Looking ahead to new human factors standards and guidances for medical devices

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Outline

• Overview of the Human Factors Engineering HFE Process for Medical Products
• Overview of Human Factors Standards and Guidances for Medical Products
• Changes now in progress
• Implications
Definitions

• Use Error
  – Use error is repetitive and can be predicted. It can be minimized by design and identified through usability testing and hazard analysis.
  – Act or omission of an act that results in a different outcome than intended by the manufacturer or expected by the USER, which may result from a mismatch situation between USER, man-machine interface, task and/or environment. HE74:2001

  *The terms User Error and Human Error are no longer used officially*

Abnormal Use

– Intentional act or intentional omission of an act by the RESPONSIBLE ORGANIZATION or USER of a MEDICAL DEVICE as a result of conduct that is beyond any further reasonable means of RISK CONTROL by the MANUFACTURER
  • Sabotage, Reckless Use
Human Factors Core Methods

Contextual Inquiry
- User Profiles: Who?
- Use Environment: Where?
- Task Analysis: What?

Risk Analysis
- Estimate Hazards & Risks

User Interface Specification
- Acceptance Criteria

Iterative Design
- Rapid Prototyping
- Simulations

Usability Testing
- Formative (early designs)
- Summative at the End
Human Factors in the Design Control Process

Design Control Activities

- Concept Phase
  - Perform Studies & Analysis
- Design Input
  - Design Requirements
  - Task Analysis
  - User Profiles
  - Use Environment
  - Heuristic Review
  - RISK ANALYSIS
- Design Output
  - Design Specifications
  - Prototyping / Simulations
  - Formative Design
  - Usability Testing
- Verification
  - Test Output Against Input
  - Expert Reviews
  - Cognitive Walkthroughs
  - Usability Testing
  - Field Studies
- Validation
  - Test Against User Needs
  - Production Units (or Equivalent)
  - Summative Usability Testing

Human Factors Activities

- Contextual Inquiry
- Literature Reviews
- Complaints Analysis
- Market Research
- Cognitive Walkthroughs
- Usability Objectives
- Iterative Design
- RISK ANALYSIS
- Formative Usability Testing
- RISK ANALYSIS
Summary: HFE Process for Medical Devices

- **Systematic and Scientific** process is required
  - Contextual Inquiry
  - User Interface Specification
  - Usability Testing with iterative design

- **Design controls** are specified by the FDA and recommended by international regulators.

- A **Design History File** must be maintained. It is auditable.

- Formal **Risk Management** is required to identify use errors that might lead to high levels of risk for patients and end users.

- **Verification** is required to show that design outputs meet design inputs.

- **Validation** of the user interfaces is required via usability testing against formal acceptance testing, which must reflect customer requirements.

- **Post market surveillance** is required to track adverse events associated with a device and to formally track customer complaints via a **CAPA** corrective action preventative action plan.
Human Factors Standards


  – Annexes include: AAMI HE 74:2001

– IEC/ISO International HF Standards

– IECEE – TRF (Test Report Forms) for Usability Standards
  • Covers how to certify against IEC 62366:2007 and IEC 60601-1-6:2010
  • Used by Notified Bodies and Certified Test Labs
Related Standards

ISO 14971:2007 Medical devices -- Application of risk management to medical devices


IEC 60601-1-8: 2006 Collateral to IEC 60601-1:2005 on general requirements, tests and guidance for alarm systems

IEC TR 60878:2003 Graphical symbols for electrical equipment in medical practice

ISO 15223-1:2007 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

ISO 15223-2:2010 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 2: Symbol development, selection and validation
International Usability Standards IEC/ISO - Updates

- IEC TR 60878:2001 - Graphical symbols for electrical equipment in medical practice
  - CD to be issued in 2013 – Additional Symbols from ISO, IEC added
  - Reorganized Categories of Symbols
- ANSI/AAMI/IEC 62366:2007 Ed 1, Medical devices - Application of usability engineering to medical devices
  - Legacy Amendment CDV issued in 2012. Goal is to issue mid-2013
  - Rewrite/Update started in June, 2011. (Completion targeted for 2015)
  - Two parts
    - IEC 62366-1 Normative Standard (Concise) – CD Nov, 2012
    - IEC 62366 -2 Informative Standard (HFE/UE Tutorial) – Working Draft
Changes to IEC 62366:2007

