Evaluating the Human/Package Interface for Medical Device Package Development

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The views expressed in this presentation are mine and do not represent the views of my employer Cardinal Health.
Topics

• Background
• Components of human/package interface
• Methods for evaluation
• Guidance for conducting your own usability assessments and interviews
• Guidance for data analysis
• Benefits
• Resources
Human Factors

• A discipline applying:
  – knowledge of human behavior,
  – methods for analysis,
  – test and evaluation techniques,

that lead to outcomes including usability and ease of use, and safe operation within the capabilities and limits of the human operator.
Usability

• Refers to the *quality of system* that includes:
  – intuitiveness of interaction
  – successful user performance
  – user preferences
  – ease of handling
  – ease of learning
  – skill acquisition
Engineering and Regulatory Fortress

- Integrity
- Protection
- Compatible with processes
- Validated
- Documented
- Optimized
- Cost effective
- Speed to market
What about the end users?

• How are they using the product?
• What do they:
  – Need?
  – Want?
  – Work around?
“The Normalization of Complexity”

• Healthcare workers compensate for complex, unclear workplaces and devices
  – Unclear or absent information and cues
  – Mastery of the complex becomes a normal strategy, without regard to reasonableness or necessity of complexity
Human/Package Interface
Perception

• Sensing: what users must see, hear, feel
  – Exposure
  – Noticing
    • Vision
    • Hearing
    • Tactile
Cognition

- Thinking: what users must interpret, understand, decide
  - Encoding
  - Comprehending
Action

• Respond: what users must physically do
  – Complying
User

- Influences on perceptual, cognitive, and physical abilities:
  - General health
  - Strength and endurance
  - Motor skills
  - Psychological characteristics
  - Emotional state
  - Personality
  - Anthropometric characteristics
  - Language
  - Culture
  - Age
  - Gender
  - Education/experience/training
    - Ability and willingness to learn
Package

– Structural elements
– Tactile elements
– Text
– Graphics
– Information location
Task

- Storage
- Retrieval
- Handling/portability
- Opening
  - Position
  - Method
- Delivery
  - Dispensing
  - Aseptic transfer
  - Device assembly
- Closing
- Disposal
### Context of Use

<table>
<thead>
<tr>
<th>Healthcare Environments</th>
<th>Physical Conditions</th>
<th>Social Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Military</td>
<td>Space</td>
<td>Colleagues</td>
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<tr>
<td>Home</td>
<td>Location</td>
<td>Time-dependency</td>
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<tr>
<td>Veterinary</td>
<td>Light</td>
<td>Unanticipated events</td>
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<td>Ambulatory</td>
<td>Sounds</td>
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<tr>
<td>Pre-hospital (ambulance)</td>
<td>Temperature</td>
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<td>Acute care facility</td>
<td>Wet vs. dry</td>
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<td>Personal protection equipment</td>
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How is your product’s human/package interface?
How do you capture all of this information?
How the customer explained it
How the Project Leader understood it
How the Analyst designed it
How the Programmer wrote it
How the Business Consultant described it

How the project was documented
What operations installed
How the customer was billed
How it was supported
What the customer really needed
Methods for Evaluation
Identify what is Known

- Databases
  - FDA
  - MAUDE
  - CDRH
  - ECRI Institute
  - Institute of Safe Medical Practices (ISMP)
  - Joint Commission
Analytical Methods

1. Contextual Inquiry
   – Observation of use within normal environment
   – Understand what is being done and why
2. Interviews and Focus Groups
   – Gather opinions, beliefs, attitudes, perceptions
3. Function and Task Analysis
   – Sequential breakdown of how product is used to identify potential use error
4. Heuristic Analysis
   – Evaluate against established rules or guidelines
5. Expert review
Formative Evaluations

• Studies within the product development process (iterative)
  – Cognitive walkthrough
    • Faster
    • Less formal
    • Early prototypes
  – Simulated use testing
    • More formalized research study in realistic environment
Usability Assessments and Interviews

• Who are the users?
• What do they have to do?
  – With the package
  – With the devices
• What environment are they working within?
• How does the package enable or disable the user?
Who

• Product Users
  – Your company
  – Competitors
• Job Function
  – Who uses the product within its lifecycle and what questions do you have for that point in time?
    • Doctors/surgeons
    • Scrub nurses/techs
    • Circulating nurses
    • Inventory
    • Transport (within hospital)
    • Disposal
    • EMT
    • Caregivers
Where

Interviews:
• Private rooms are best
  – Within their work or public environments will be more disruptive and subject to biased responses
    • Hospitals
    • Conference events

User Assessments:
• Simulated use environments
  – Mock
  – External
Advantages of External Simulation Centers

• Services:
  – Planning
  – Recruitment
  – Administrative services (forms, etc.)

• Representative use environment

• Objective controlled research

• Video capture

• Can be cost-effective for all that is included
Know the rules!
Rule #1: Develop a Discussion Guide

- DOE
- Script
- Consistency
- Information capture
- Match to simulation
- 8-12 questions
Rule #2: Be Deliberate with Topics

New Product
- General – currently know little
  - What is important, critical, desired?
  - What is confounding, detrimental, aggravating?

