Identifying Use Errors and Human Factors Approaches to Controlling Risks

Molly Follette Story, PhD
QuynhNhu Nguyen, BS
Human Factors Premarket Evaluation Team
FDA / CDRH / ODE

Public Workshop: Quarantine Release Errors
September 13, 2011
Overview

• Introduction to Human Factors (HF)
• Human factors methods for studying the problems and testing potential solutions
• Summary of use-related errors related to blood product handling
• Examples from Quarantine Release Error (QRE) reports
• Discussion/Review
Brief History of HF at FDA

• The FDA Human Factors program developed over the past 30 years within CDRH and is currently located in the Office of Device Evaluation

• The FDA-CDRH HF program focuses on “use safety” of medical devices for their intended users, uses, and use environments

• FDA-CDRH HF staff:
  ▪ Reviews HF content in premarket device submissions
  ▪ Participates in selected postmarket and compliance activities

• FDA encouraged AAMI to publish its first HF standard in 1988, followed by others, notably AAMI/ANSI HE75:2009, Human Factors Engineering – Design of Medical Devices
Regulatory Basis for HF at FDA

• Quality System regulation, 21 CFR Part 820 Section 30, Design Controls - Implies human factors in design and evaluation
  
  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.”

• Use errors and failures are specific types of risk
Human Factors of Device Use

HF CONSIDERATIONS

- USERS
- USE ENVIRONMENT
- DEVICE / INTERFACE

DEVICE USE

OUTCOME

- SAFE & EFFECTIVE
- UNSAFE, INEFFECTIVE
Human Factors of Device Use

HF Considerations

- Users
- Use Environment
- Device / Interface

Device Use

Outcome

- Safe & Effective
- Unsafe / Ineffective

Error
Human-Machine Interface

Information Perception → Information Processing → Control Actions

Human Interface

Machine Interface

Output → Processing → Input
Human-Machine Interface

Information Perception → Information Processing → Control Actions

ERROR

Human

INTERFACEINTERFACE

Machine

Input → Processing → Output

ERROR
Human Factors of Device Use

HF CONSIDERATIONS

- Users
- Use Environment
- Device / Interface

DEVICE USE

OUTCOME

- Safe & Effective
- Unsafe / Ineffective
System Users

- Professional specialties
  - Job titles, responsibilities
- Knowledge and experience levels
- Age and functional capabilities
  - Physical, sensory/perceptual, cognitive/intellectual
- Mental and emotional condition
Use Environments

• Licensed Blood Establishments
• Unlicensed Blood Establishments
• Transfusion Services
User Interface

- **Tasks**
  - Donor screening
  - Donor deferral
  - Blood collection
  - Viral testing
  - Component preparation
  - QC and distribution

- **User input**
  - Product movement, labeling, data entry, documentation

- **System output**
  - Product location, labeling, time, temperature, SOP
Human factors engineering process for medical devices

Source: ANSI/AAMI HE75:2009
Risk Analysis

Two types of use-related hazards:

1. Anticipated hazards
   - Identified by using analytical techniques
     • Can be difficult to anticipate all hazards

2. Unanticipated hazards
   - Not identified by risk analysts
   - Most important goal of user-based evaluations
     • Sometimes called “Usability Testing” or “Use Testing” or “User Testing” or “Formative” Evaluations
Risk Analysis

Risk management process for use-related hazards:

- Identify anticipated use-related hazards (using analytical methods);
- Identify unanticipated use-related hazards (through formative studies);
- Develop and implement mitigation strategies;
- Demonstrate safe and effective use through human factors validation.
Analytical HF Methods (1 of 3)

Identify known problems

- Internal adverse event and complaint files
- Knowledge of facility staff
- Publications
  - Journal articles, proceedings, newsletters
  - Web sites – for example:
    - FDA/CBER: AERS/FAERS, CEARS
    - FDA/CDRH: MAUDE/MDR, MedSun, recalls, alerts and notices, public health notifications
Analytical HF Methods (2 of 3)

Analyze needs of current system users

- Who will use the system?
- Where will they be working?
- What tasks will they perform?

- Contextual inquiry
  - User demonstration
  - Investigator observation and inquiry

- Interviews and focus groups
  - Targeted discussion
Analytical HF Methods (3 of 3)

Analyze critical risks

• **Risk analysis** *(top-down)*
  - Identify critical use-related risks.
  - What hazardous scenarios could lead to these risks?

• **Function and task analysis** *(bottom-up)*
  - Break down use tasks into discrete steps.
  - Are any use errors possible?
  - How might these use errors occur?
  - What are the possible consequences of each use error?
  - How might the use errors be prevented?

