

**Usability Testing on Medical Device Labeling:  
Managing Use Error Risk through  
Human Factors Methodology**

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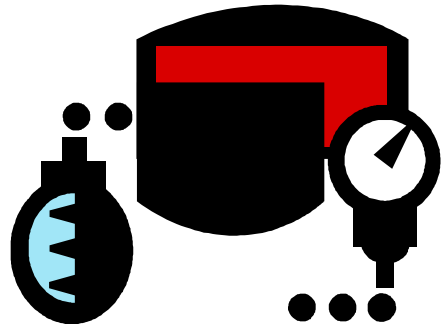
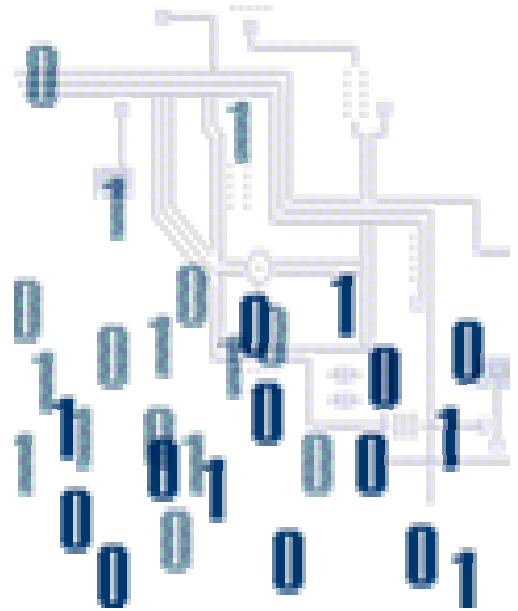
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# What do you get when you cross a computer with a...



# ***Usability Testing on Medical Device Labeling***

- What's the problem we're trying to solve?
- What's the relationship between risk management and human factors?
- What does a usability test look like?
- What's the critical component for successful medical device labeling?



# ***The Problem***

*Research on medical errors suggests that the frequency and consequences of medical device **use** errors far exceed those arising from device failures  
(Cooper, Leape and others)*



# *What the FDA Says*

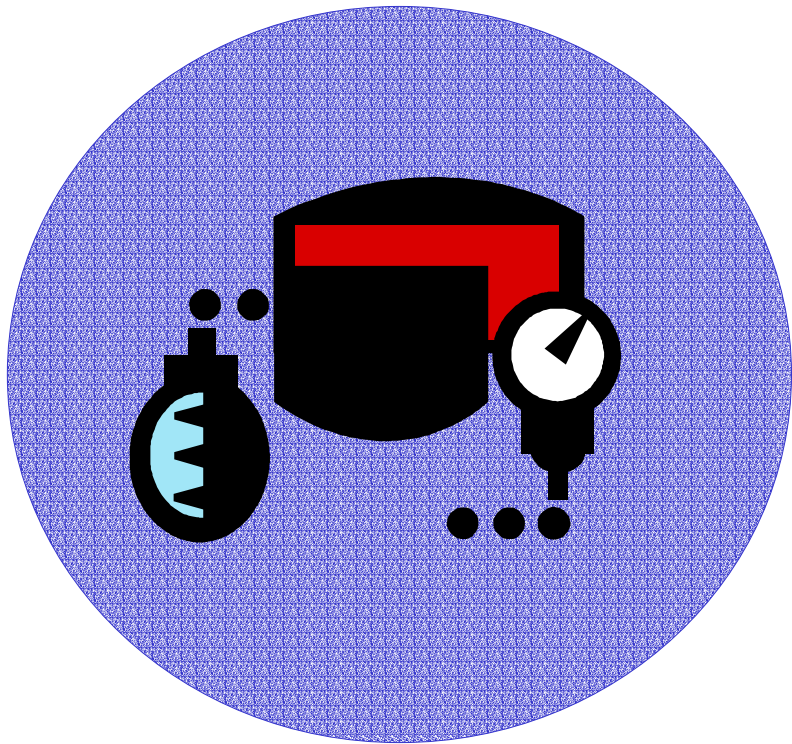
- More than **1/3** of medical device incident reports involve use error and more than **1/2** the recalls due to design problems can be traced to design of the **user interface**.
- Medical manufacturers are required to “conduct appropriate human factors studies, analyses, and tests...” and that “...human interface includes both the hardware and software characteristics...”
- The FDA also cautions that firms should not rely on clinical trials to validate usability of devices, or solely on standard engineering analyses such as FMEAs.
  - Comments from FDA Spokesperson at AAMI Conference, June 28-30, 2005 in Washington, DC

