Medical devices
Usability and design

Ing. Alice Ravizza
Hard truth...
Between 2005 and 2009, FDA reported:
- 56,000 infusion pump incidents
- 710 deaths
- 87 recalls

Infusion devices account for up to 35% of all medication errors that result in significant harm.

A large percentage of these adverse events are due to programming errors that can be attributed to poor usability.

- Entering weight in pounds instead of kg – results in 2.2x overdose
- Incorrectly placed decimal point – results in 10x under or over infusion
- Select incorrect dose mode – mg/kg/min instead of mcg/kg/min – results in 1000x overdose
Overdosing from dermal patch

Transdermal Patch Products
• Original user instructions: where to apply patch
Examples from the web

WARNING: Photographs depict oxygen tubing erroneously connected to a needleless IV port. DO NOT DO THIS!
Pleasurable device

Which tube does your patient deserve?

Standard Feeding Tube

MIC-KEY® G Feeding Tube

DISCOVER THE “NO-SHOW DIFFERENCE.”
Usability: what is it
63366-1 3.16

• characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT

• All aspects of USABILITY, including EFFECTIVENESS, EFFICIENCY and USER satisfaction, can either increase or decrease SAFETY.
Safe, effective, easy, pleasurable

Source: Hancock, Pepe & Murphy (2005), *Ergonomics in Design*, 13 (1), 8-14
Medical device use

- Normal use
  - Correct use
  - Use error
- Abnormal use
NORMAL & INTENDED USE

• NORMAL: operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

• INTENDED purpose: the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials
A “wrong” use

- 3.21 USE ERROR: USER action or lack of USER action that leads to a different result than that intended or expected

**USE ERROR caused by cognition error**

- **Memory Failures:**
  - Inability to recall knowledge which was gained before
  - Omitting (e.g. forgetting) a planned step
- **Rule-based Failures:**
  - Misapplication of appropriate generally accepted rule
  - Inability to recall knowledge which was gained before
- **Knowledge-based Failures:**
  - Improvisation under unusual circumstances
  - Misinterpretation of information due to incorrect mental model
A “bad” use

• 3.1 ABNORMAL USE: conscious, intentional act or intentional omission that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER
  • Reckless use or sabotage or intentional disregard of information for SAFETY
  • “reasonably foreseeable misuse” from 4.2 of ISO 14971
• Usually not controllable by Usability Engineering processes
Examples of ABNORMAL USE
IEC 62366-1 Annex A

• exceptional violation (e.g. using the MEDICAL DEVICE as a hammer);
• conscious disregard of contraindications
• reckless use (i.e. USERS making their own RISK benefit decision)
  • EXAMPLE 1 Using a MEDICAL DEVICE after removing its protective guards.
  • EXAMPLE 2 Ignoring the output limit
• sabotage.
A “right” use

• 3.3 CORRECT USE: NORMAL USE without USE ERROR
  • Deviation from instructions for use is only considered USE ERROR if it leads to device response that is different than intended/expected
  • Off label may not be Use error
HF engineering: actors

• The people
  • Intended user
  • User groups

• The machine
  • Human-machine interface
involved people

- 3.10 PATIENT: living being (person) undergoing a medical, surgical or dental PROCEDURE
- 3.24 USER: person interacting with (i.e. operating or handling) the MEDICAL DEVICE
  - clinicians, PATIENTS, cleaners, maintenance and service personnel
And more...

• 3.25 USER GROUP: subset of intended USERS who are differentiated from other intended USERS by factors that are likely to influence USABILITY, such as age, culture, expertise or type of interaction with a MEDICAL DEVICE
  • Different user profiles in a SW interface
  • Special needs patients
  • Caregivers
Device users

- The intended users of the device
  - physician, nurse, professional caregiver, patient, family member
  - installer, maintenance, reprocessor, disposer

- User characteristics
  - functional capabilities (physical, sensory and cognitive),
  - experience and knowledge levels and behaviors

- The level of training users are expected to have and/or receive.
User profiles: general

- Physical size, strength, and stamina, dexterity, flexibility, and coordination,
- Sensory abilities (i.e., vision, hearing, tactile sensitivity),
- Cognitive abilities: memory, Literacy and language skills, emotional state
- Willingness and motivation
User profiles: health state

