Product Development for Medical, Life Sciences, and Consumer Health
Fundamentals of Usability Testing for FDA Validation

MassMEDIC
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Topics

What is a usability test?
Why is usability testing required by the FDA?
Designing a usability test
Conducting a usability test
Analyzing and reporting the results
What is a usability test?
What is a usability test?

The primary focus is on **usability & safety**

Actual or potential users participate

Users **attempt tasks** with the product, unaided

Moderator leads the session, observes, records data

The team diagnoses usability problems and **use errors**

The team recommends design improvements and/or risk mitigation
Focus is on usability & safety

Real users attempt real tasks on their own

A usability test is not a research study

A usability test is not a marketing study

A usability test is not a preference test
Why is usability testing required?
Why is usability testing required?

Portions of the Quality System Regulation that apply to human factors:
Subpart C - Design Controls
The need for human factors techniques or data in the design process is implicit in paragraphs c, f, and g of Section 820.30.

(g) Design validation: "Design validation shall ensure that devices conform to defined user needs and intended uses, and shall include testing of production units under actual or simulated use conditions."

Human factors relevance: Design validation should be used to demonstrate that the potential for use error that can lead to patient injury has been minimized. The regulation requires testing the device under actual or simulated use conditions. Realistic use conditions, therefore, should be carried out by test participants who represent a range of typical intended users in terms of their ability to acquire information from, manipulate, and maintain the device and understand the accompanying labeling.

From the FDA -- “Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation”
Why is usability testing required?

Testing for ease and accuracy of use is the only way to ensure that users can safely and effectively operate, install, and maintain devices.

This process culminates in full testing of a model embodying all the user-interface characteristics for both hardware and software of a fully functioning device.

-- from the FDA (1996), *Do It By Design*
Designing a usability test
Designing a usability test

Select & recruit **participants**

Select **tasks or features** to be tested

Select measures

Prepare the test materials

Handle **logistics** & preparation

Run a practice test
Selecting the **right participants** is key to a valid test

Create an effective screener

Relevant **demographics** should have been defined earlier

Select user profiles based on the **purpose of the test**

Who should **recruit** the participants?
Example

What are some user profiles for a test of an infusion pump?

How many participants?

What about training?
## Example

<table>
<thead>
<tr>
<th>Job Description</th>
<th>Gender</th>
<th>Age Groups</th>
<th>Pumps Used</th>
<th>Specialty</th>
<th>Frequency of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (N=12)</td>
<td>RN or NP</td>
<td>80% female, 20% male</td>
<td>25-40 (N=4) 40+ (N=8)</td>
<td>A, B, C</td>
<td>Pediatrics Adult non-acute Adult acute</td>
</tr>
<tr>
<td>Group 2 (N=12)</td>
<td>RN or NP</td>
<td>90% female, 10% male</td>
<td>25-40 (N=4) 40+ (N=8)</td>
<td>A, B, C</td>
<td>Pediatrics Adult non-acute Adult acute</td>
</tr>
<tr>
<td>Group 3 (N=12)</td>
<td>Physician</td>
<td>50% female, 50% male</td>
<td>25-40 (N=4) 40+ (N=8)</td>
<td>A, B, C</td>
<td>Pediatrics Adult non-acute Adult acute</td>
</tr>
</tbody>
</table>
Select tasks or features

Typical or frequently performed

Critical to operation

Address a safety concern

Performed under stress

Redesigned after previous validation testing

Illustrates error recovery
Example

What are some **tasks** you might test on an infusion pump?
Example

What are some tasks you might test on an infusion pump?

• Turn on the pump
• Set it up for drug administration by keying in the flow rate and volume-to-be-infused parameters
• Install the administration set
• Perform primary and secondary infusion
• Change parameters
• React to an emergency
• Set alarms
• Silence alarms
Select measures

**Objective** measures
- Measures of performance
- Observable

**Subjective** measures
- Preferences, opinions, impressions

Base these on your *usability goals*

Which ones can be quantified?
Example

What are some **measures** you might use when testing an infusion pump?
Example

What are some **measures** you might use when testing an infusion pump?

- Task times
- Number of errors
- Types of errors
- Completed tasks (%)
- Usability ratings
- Design suggestions
- Failure to react to alarms
- Preferences for control layout
Handle logistics & preparation

Use a checklist
Identify setup requirements
Prepare the **materials**
   - Informed consent & NDA
   - Moderator’s script
   - Task cards
   - Data collection tool
   - Pre- or post-test questionnaires
Run a **pilot test**
Conducting a usability test
Conducting a usability test

Where to conduct the test?
How long should sessions take?
Who should moderate?
Who should collect the data?
Should participants think aloud?
Conducting a usability test

**Where** to conduct the test?

How long should sessions take?

