The FDA Perspective on Human Factors in Medical Device Software Development

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Overview

• Background
• Guidance for FDA premarket submissions involving medical device software
• Guidance for FDA premarket submissions involving human factors data
• Human factors/usability validation
Device-User Interface

Input

Processing

Output

User

Information Perception → Information Processing → Control Actions

Device Interface

Software Validation

Human Factors

HF/U Validation

Background
Use Errors

Action

Unintended

Slip

Attentional failure

Mistake

Lapse

Memory failure

Rule-based error
Knowledge-based error
Ignorance-based error

Correct Use

Abnormal Use

Intended

Source: IEC 62366:2007-10
and ANSI/AAMI HE75:2009
Common Reasons for Use Errors

- The use environment has negative effects
- The demands associated with use of the device exceed the user’s capabilities
- Aspects of device use are inconsistent with the user’s expectations or intuition
- The device is used in unexpected ways
- The device is used in inappropriate but foreseeable ways, for which adequate controls were not applied
Common User Interface (UI) Issues

- UI complexity causes user confusion, delay in use, or inability to use the device
- UI makes it difficult for user to correct data entry errors or modify device settings in a timely fashion
- UI falsely causes the user to believe a critical situation exists when it does not, or vice-versa
- UI does not draw attention to dangerous conditions of device operation or patient status
- UI does not prevent known, likely data input errors
Medical Device Software

- Primary standard recognized by FDA
- Guidance documents issued by FDA
- Guidance for FDA premarket submissions involving medical device software
Software Standard

IEC 62304:2006

Medical device software – Software life cycle processes

- SW development
- SW maintenance
- SW risk management
- SW configuration management
- SW problem resolution
FDA SW Guidance

**General Principles of Software Validation**

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

– Note: issued in 2002
FDA SW Guidance

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm

– Note: issued in 2005
Device Hazard Analysis

- Include all foreseeable software-related hazards
  - Identification of the hazard
  - Severity of the hazard
  - Cause(s) of the hazard
  - Method of control (e.g., hardware, software, alarm)
  - Corrective measures (e.g., to eliminate, reduce, or warn)
  - Verification
  - Validation
Software “level of concern”

- Estimate (in the absence of mitigations) of the severity of injury that a device failure or latent design flaw could permit or inflict, either directly or indirectly, on a patient or device operator:
  - **Major**: could directly result in death or serious injury
  - **Moderate**: could directly result in minor injury
  - **Minor**: unlikely to cause any injury

- **Documentation recommended for an FDA submission depends on the level of concern**
Software-related documentation: Overview

- Describe the **design** of your device
- Describe how your design was **implemented**
- Demonstrate how the device, with your design implementation, was **tested**
- Show that you identified **hazards** appropriately and managed **risks** effectively
- Provide **traceability** to link the design, implementation, testing, and risk management
FDA Software Guidance (4 of 7)

Software-related documentation:
Verification and Validation (V&V)

• MINOR level of concern:
  – Software functional test plan
  – Pass/fail criteria
  – Test results
Software-related documentation: Verification and Validation (V&V)

- MODERATE level of concern:
  - V&V activities at the unit, integration, and system level
    - System-level test protocol
    - Pass/fail criteria
    - Test results
FDA Software Guidance (6 of 7)

Software-related documentation: Verification and Validation (V&V)

• MAJOR level of concern:
  V&V activities at the unit, integration, and system level
  – Unit, integration and system-level test protocols
  – Pass/fail criteria
  – Test report, summary, test results
Software design needs to address HF

- Weave human factors engineering into entire design and development process, including device design requirements, analyses, and tests.
- Consider device safety and usability issues when developing flowcharts, state diagrams, prototyping tools, and test plans.
- Perform task and function analyses, risk analyses, prototype tests and review, and full usability tests.
- Include participants from the user population(s).
Medical Device Human Factors

- Standards recognized by FDA
- Guidance documents issued by FDA
- Guidance for FDA premarket submissions involving human factors data
Human Factors Standards (1 of 4)