• Normative standard (IEC 62366-1)
  – Streamlined
  – Harmonized with draft FDA HFE/UE Guidance (June, 2011)
  – Improved and simplified terminology
    • Use Specification (not Application Spec)
    • User Interface Specification (not Usability Spec)
  – More thoroughly integrated with Risk Management (ISO 14971)
  – Controversy over the name – HFE, UE or UE/HFE

• Informative tutorial (how to do) information moved to TR technical report (IEC TR 62366-2)
  • More informative annexes
  • More examples with illustrations
• 5: Usability Engineering Process (UE/HFE Process)
  5.1 Application Specification (Use Specification)
  5.2: Frequently Used Functions (Part of Primary Operation Functions)
  5.3 Identify Hazardous Situations (Hazard Related Use Scenarios)
    5.3.1 Identify characteristics related to safety
    5.3.2 Identify known or foreseeable hazards
  5.4: Primary Operating Functions
  5.5: Usability Specification (User Interface Specification)
  5.6 Usability Validation Plan
  5.7 User Interface Implementation
  5.8 Usability Verification (Formative Usability Evaluation)
  5.9 Usability Validation (Summative Usability Evaluation)

• 6: Accompanying Documents
• 7: Training/Training Materials
• Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP). THREE SCENARIOS:
  o MEDICAL DEVICES on the market that were not developed using the USABILITY ENGINEERING PROCESS of IEC 62366:2007 (so called legacy MEDICAL DEVICES);
  o MEDICAL DEVICES that have changes to the USER INTERFACE and that were not originally developed using IEC 62366:2007; and
    NOTE Only the unchanged portions of the USER INTERFACE are considered UOUP.
  o MEDICAL DEVICES that incorporate an off-the-shelf component that itself was not developed using the USABILITY ENGINEERING PROCESS of IEC 62366:2007.

• Legacy UOUP process to be carried over to updated 62366 as well

• Comments to CDV to be resolved in April, 2013
IEC 62366:2007 Legacy Amendment- Annex K

• Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)

• K.2 Usability engineering process for user interface of unknown provenance
  – K.2.1 Application specification (Intended Use)
  – K.2.2 Frequently used functions
  – K.2.3 PRIMARY OPERATING FUNCTIONS (Tasks that could lead to Harm)
  – K.2.4 Review of post-market information (Complaints, recalls, CAPA)
  – K.2.5 HAZARDS and HAZARDOUS SITUATIONS caused by USABILITY problems (Use Risk Analysis e.g. Use FMEA)
  – K.2.6 RISK CONTROL (If Residual Risk is not acceptable—Use HFE/UE process)
Life Cycle Amendment to IEC 60601-1-6:2010

• IEC/ISO International HF Standards
    • Draft Amendment to remove erroneous Lifecycle reference to IEC 62366
  • Excludes:
    – Post Production Monitoring for Usability
    – Maintenance of the USABILITY ENGINEERING PROCESS.
• CDV Comments to be resolved in April, 2013
ANSI/AAMI HE75: Human Factors Principles for Medical Device Design

– Comprehensive design guidelines
  • 465 pages in 25 sections
– Special issues related to medical practices and process giving context to best design practices
– FDA sponsored companion book to HE 75 published by CRC/Taylor and Francis
  – 850 pages
HE75: Scope

• Organized in 3 General Areas (25 Sections)
  • General Considerations and Principles
  • Design Elements
  • Integrated Solutions

• Specific Design Guidance & Recommendations
  • Authors are Human Factors Experts
  • Vast HF Literature is Distilled and Summarized
  • Intended to Save Design Time
  • Specific Numbered Guidance Statements are Included
  • Extensive References are Provided
HE 75 at a glance...

