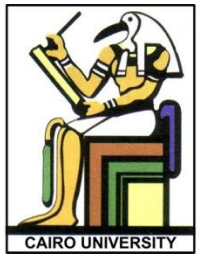

HUMAN FACTORS ENGINEERING: DESIGN OF MEDICAL DEVICES

Chapter 5

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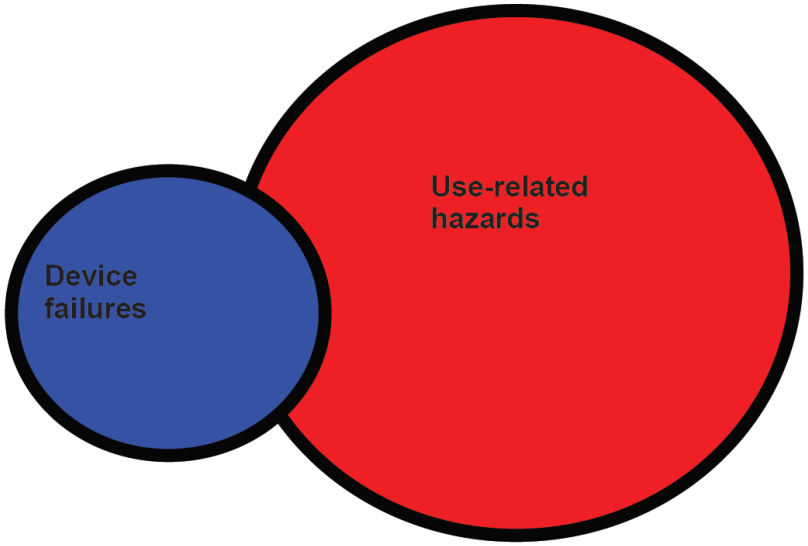
Managing the risk of use error

- Reports compiled by the Food and Drug Administration (FDA) indicate that as many as one-third of "device failures" that involve use of medical devices and that result in suboptimal medical treatment, injuries, and even deaths appear to be failures of device use rather than failure of the device itself.
- Multiple cases of device recalls resulting from clear-cut problems have been successfully addressed by modification of the device–user interface, the source of the problem.
- It is desirable to prevent unfortunate use-related "failures" before they become part of the health care system.