AAMI/ANSI HE75:2009

• General considerations and principles
  – Managing the risk of use error
  – Usability testing

• Design elements
  – Controls
  – Software

• Integrated solutions
  – Mobile medical devices
  – Home health care
Human Factors Standards (2 of 4)

ISO/IEC 62366:2007

Medical devices – Application of usability engineering to medical devices

- Usability engineering process
- Accompanying document
- Training
Human Factors Standards (3 of 4)


Medical devices – Application of risk management to medical devices

- Risk management
- Risk analysis
- Risk evaluation
- Evaluation of overall residual risk acceptability
Human Factors Standards (4 of 4)

IEC 60601-1-8:2006

Medical electrical equipment… Collateral standard: …alarm systems

- Alarm systems
  - Alarm condition
  - Generation of alarm signals
  - Alarm presets
  - Distributed alarm system
  - Etc.
FDA HF Guidance

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm

– NOTE: issued in 2000

Guidance for Industry and FDA Premarket and Design Control Reviewers

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

document issued on July 15, 2000

This document replaces the draft guidance document of August 3, 1999, entitled "Device Use Safety: Incorporating Human Factors in Risk Management."
FDA HF Guidance

Applying HF&UE to Optimize Medical Device Design

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm

– NOTE: issued in 2011 – It is not yet in effect but it reflects FDA-CDRH’s current thinking and approach to human factors
2011 Draft Human Factors Guidance

- Considerations: Device Users, Use Environments and User Interfaces
- Preliminary Analyses
- Exploratory HF/Usability Evaluations
- Hazard Mitigation and Control
- Human Factors/Usability Validation
Human Factors of Device Use

HF CONSIDERATIONS

- USERS
- USE ENVIRONMENT
- DEVICE / INTERFACE

DEVICE USE

OUTCOME

- SAFE & EFFECTIVE
- UNSAFE, INEFFECTIVE

Background  Software  Human Factors  HF/U Validation
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

- **Example software interaction tasks**
  - Data entry (initial)
  - Data review
  - Data revision

- **Interactions (device hardware)**
  - Input
    - Knobs/dials, switches, buttons, keyboards, touch screens, etc.
  - Output
    - Visual: displays (GUI), lights, control settings, etc.
    - Auditory: alerts/alarms, beeps, voice, motors, fans, etc.
Regulatory Basis for HF at FDA

Quality System regulation: 21 CFR 820.30, Design Controls

- The need for human factors is implied:
  c) Design input – includes “needs of the user and patient”
  f) Design verification – performance criteria met
  g) 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....” [incl. use-related risks]
Human factors engineering process for medical devices

Source: ANSI/AAMI HE75:2009
Preliminary Analyses: Inquiries

• **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 or the severity of any negative consequences be reduced?
Preliminary Analyses: Methods (1 of 3)

- **Contextual inquiry**
  - User demonstrates; researcher observes, inquires

- **Interviews and focus groups**
  - Discussions are targeted; researcher is neutral

- **Function and task analyses**
  - Break down device use into discrete steps
  - Identify use-related hazards associated with each step of use
  - Identify potential causes and consequences of user encountering each hazard
  - Develop risk mitigation strategies, if needed
Preliminary Analyses: Methods (2 of 3)

- **Heuristic analysis**
  - Formally evaluate user interface against well-established design rules or heuristic guidelines

- **Expert review**
  - Use clinical and human factors experts
  - Experts provide personal opinions of usability and safety of user interface, based on professional knowledge and experience
Preliminary Analyses: Methods (3 of 3)

Two ways to discover use-related hazards:

1. **Analytical techniques**
   - To identify use-related hazards and risks
     - *Use-related hazards and user behavior can be difficult to predict*
   - To focus the process and prioritize resources

2. **Human factors/usability evaluations**
   - Conduct exploratory, hands-on testing to discover and explore unanticipated hazards
     - *Sometimes called “Usability Testing” or “Use Testing” or “User Testing” or “Formative” Evaluations*
Exploratory HF/U Studies (1 of 2)