# ***Examples of Use Related Errors***

- Woman holds her blood glucose meter upside down and doses herself based on a BG reading of 522 instead of 225
- Hospital nurse incorrectly programs the infusion pump and under doses patient
- More than 50% of people using in-home drug delivery devices admit that they cannot remember or understand the instructions
- Man incorrectly links his wireless devices and gets the reading for the person standing next to them



# ***Risk Management***

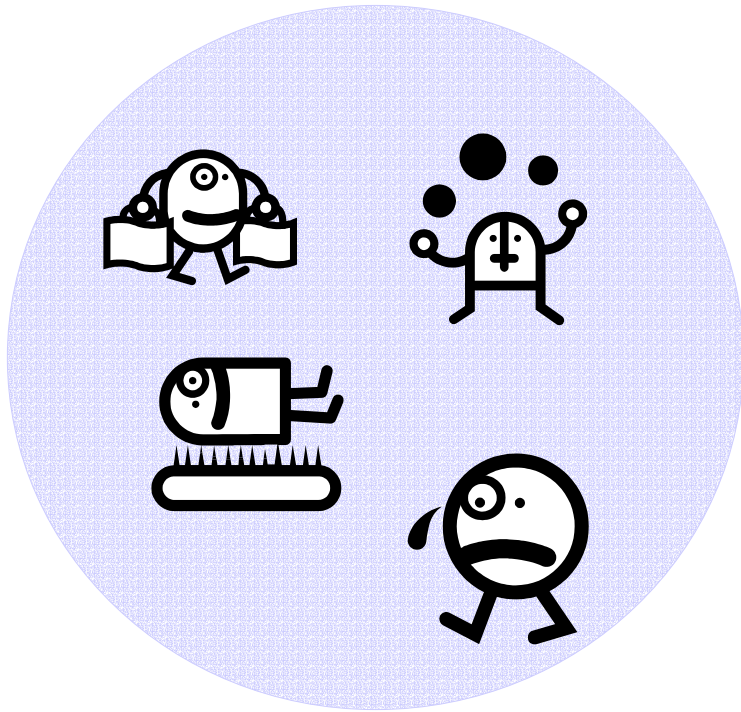


The systematic application of management policies, procedures, and practices to the task of identifying, analyzing, controlling, and monitoring risk.

When conducting a risk analysis, manufacturers are expected to identify:

- Possible hazards
- Risks associated with the hazards
  - 21 CFR 820.30 Preamble Comment #83