• Medical condition, comorbidities (i.e., multiple conditions or diseases)
• Health literacy
  • General knowledge of similar types of devices,
  • Knowledge of and experience with the particular device,
• Ability to learn and adapt to a new device
Different users
Different use profiles
Device Use Environments

- Light, noise, clutter or busy room, External use, rain, darkness
- Moving vehicle
- Multiple models of the same device in the same room
- Multiple other alarms or sounds
Use environment description
IEC 62366-2 annex H

- provide designers with information
Human-machine interface

- Information Perception
- Information Processing
- Control Actions

INTERFACE

Human

INTERFACE

Machine

Output
- Processing
- Input
User interface
FDA guideline 3.12

• All points of interaction between user and device
  • including all elements of the device with which the user interacts (see, hear, touch).

• All sources of information transmitted by the device
  • including packaging, labeling

• All physical controls and display elements
  • including alarms
Interface description

- **Tasks**
  - Device set-up: installation, assembly, calibration, etc.
  - Device use: various aspects
  - Device cleaning, maintenance, disposal, etc.

- **Interactions**
  - Input: Connections, knobs/dials, switches, buttons, touch screens, etc.

- **Output**
  - Visual: component status, displays, lights, etc.
  - Auditory: motors/fans, clicks, alerts/alarms, beeps, voice, etc.
  - Tactile: resistance, vibration, temperature, etc.
User interface: general considerations

• the “look and feel” logical and intuitive
  • More effective than labeling or training

• information display and control actions consistent with expectations

• Kind of interaction:
  • knob, handle,
  • keyboard, mouse, stylus, touchscreen;
  • future devices might be controlled through other means, such as by gesture, eye gaze
User interface: HW examples

• The size and shape of the device
  • hand-held and wearable devices

• Components that the operator connects, positions, configures or manipulates,

• Components or accessories that are applied or connected to the patient

• Packaging

• Labeling, including operating instructions, training materials, and other materials.
User interface: SW examples

- Elements that provide information to the user
  - indicator lights, displays, alarms,
- Graphic user interfaces of device software systems,
- The logic of overall user-system interaction, including how, when, and in what form information (i.e., feedback) is provided to the user
PRIMARY OPERATING FUNCTION
IEC 62366-1 3.11

- function that is directly related to the SAFETY of the MEDICAL DEVICE
  - setting alarm–related USER controls;
  - setting of parameters
  - components that have to be assembled;
  - Connections
  - MEDICAL DEVICE controls that the USER has to understand
  - series of display screens that the USER has to navigate through;
  - MEDICAL DEVICE operating PROCEDURES that the USER has to learn
Examples of hazardous situations
FDA guideline

- Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user;
- Device use is inconsistent with the user’s expectations or intuition about device operation;
- The use environment affects operation of the device and this effect is not recognized or understood by the user;
- The particular use environment impairs the user’s physical, perceptual, or cognitive capabilities when using the device;
Inducing factors
IEC 62366-2 clause 6.5.1

• External
  • environmental distractions; inattention; excessive workload; fatigue;
  • working at a fast pace;
  • TASK interruptions

• Personal
  • insufficient experience, insufficient training;
  • Overconfidence
  • lack of familiarity with terminology; lack of fluency in the language
  • misapplication of experience using other existing MEDICAL DEVICES (i.e. negative transfer of learning)

• USER impairments
  • vision, hearing, body movement, cognition
Design for Usability

The "Spiral Model"
USER INTERFACE EVALUATION conducted with the intent to explore USER INTERFACE design strengths, weaknesses, and unanticipated USE ERRORS.

- generally performed iteratively throughout the design and development
- prior to SUMMATIVE EVALUATION, to guide USER INTERFACE design as necessary
Function analysis
IEC 62366-2 clause 9.3

• identify those functions a MEDICAL DEVICE should perform automatically or semi-automatically
• identify functions to be performed by the USER
• including PRIMARY OPERATING FUNCTIONS listed in applicable product standards
  • Manual
  • Automatic
How to

• Identify functions
• Assign the functions to the MEDICAL DEVICE or the USER based on the known competencies of each