- **Done while the device is under development**
  - Conduct studies iteratively to optimize the device design and ensure the human factors/usability validation testing results will be successful
  - Testing can involve simple product mock-ups or early prototypes, or even partial designs (e.g., components) operating in simulated-use modes
  - Test participants should be representative of the intended user population(s)
  - At early stages, use-related problems can be addressed more easily and less expensively
**Exploratory HF/U Studies (2 of 2)**

- Conduct separate studies on labeling and training:
  - Assess the clarity and effectiveness of all labeling (e.g., instructions for use, other documentation, packaging)
  - Determine the level and nature of training that will be necessary (if any)
Risk Mitigation

• **Develop risk mitigation strategies as needed:**
  – Modify the interface design, user instructions, and/or training to address the problems found

• **Re-test to assess whether mitigation strategies:**
  – Effectively reduced the known risks and
  – Did not introduce any new risks

• **Residual risk is acceptable if it is:**
  – Reasonably limited, not capable of elimination or further reduction, and outweighed by the device’s benefits
820.30(f) Design Verification

820.30(g) Design Validation

Design Verification:
– Did I make the product right?

Design Validation:
– Did I make the right product?

Source: Kimberly A. Trautman, FDA
Human Factors/Usability Validation

• Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:
  – By people who are representative of the intended users
  – Under expected use conditions
  – For essential and critical (high-risk) tasks

• Includes both objective and subjective data:
  – Use errors and failures are observed and recorded
  – User feedback is collected after use regarding essential and critical task errors, failures and difficulties
Device Testing Conditions

- Use finalized device design and labeling
- Identify expected use conditions
  - E.g., lighting, sound, and activity (distraction) levels
- Allow realistic device-user interactions
  - Provide participants with device as they would receive it (e.g., in its original packaging, with all documentation)
  - Allow participants to use the device as they normally would (e.g., without interference from test facilitator)
Selection of Tasks Tested (1 of 2)

- Include in the HF/U validation study protocol and report a rationale for the tasks you choose to include in your testing
  - Base task selection on results of preliminary analyses
    - E.g., task analyses and assessment of use-related risks
  - Incorporate findings of exploratory HF/U studies
    - E.g., tasks found to be problematic for users
Selection of Tasks Tested (2 of 2)

- Tasks tested in validation do not necessarily include everything in the instructions for use
  - Include *essential tasks* – i.e., tasks necessary for successful use of the device
  - Include *safety-critical tasks* – i.e., tasks on which users could make errors or could fail to complete, which would have negative clinical impact
    - All warnings and most caution statements in the device labeling imply safety-critical tasks
    - All tasks requiring responses to alarms are safety-critical
Instructions and Training

- Participant interaction with instructions and training should approximate reality
  - Labeling used in device validation should be final versions
  - Training used in device validation should be comparable to the training that actual users will receive
Validation Test Data

• **Assessment of device-user interactions**
  - User performance
    • Through observation, automated data collection, etc.
    • Essential and critical tasks
  - User knowledge
    • Through questionnaire or interview (worded neutrally)
    • Essential and critical knowledge
      - E.g., warnings and cautions
  - User subjective feedback
    • Through interview, after user has completed all test tasks
    • Overall use, essential/critical tasks, all performance failures
Human factors engineering process for medical devices

Source: ANSI/AAMI HE75:2009
Advice: Consult FDA Early

- Discuss product development plans with FDA before your design is considered “final” (and changes would be difficult)
  - Staff in CDRH, CDER and CBER can advise
    - E.g., on software level of concern
  - FDA will review human factors/usability testing protocols on request
    - *Before implementation is recommended!*
FDA/CDRH Human Factors Program

http://www.fda.gov/humanfactors

- Premarket Info
  - Design & Documentation
- Postmarket Info
  - Surveillance & Reporting
- Info for Consumers, Patients, Caregivers
- General Human Factors Info and Resources
New HFES-AAMI Web Site

http://www.medicaldevicehumanfactors.org

- Resources
- Consultant Directory
- Organizations
- Events
Acknowledgment and Questions

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