# Human Factors

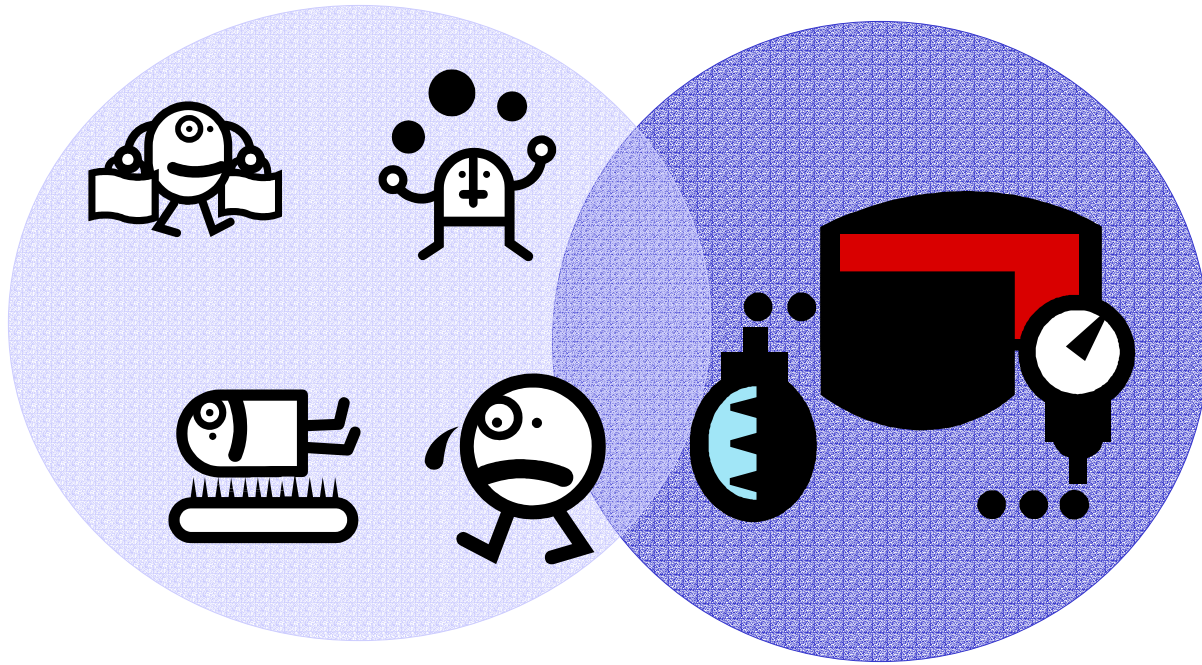


The interaction of human abilities, expectations, limitations and environment

- Includes user interface and all components including “labels, and instructions”

- FDA standard HE74:  
Human Factors  
Design Process for  
Medical Device  
Manufacturers

***There is Overlap!***



# ***What is Use-related Labeling?***

A tool that **stores information** on how to safely and effectively use a medical device, which is accessed in **real-time**, written at a level of detail to **minimize trial and error**, **reduces** reliance on **recall**, gives directions on when and how to perform relevant on and off device tasks.



# *What is Usability Testing?*



The formal method of systematically **observing** and recording representative members of the **target audience** performing **real tasks** with a real or simulated product and assessed against **measurable criteria**



# ***Examples of Usability Goals***

- Using the device and user manual, at least 14 out of the 15 subjects tested will be able to determine the type of alarm and determine appropriate action, if required.
- Using the device and user manual, at least 18 out of the 20 subjects tested will be able to access event history menu and view an event in less than or equal to two attempts



# ***What we're looking for***

- Information that is open to interpretation
- Sources of confusion/gaps in logic
- Information that is missing or out of sequence
- Information that prompts unexpected; but predictable behaviors



# ***Outputs from a Labeling Usability Test***

- “People were confused that steps 1 through 3 in Section 3 don’t flow from the last step in Section 2”
- “When this error occurred, several people did not know what to do”
- “Confusion over which hole to insert the test strip; thought it was the communication port hole”
- “The picture in the middle of page 12 confused people; they didn’t know how it fit into the sequence”
- “There was confusion with the meaning of these terms: ‘monitor’, ‘icon’ and ‘review reports’”



# ***What Usability is NOT!***

- A substitute for product validation
- A focus group
- Soft data
- A conference room discussion with project/company staff
- A 'finger in the dike' for a poorly designed device/user interface



# ***What Does a Usability Test Look Like?***



# *Preparing to Test*

1. Determine type of usability test:
  - Formative – early and often/informal: looking for design flaws
  - Summative – final stage/formal: testing ability to perform tasks
2. Draft protocol
3. Draft usability goals
4. Select tasks for testing
5. Draft scenarios of use
6. Arrange logistics including location, number of participants, session length, video recording, screen capture, eye scan capture, etc.
7. Determine data collection, type of analysis and report
8. Train test administrators to ensure against bias
9. Recruit subjects based on user profiles
10. Dry-Run test