Who should **moderate**?

Who should collect the data?

Should participants **think aloud**?

**Typical outline:**

- Introduction & informed consent
- Pre-test questionnaire
- User performs tasks
  
  Objective & subjective data collected
- Post-test interview and ratings
Moderating the session

This is the art of usability testing

Roles: host, leader & neutral observer

Avoid bias
  The less you say the better!
  Turn the question around

Give as little assistance as possible

Keep control of the session
Analyzing and reporting the results
Analyzing the data

Transcribe notes

Review photos and video

Analyze **quantitative** data
  
  Calculate descriptive stats

Analyze **qualitative** data
  
  Moderator’s & observers’ notes
  
  Questionnaires & rating sheets
  
  Lists of issues from observers
  
  Pre- and post-test interview results
Examples of usability issues

Nurses can’t figure out how to insert tubing in an infusion pump

Lab technicians load disposables into the wrong drawer

Nurses incorrectly program parameters in a patient monitor

Patients misinterpret the LEDs on a ventricular assist device

Surgeons experience pinch points with a hand-held instrument
Severity of usability issues

Based on your hazard analysis, usability goals, and/or usability validation plan

Example:
Level 1: Prevents completion of task or could be hazardous
   Users cannot enter correct dosage
Level 2: Creates delay and/or frustration
   Users repeat tasks because of lack of feedback
Level 3: Causes minor problem
   Poor label choice
Level 4: Would enhance usability
   Quick reference card needed
What constitutes a successful task outcome?

Example:
For this study, at least 26 of the 30 subjects must have registered a “success” for a particular scenario for the design to pass usability validation. The design must also score an average of 4.0 or higher on a 5-point scale in order to pass usability validation. Any design that fails to be successfully completed by the appropriate number of subjects or averages below a 4.0 rating will not be accepted.
## Example

<table>
<thead>
<tr>
<th>Participant</th>
<th>Task 1 – Turn on device and check battery</th>
<th>Task 2 – Switch to backup</th>
<th>Task 3 – Switch to manual mode</th>
<th>Task 4 – Interpret alarms</th>
<th>Task 5 – End therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>correct</td>
<td>correct</td>
<td>correct</td>
<td>one error</td>
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<td>all correct</td>
<td>correct</td>
</tr>
<tr>
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<td>correct</td>
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<td>correct</td>
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<td>correct</td>
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<td>correct</td>
<td>correct</td>
<td>all correct</td>
<td>incorrect</td>
</tr>
<tr>
<td>9</td>
<td>correct</td>
<td>correct</td>
<td>correct</td>
<td>all correct</td>
<td>incorrect</td>
</tr>
</tbody>
</table>
Communicating results to the team

- Informal debriefing
- Short memo with findings
- Full test report
- Formal presentation
- Highlights video
Preparing the FDA report

There is no prescribed format

**Tie it back** to the FMEA

Was usability **validated** or not?

Additional design changes needed?
Preparing the FDA report

There is no prescribed format
Tie it back to the **FMEA**
Was usability **validated** or not?
Additional design changes needed?

**Typical outline:**
- Purpose
- Methodology
- Data analysis
- Task success rates
- Errors and usability issues
- Conclusions (pass/fail)
Case study: Drug delivery device

Client submitted for 510(k) clearance, FDA required validation testing

User profiles: Patients and health care professionals

Selected tasks: All primary operating functions

Measures: Objective and subjective, based on hazards analysis

Materials: Two detailed moderator’s scripts, training, IFUs

Test environment: Market research facility

Data collection: Read-time using carefully designed spreadsheets

Analysis: Completed by client, reviewed by Farm

Results: Showed hazards had been addressed, no new issues
Final thoughts

Usability testing should be **iterative** during the design process.

It is **required** as part of design validation for the FDA.

Final testing must include **safety-critical** tasks.

Final testing must be done with **actual users** in actual or simulated environments.
References

FDA Quality System Regulations
21 CFR 820.30, Subpart C
Design Controls, paragraphs c, f, and g

ANSI/AAMI HE74:2001
Human Factors Design Process for Medical Devices

ANSI/AAMI HE75:2009
Human Factors Engineering – Design of Medical Devices (in publication)

ISO/IEC 62366:2008
Application of Usability Engineering to Medical Devices

Do It By Design (FDA, 1996)
An Introduction to Human Factors in Medical Devices

A Practical Guide to Usability Testing (Dumas & Redish)
Moderating Usability Tests (Dumas & Loring)
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