- **General Considerations**
  - General UI Design Principles
  - Managing Risk of Use Error
  - Basic Skills and Abilities
  - Anthropometry & Biomechanics
  - Environmental Considerations
  - Usability Testing

- **Design Elements**
  - Signs, Symbols, Markings
  - User Documentation
  - Packaging Design
  - Cross-Cultural/Cross-National Design
  - Design for Post-Market
  - Alarm Design
  - Accessibility Considerations

- **Integrated Solutions**
  - Use of Automation
  - Displays
  - Controls Design
  - Connectors/Connections
  - Software User Interfaces
  - Mobile Devices
  - Home Health Care Considerations
  - Workstation Design
  - Design of Hand Tools

• Work started to draft Updated HE-75 Edition 2
  – New sections including: Medical apps, Auditory Displays, Combination Products, Robotics, Training, Virtual Reality, Wearable Devices, Simulation, Telemedicine, Medical Info Systems, Maintenance
  – Correct/Update current sections
Future Standards Work Items

• AAMI Human Factors Engineering Committee
  – Post-market surveillance (event detection) and complaint analysis for use error- TIR HE_1
    • CDV issued and comments being resolved (expect to be issued mid-2013)
  – Contextual Inquiry/Observational Research Standards – draft completed
  – Human Factors Engineering integration into Design Controls – New Work Item

• IEC MT 25 on Usability
  – Accompanying Documents Symbols usage proposed
  – Addressed HF issues in IEC 60601-1 Amendment 1 (Finalized in Nov, 2011)
  – Update to IEC TR 60878:2003 Symbols – Additional Symbols and Categories
FDA Increased Expectations for Human Factors

- CDRH HF Guidance Documents
  - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, DRAFT June 22, 2011
  - Medical device use safety: Incorporating HFE into risk management, July 18, 2000
- CDER HF Related Guidance Documents
  - Safety Considerations for Product Design to Minimize Medication Errors, DRAFT December, 2012
  - Design Considerations for Devices Intended for Home Use, DRAFT December 12, 2012
FDA Increasing Expectations for HF

- New Revised Draft CDRH Guidance (June 22, 2011) requires:
  - Contextual Inquiry (Intended Use, Task Analysis, UI Description)
  - Known Use Errors (Complaints, CAPA, MDR’s)
  - Use Error Risk Analysis Required
  - Summary of Formative Usability Evaluations and Design Modifications
  - Validation of Usability
    - Rational (Users, Use Environment, Simulated Use vs. Clinical Evaluation)
    - Tasks Prioritized by Risk Analysis
    - Sample size (15 minimum, 25 for infusion pumps)
    - Learning decay addressed by delay between training and usability testing
    - Explain All Task Failures (Safety Critical Tasks Require No Task Failures with Negative Clinical Impact)
    - Subjective Assessment of Safety (Especially for close calls)

- Conclusions (Residual Risk)
## HFE/UE Report for FDA CDRH - Seven main components

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HFE/UE Report - Seven main components

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<td>The &lt;Name Model&gt; has been found to be reasonably safe and effective for the intended users, uses and use environments.</td>
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<td>The methods and results described in the preceding sections support this conclusion.</td>
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<td>Any residual risk that remains after the validation testing would not be further reduced by modifications of design of the user interface (including any accessories and the IFU), is not needed, and is outweighed by the benefits that may be derived from the device’s use.</td>
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# IEC 62366:2007 Process vs. FDA Report Deliverables

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CDER HF Guidances

• CDER announced plans for more FDA guidances relevant to Human Factors:
  – Safety Considerations for Product Design to Minimize Medication Errors, DRAFT December, 2012
    • Study User Profiles and Use Environment
    • Perform Risk Analysis – Use-FMEA recommended
    • Perform Simulated Use Testing
  – Additional Planned Guidances
    • Good labeling/packaging HF practices
      – Examples of poor HF in labeling and packaging (things to avoid)
    • Drug naming practices
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Implications

• Bar is being raised for quality of Human Factors Engineering Work
  – Internationally (Notified Bodies are better informed)
    • Legacy Devices being addressed
    • Improved IEC 62366 (harmonized with FDA for consistency)
  – US FDA expects more
    • FDA Recognizes major HFE/UE Standards (HE-75, IEC 62366, etc)
    • CDRH New Draft Guidance on Medical Devices
    • CDER Draft Guidances for all Medical Products
      • Combination Products
      • Packaging/Labeling
      • Naming
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Thank You.

Questions?