# ***Conducting the Test***

1. Welcome and orient test participants
2. Administer paperwork:
  - Consent forms
  - Non-disclosure
  - Pre-questionnaire
3. Train participants, if necessary
4. Conduct test
5. Administer post-questionnaire
6. Debrief participants



# ***Reporting Test Results***

1. Review videos and notes taken during test
2. Identify participants and test times
3. Indicate task completion including
  - Missed steps
  - Significant errors
  - Verbal comments
4. Summarize findings and mitigation strategies in report



# Formative Usability Test




## Small, entrepreneurial start up

- Test conducted in-house
- 6 participants
- Draft labeling
- Mock up of device
- Useful Findings
  - UI timing issues
  - Language/jargon
  - Physical limitations

# Summative Usability Test

Figure 7: Harmony's Owner's Booklet

When you see this:	Do this:						
 <p>Example</p> <p>This could be any number from 0.8 to 8.0, LD, HI, or an error (ER) message.</p>	<p>12. In your logbook, write the test result displayed on your monitor. Also record the time and date on the display.</p> <p>13. Compare the INR test result with your therapeutic INR range. This range is given to you by your doctor or healthcare professional.</p> <table border="1"><thead><tr><th>IF the test result is</th><th>THEN</th></tr></thead><tbody><tr><td>Outside your therapeutic range (Above or Below)</td><td>Call your doctor or healthcare professional to report a result outside of your therapeutic range.</td></tr><tr><td>Within your therapeutic range</td><td>1. Do as directed by your doctor or healthcare professional. 2. Continue with Step 14.</td></tr></tbody></table>	IF the test result is	THEN	Outside your therapeutic range (Above or Below)	Call your doctor or healthcare professional to report a result outside of your therapeutic range.	Within your therapeutic range	1. Do as directed by your doctor or healthcare professional. 2. Continue with Step 14.
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Source: LifeScan, a Johnson & Johnson company.

## Large, multi-national company

- Professional testing site
- Video recording
- 22 participants
- Final labeling materials
- Actual device
- Useful Findings
  - UI timing issues
  - Physical limitations
  - Validated usability goals

OBTAINEERING SAMPLE

# ***The Critical Component to Successful Usability***

A **performance-based analysis** driven by what the **user will accomplish** using the device followed by a task analysis that describes in specific **behavioral terms** how to produce that accomplishment including what they will **perceive** (see, hear, feel, etc.), **understand** and **physically manipulate** (press, move, etc.)



# ***Example of an Accomplishment***

Using the Princeton immunochemistry system, medical technicians will be able to produce a **test result with no errors or omissions** that is **usable by the prescribing physician.**