Is the machine better than the human?
<table>
<thead>
<tr>
<th>Humans do not excel in</th>
<th>Machines excel in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force: Limited strength.</td>
<td>Great forces possible.</td>
</tr>
<tr>
<td>Speed: Significant time needed for decision-making and movement.</td>
<td>High speed.</td>
</tr>
<tr>
<td>Accuracy: Unreliable, makes constant and variable errors.</td>
<td>Great accuracy attainable.</td>
</tr>
<tr>
<td>Decision-making: Best strategy not always adapted; emotions interfere.</td>
<td>For narrow applications, superior long-term memory.</td>
</tr>
<tr>
<td>Information processing: Basically a single-channel processor that is easily overloaded; performance greatly dependent on motivation.</td>
<td>Complex problems can be handled deductively.</td>
</tr>
<tr>
<td>Limited short-term working memory; long-term memory, although large, has unreliable and slow access.</td>
<td>Excellent for repetitive work; unaffected by emotions and motivational needs.</td>
</tr>
<tr>
<td></td>
<td>Can perform simultaneous operations easily.</td>
</tr>
</tbody>
</table>
...and no

<table>
<thead>
<tr>
<th>Humans excel in</th>
<th>Machines do not excel in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual acuity and range very good.</td>
<td>Need to be monitored.</td>
</tr>
<tr>
<td>Visual information processing system extremely logical and flexible.</td>
<td></td>
</tr>
<tr>
<td>Range of detection extremely wide with good sensitivity for audition and vision.</td>
<td></td>
</tr>
<tr>
<td>Perception: Ability to make order out of complex situations; detection possible</td>
<td>Decision-making limited.</td>
</tr>
<tr>
<td>under high noise.</td>
<td></td>
</tr>
<tr>
<td>Can reason inductively; can follow up intuition.</td>
<td>Inductive reasoning not possible.</td>
</tr>
<tr>
<td>Very flexible; can easily change rules of operation with changes in situation.</td>
<td>All activities need to be planned and pre-programmed thoroughly.</td>
</tr>
<tr>
<td>Attention is easily shifted; only essential information can be selected for</td>
<td>Needs to get careful maintenance.</td>
</tr>
<tr>
<td>processing.</td>
<td>Might not operate at all, if some parts are broken.</td>
</tr>
</tbody>
</table>
Planning FE

• Simple mock-up devices, preliminary prototypes or more advanced prototypes as the design evolves.

• May be tailored to focus on specific accessories or elements of the user interface or on certain aspects of the use environment or specific sub-groups of users

• Iterative evaluation of Design modifications
WIREFRAMES:

Taking the team’s research into consideration, I sketched wireframes for a card-like design that incorporated all desired features into a cheerful and user-friendly interface. For added security, we decided to implement a fingerprint recognition mechanism to be sure that a user's personal medical information stays private.
concept sketches

- beneficial to generate multiple hardware design sketches or 3-D prototypes
- obtain USER feedback on them
From the web: dialysis machine
Figure 3 – Progression of concepts from multiple concepts to a few concepts to a preferred concept
Usability tests

- **real** users, doing **real** tasks
- observed, not guided
Usability tests

- observing USERS while they perform TASKS with the MEDICAL DEVICE
  - recruiting USERS of a specific USER GROUP
  - asking those USERS to complete a set of TASKS
  - test moderator follows a test script

- simulated-use conditions
  - Group of USERS performing specific TASKS of interest
Different user groups
IEC 62366-2 annex L

• a sample of representative USERS
• include all intended USER groups
• Differentiate
  • the intended USERS’ occupational backgrounds, expected knowledge and skill levels
  • MEDICAL DEVICE use patterns
Examples

• 1 USER GROUP: trained physicians;
• 2 USER GROUPS: trained nurses, untrained nurses;
• 3 USER GROUPS: asymptomatic adults, symptomatic adults, lay caregivers;
• 4 USER GROUPS: physicians, nurses working in high acuity settings (e.g. intensive care units), nurses working in low-acuity settings (e.g. medical/surgical units), PATIENTS;
• 5 USER GROUPS: child, adolescent, adult, elderly, healthcare professional (PATIENT educator)
• 6 USER GROUPS: adults with no impairments, adults with visual impairments, adults with hearing impairments, adults with dexterity impairments, adults with mild cognitive impairments, lay caregivers
Example setting
Other sources of data: Observational

Objective, no interaction
Other sources of data: knowledge task

- Objective, interaction
Other sources of data: interview

Subjective, interaction
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