• **Apply risk mitigations; reassess hazards**
Formative Studies

With potential system users

- Test design ideas and prototypes
  - Fidelity can be low
- Representative test participants
  - Numbers can be low
- Simulated use conditions
- Identify major problems; develop solutions
- Best when performed iteratively
Human Factors Validation

- Final design of device/system and labeling
- Critical tasks and use scenarios
- Realistic use environments and conditions
- Representative test participants
  - Test the device, not the users
- Realistic training levels and methods
- Data collection
  - User performance and subjective data
Validation: Post-Test Interview

- Open-ended and non-judgmental debrief
- Obtain general participant impressions of the system and the use experience
- Ascertained participant awareness of and reasons for making errors
- Solicited specific comments on design of the system, including labeling and training
Analysis of HF Validation Data

• Identify use errors, “close calls,” difficulties
• Identify potential negative clinical consequences and root causes
• Determine whether risk mitigation strategies are needed
• If so, design and implement strategies and revalidate:
  ▪ Were strategies successful at reducing risks?
  ▪ Did strategies introduce new risks?
Use Errors

Unintended

- Slip
  - Attentional failure

- Lapse
  - Memory failure

- Mistake
  - Rule-based error
  - Knowledge-based error
  - Nescient error

Intended

Correct Use

Abnormal Use

Types of QRE Reports Received

**Licensed Blood Establishments**

- Donor Screening: 52%
- QC & Distribution: 30%
- Testing: 2%
- Collection: 4%
- Component Preparation: 6%
- Donor Deferral: 6%

**Unlicensed Blood Establishments**

- Donor Screening: 38%
- QC & Distribution: 49%
- Testing: 3%
- Collection: 2%
- Component Preparation: 5%
- Donor Deferral: 3%
Factors Contributing to QREs

Licensed Blood Establishments

**Donor Screening**
- Human: 81%
- Process Controls: 17%
- Computer: 0%
- Equipment: 0%

**QC and Distribution**
- Human: 75%
- Process Controls: 13%
- Computer: 1%
- Equipment: 6%
Factors Contributing to QREs

Unlicensed Blood Establishments

Donor Screening

- Process Controls: 18%
- Computer: 0%
- Equipment: 3%
- Human: 76%

QC and Distribution

- Process Controls: 24%
- Computer: 1%
- Equipment: 0%
- Human: 74%
Interface Design and Use Errors

- Errors often result from well-intended use
- Flaws in the design of a medical device user interface can allow and even induce use errors
  - Errors are not created equal; some are more significant
- Human factors methods can be applied to address hazardous user interface designs before (or after) products reach the market
- Warnings and instructions in user manuals can help but should not be depended on to compensate for flawed design
Examples from QRE Reports

1. “A unit was labeled and transfused before required viral markers and NAT testing were performed”

HF Approaches:

- Debrief the user to understand root causes of the error
- Interview co-workers to understand user expectations of typical task processes and workflow
- Observe workers performing critical tasks and identify sources of use error and difficulty
- Consider modifications to labeling and use of SOP:
  - E.g., add a set of check boxes to the unit label for users to mark tests that have been performed
  - E.g., create SOP quick-guides or checklists and place them strategically so that it is obvious to all of the users
Examples from QRE Reports

2. “...Units... were not used after being out of storage for 45 minutes.... Tech did not notice... and accepted the units back to inventory.”

HF Approaches:

- Debrief the user/co-workers to understand root causes of error
- Identify sources of use error and difficulty
- Consider modifications to check-in/out procedures:
  - E.g., provide timers: one would accompany each bag and be started when the unit is checked out
  - E.g., create a computer-based system: scan the unit when it is taken out of the refrigerator; scan it again when it is returned and reject any that has been out for more than 30 minutes
Examples from QRE Reports

3. “...Unit on the return shelf in quarantine was not investigated and returned to inventory. This unit was subsequently issued and transfused.”

HF Approaches:

- Debrief the user/co-workers to understand root causes of error
- Identify sources of use error and difficulty
- Consider modifications to quarantined unit handling process:
  - E.g., store quarantined units in a secured and separate location
  - E.g., require users to complete a status verification process before allowing any units to be returned to inventory
Hazard Control Hierarchy

From most to least desirable:

1. **Attempt to reduce or eliminate the problem through design modifications;**
   - *E.g., Add a set of check boxes to the physical device label to mark tests performed (QRE example #1)*

2. **Implement protective measures to reduce the probability that users will come into contact with the hazard;**
   - *E.g., Store quarantined units in a secured and separate location (QRE example #3)*

3. **Provide users with information for safety, such as specific instructions, warnings, and other information necessary to avoid hazardous situations.**
   - *E.g., Create SOP quick-guides or checklists and post them in strategic locations (QRE example #1)*
Review and Discussion

• Introduction to Human Factors (HF)
• Human factors methods for studying the problems and testing potential solutions
• Summary of use-related errors related to blood product handling
• Examples from QRE Reports
FDA Guidance on Human Factors


  
  **NOTE:** This guidance is not yet in effect but it reflects FDA-CDRH’s current thinking and approach to human factors.
  
  The public comment period will be open until September 19, 2011.
Questions

Molly Follette Story
Molly.Story@FDA.HHS.gov

QuynhNhu Nguyen
Quynht.Nguyen@FDA.HHS.GOV

Web site: www.fda.gov/humanfactors