# ***Sample Tasks***

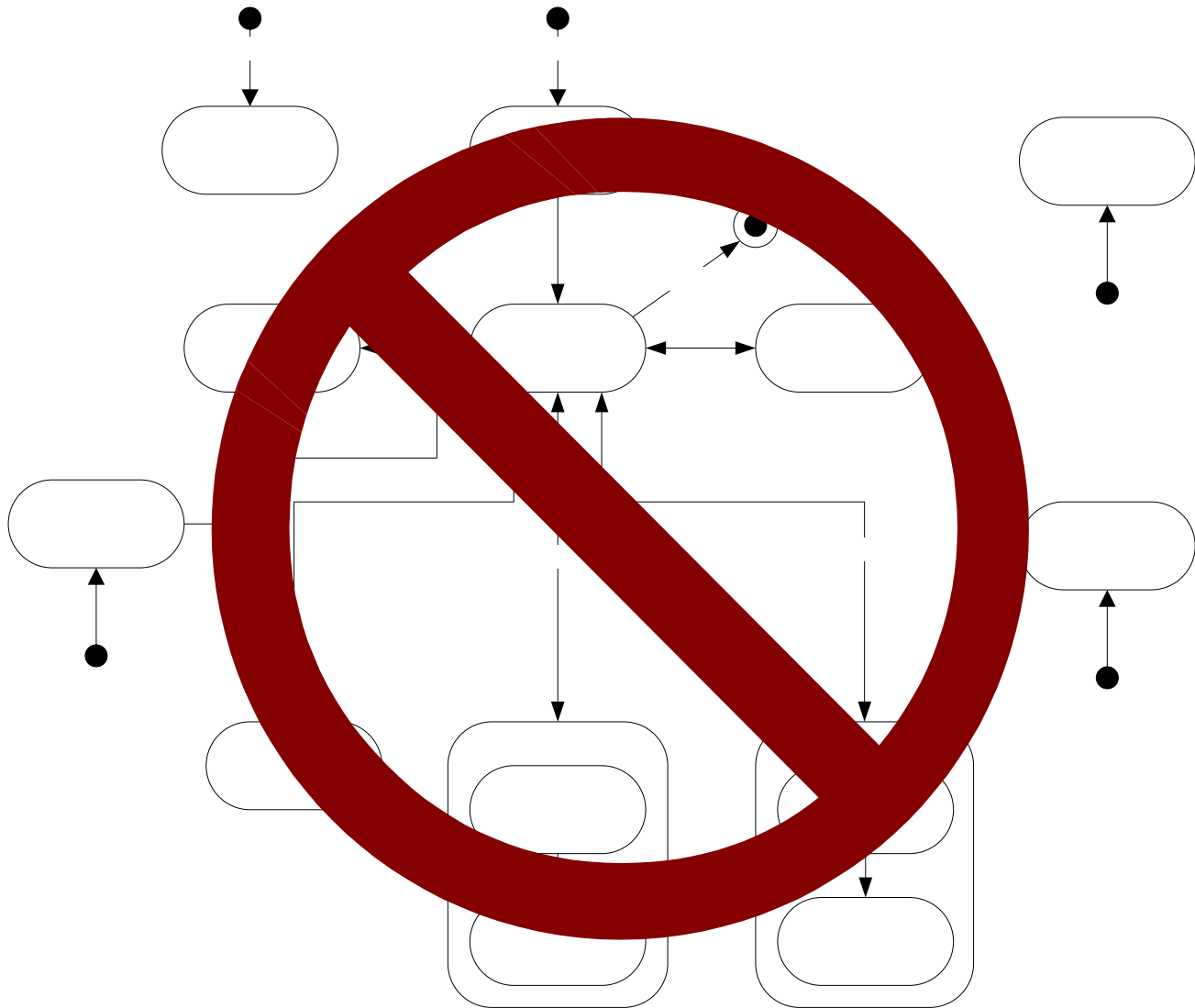
1. Prepare patient sample tubes
2. Program patient samples
3. Load prepared sample tubes into racks
4. Start run



# Task Analysis

Task Analysis				Usability Spec.	Use Error Risk Analysis	
Task	Step	P/C/B Req.	Speed an Issue?	Success Criteria	Error?	Consequences





AC P

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# ***What Good Labeling can Accomplish***

- Clinical tests conducted with patients having:
  - No experience using a self-testing medical device
  - No prerequisite skills or knowledge
  - No consistent reading or language skills
- Produced accurate blood test results with a deviation of less than +0.5 INR units from that produced by HCPs and sustain this level of performance three years after training



# ***Benefits for Usability Testing Labeling***

- Demonstrates compliance with FDA HE74: Human Factors Design Process for Medical Device Manufacturers
- Increases likelihood of successful 'first time' use
- Fewer errors means fewer opportunities to frustrate and disappoint your customers
- Good labeling promotes brand image and product satisfaction
- Reduces after-sales support costs
- Industry experts estimate a 10:1 ROI

