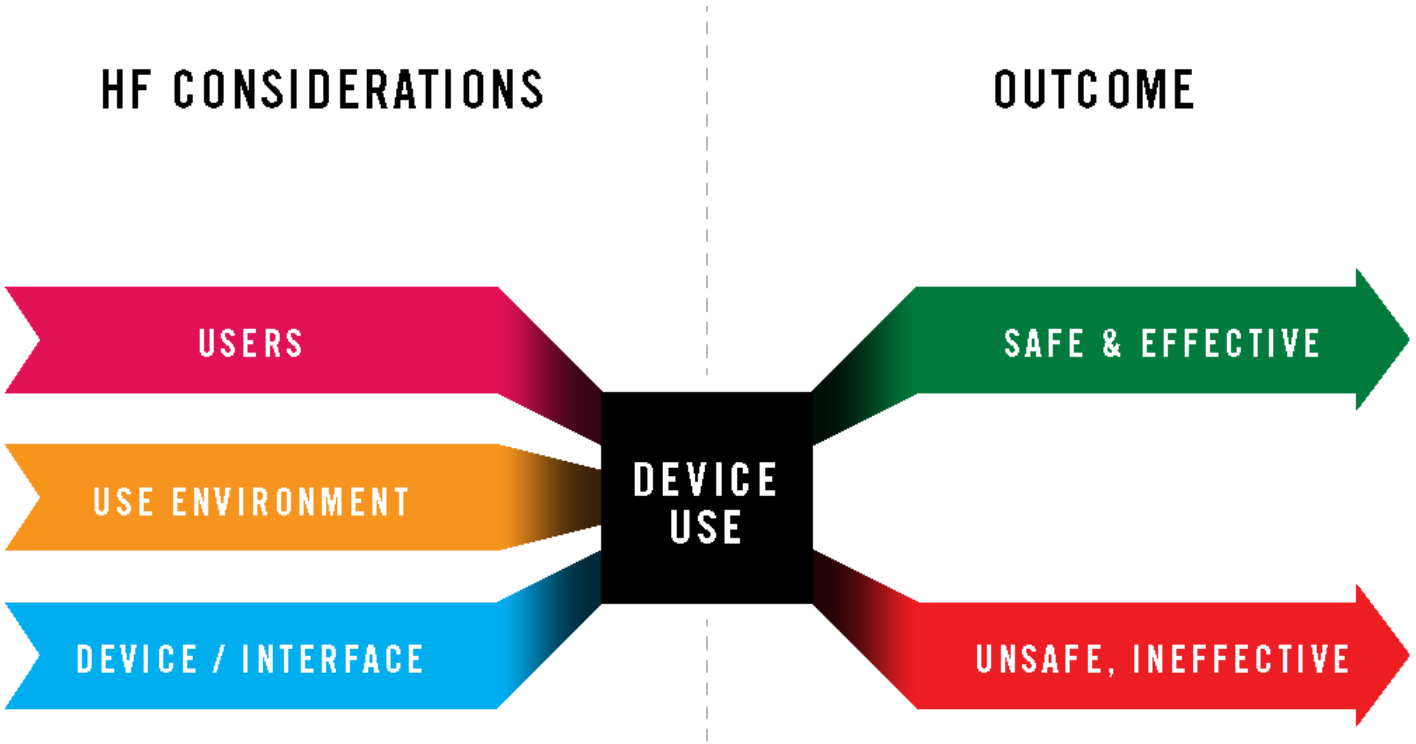
You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 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.

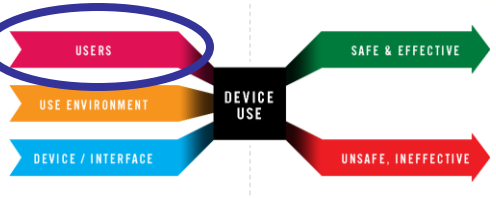
When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

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

Human Factors of Device Use

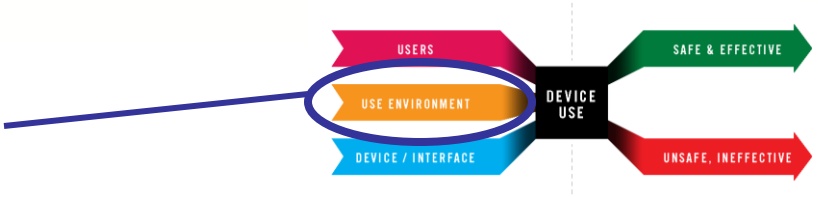


Users



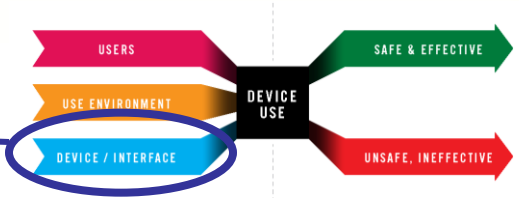
- **Professional or non-professional**
  - Job title and responsibilities
- **Knowledge and experience levels**
- **Age and functional capabilities**
  - Physical, sensory/perceptual, cognitive/intellectual
- **Mental and emotional condition**

Use Environment



- **Clinical environment**
  - Hospital, clinic, etc.
- **Transitional care environment**
  - Rehabilitation, assisted living, long-term care, etc.
- **Home environment**
  - House, mobile home, townhouse, apartment, etc.
- **Community setting**
  - Office, school, retail, outdoors, etc.
- **Mobile environment**
  - Car, plane, train, bus, ambulance, medevac, etc.

User Interface



- **Tasks for EHRs**
  - Data entry (initial)
  - Data review
  - Data revision
- **Interactions**
  - Input
    - Knobs/dials, switches, buttons, touch screens, etc.
  - Output
    - Visual: displays (GUI), lights
    - Auditory: alerts/alarms, beeps, voice

Preliminary Analyses

- **Analyze needs of current system users**
  - Who will use the system?
  - Where will they be working?
  - What tasks will they perform?
- **Analyze system-user interactions**
  - How will the users interact with the system?
  - What use errors and failures might occur?
  - How might errors and failures be prevented?

Preliminary Analyses

Two ways to discover use-related hazards:

1. **Apply analytical techniques**
   - Apply variety of techniques to identify use-related hazards and risks
     - *Can be difficult to anticipate all hazards*
2. **Conduct user-based evaluations**
   - Conduct hands-on testing to identify unanticipated hazards
     - *Sometimes called "Usability Testing" or "Use Testing" or "User Testing" or "Formative" Evaluations*

Formative Evaluations

- **While the device is still under development**
  - Include representative end users
  - Test simple product mock-ups or early prototypes
- **Done early in the design process**
  - At this stage use-related problems can be addressed more easily and less expensively
- **Best when performed iteratively**
  - Repeat until the device is optimized and ready for human factors/usability validation testing

Risk Mitigation

- **Develop a risk mitigation strategy**
  - Modify interface design, user instructions, and/or training to address the problems found
- **Re-test to demonstrate effectiveness of mitigation**
  - Not sufficient to simply state that the device will be reviewed or that mitigations will be implemented later
- **Residual risk is acceptable if reasonably limited, not capable of elimination or further reduction, and benefits of using device outweigh the risks**

Human Factors/Usability Validation

- **Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:**
  - By representative intended users
  - Under realistic use conditions
  - For critical (high-risk) and essential tasks
- **Objective and subjective data:**
  - Use errors and failures are observed and recorded
  - User opinion and feedback is collected from users afterward, particularly related to any use problems

Questions

Molly Follette Story: molly.story@fda.hhs.gov

FDA/HF web site: www/fda.gov/humanfactors