Existing Product
- Specific – typically already know something
  - Verify what you think you know
  - Get specific about what you need to know
Rule #3:
Ask Open-ended Questions

• What and How
• Examples:
  – What packaging characteristics are most important to you for aseptically presenting this device?
  – What are the biggest frustrations that you experienced with the current packaging system?
  – How did the tray affect your workflow?
Avoid

• Binary
• Choices
• Rankings
• Preferences
  • Save for last
  • Clarify with “Why”
## Examples

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<tbody>
<tr>
<td><strong>What did you like about the current package design?</strong></td>
<td><strong>Did you like this?</strong></td>
</tr>
<tr>
<td><strong>How do you dispense the device from the current package?</strong></td>
<td><strong>Do you pick or dump the product?</strong></td>
</tr>
<tr>
<td><strong>How does using the package make you feel?</strong></td>
<td><strong>On a scale of 1-5, how frustrated were you with this package?</strong></td>
</tr>
<tr>
<td><strong>What are your thoughts on this tray concept?</strong></td>
<td><strong>Do you prefer a or b?</strong></td>
</tr>
</tbody>
</table>
Rule #4: Provide Agenda

• Provide general outline of what user will be experiencing
  – “We will start with a series of questions, then ask you to perform a mock procedure, and then close out the session with a final series of questions.”
Rule #5: Encourage Free Speech

• Inform the user that:
  – they were asked participate because of their experience/expertise
  – you are testing the system and not them
  – you are looking for objective honest feedback
  – there will be no judgment or hurt feelings

• May ask them to think out loud as they are using the system
Rule #6: Leave Them Be

• Inform them that you cannot train or help with their tasks (unless training is a variable you are testing)

• Do not speak or assist if they begin to struggle or do things in an unexpected way! Remember, the purpose of the study is to learn what you do not know!

  – If they continue to struggle for a long period of time, you may need to use judgment on when it is appropriate to intervene or conclude

  – If struggle is expected, a time limit may be set prior to the study as the “failure” point
Rule #7: Zip It

- Let them speak
- When complete, ask if they have any other comments
Rule #8:
Video Record
Data Analysis

• Depends on scope
  – Qualitative data is difficult to analyze – try to maintain integrity and authenticity of responses

• Video review can be time consuming
Data Analysis

• Interviews
  – Spreadsheets of responses
    • Categorize and tally responses on specific topics
    • Sometimes one statement can apply to multiple topics
  – Identify and rank trends/themes
  – Identify unexpected responses and workarounds
  – Compare what they say and actually do
  – Do not draw conclusions – this information is formative, not statistically significant
    • Use to direct development of packaging system features which can then be validated in the laboratory or in a controlled user study
Data Analysis

• Usability Assessments
  – What are your metrics?
    • Binary response – could objective be completed?
    • Time to complete task
      – Locate expiry date, opening cue, etc.
    • Number of hand repositions to open, transfer, etc.
    • Path of hand repositions to open, transfer, etc.
    • Workflow order
    • Relationships of handedness and laterality to opening, repositioning, time, etc.
Validation

• Design Verification Testing

• Human Factors Validation Testing
  – Production version device
  – Representative users
  – Actual or simulated use in a representative environment
  – Address all aspects of intended use
“Documenting your HFE/UE testing, risk management and design optimization processes provides evidence that you have adequately addressed the needs of the intended users and optimized the design of your device and therefore demonstrated that a new device is safe and effective for users. Submitting this information as part of premarket approval application (PMA) for a new device will facilitate the premarket review process, reduce the need for requests for additional information and directly support review of all HFE/UE relevant information contained in your submission. In addition, FDA staff may request human factors documentation with other submission types if: (i) submission of human factors information is required (for example, as a special control): (ii) submission of human factors information is recommended in a specific guidance for a device type and you cannot justify forgoing such testing; or (iii) on a for-cause basis if it is the least burdensome method to address FDA’s concerns regarding human factors issues.”
Benefits

• Accelerate innovation
  – Identify latent customer needs and create products/solutions they do not even know they desire, or have difficulty envisioning, because they are locked in an old mindset.

• Optimize user interface: better match devices to their users
  – ensure proper design
  – improve quality
  – enhance product appeal
Beneficiaries

- Patients
- Your customers
- Your company
Patient

- Better outcomes
  - Increased safety
  - Less socioeconomic impact
Customer

• Satisfaction! Products fit their lifestyle and workflow.
  – Safety
    • Reduction of errors and misuse
  – Efficiency
    • Ease of use
    • Faster procedures
  – Reduced costs
    • Less corrective treatments
    • Less malpractice claims
Company

• Competitive advantage!
  – Increased sales/revenue
  – Reduced costs through fewer recalls, complaints, modifications, and updates post-market
  – Speed to market
    • Product development and submission efficiencies
  – Improved product and company image
    • Set the standards
    • Get ahead of the game
    • Exceed standards of most stringent market

References

1. Applying Human Factors and Usability Engineering to Optimize Medical Device Design (FDA draft guidance)
2. AAMI/ANSI HE75:2009 Human Factors Engineering – Design of Medical Devices
3. ISO/IEC 62366:2007 Medical Devices – Application of usability engineering to medical devices
4. ANSI/AAMI/ISO 14971:2007 Medical Devices – Application of risk management to medical devices
5. ISO 11156:2011 Packaging-Accessible design-General requirements
What questions do you have?

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