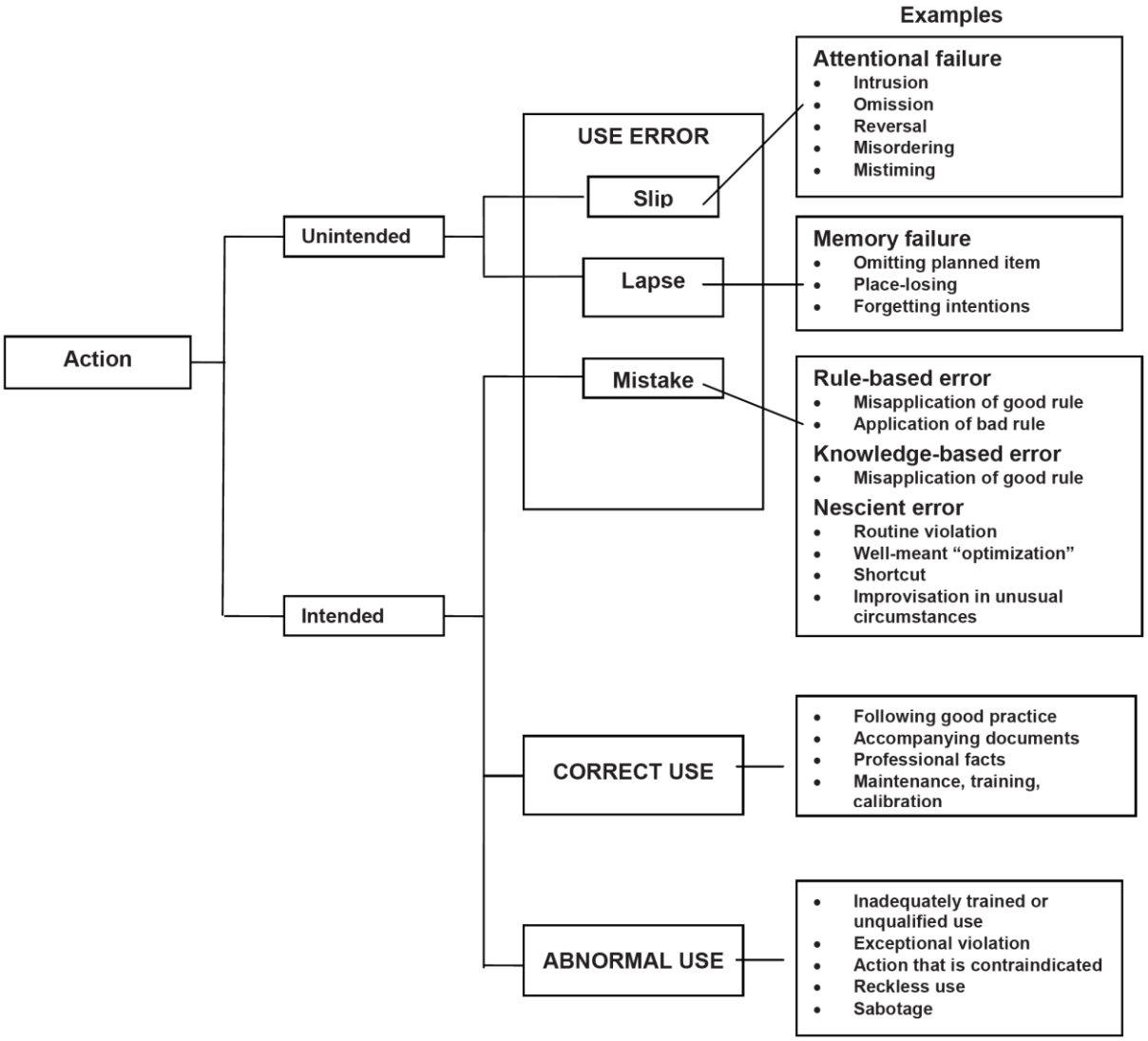
Managing the risk of use error

- Use-related hazards vs. traditional device-failure hazards



- Behavioral variability in human users
- Definition of use error

Types of use errors



Example design problems that lead to unintentional use errors

- Mismatch between device capability and user input
- Insufficient feedback for user actions or device status
- Insufficient physical resilience to user actions
- Cumbersome interactions that slow down user's ability to use a device
- Unnecessary confusion
- Lack of alarms or critical indicators
- Lack of replacement parts for critical devices

Managing the risk of use errors

Interaction stage	Examples	Use-error types	Risk control design steps
When user is perceiving information	• Hearing auditory alarm signals • Reading text on a display • Seeing a color code on a connector • Seeing warning lights • Feeling a click when a connector engages	Slips: • Failing to detect an alarm condition because of noise • Not seeing a displayed warning because the user's attention is directed elsewhere • Not feeling a connector click while wearing gloves	• Identify user visual, auditory, and tactile limitations in the environment of use. • Apply best practice for displays, alarm signals, and tactile feedback. • Evaluate with appropriate usability tests.
When user is processing information	• Recalling procedures • Associating an icon or a color with meaning • Understanding text instructions • Deciding next action based on data • Categorizing a test result • Performing calculations	Slips: • Performing steps in the wrong order when loading parts into a device Lapses: • Forgetting to clear air in an IV line • Confusing the meaning of a warning or error signal Mistakes: • *Rule*: Assuming a device is working properly when it has actually failed • *Knowledge*: Applying the wrong therapy on the basis of information given by the device • *Nescience*: Inverting a glucose meter to steady the finger, but then reading the display result upside down	• Identify anticipated training, knowledge, and mental capabilities of users. • Apply best practice for information presentation, user interface, and human–computer interaction design. • Evaluate by both contextual inquiry and observational studies.
When user is executing actions	• Selecting keys or buttons • Maneuvering a surgical tool • Inserting a connector • Removing caps or device covers • Holding an object or finger steady	Slips: • Selecting the wrong key • Moving a lever or dial in the wrong direction • Not applying enough force to fully insert a part or connector • Damaging a part by using heavy force	• Identify user limitations in dexterity, force, reach, and maneuverability in the environment of use. • Apply best ergonomic practices for control, tool, and instrument design. • Evaluate with appropriate usability tests.

General considerations for managing use-related hazards

- Failures of the device for reasons other than use should generally be treated separately.
- Mitigations for identified use errors related to important tasks should be validated by actual users
- Specifically consider use-error scenarios that could lead to catastrophic consequences
- Include scenarios that cover aspects of use associated with risk emphasized by priority
- In general, at least 15 or more users should be involved in usability study and they should be broadly representative of the population of intended users in terms of their abilities.
- Members of the design team should not participate in evaluations of use
- Assessment tools that include ratings of “ease of use,” “intuitiveness,” and other global concepts should only be used early in the evaluation process

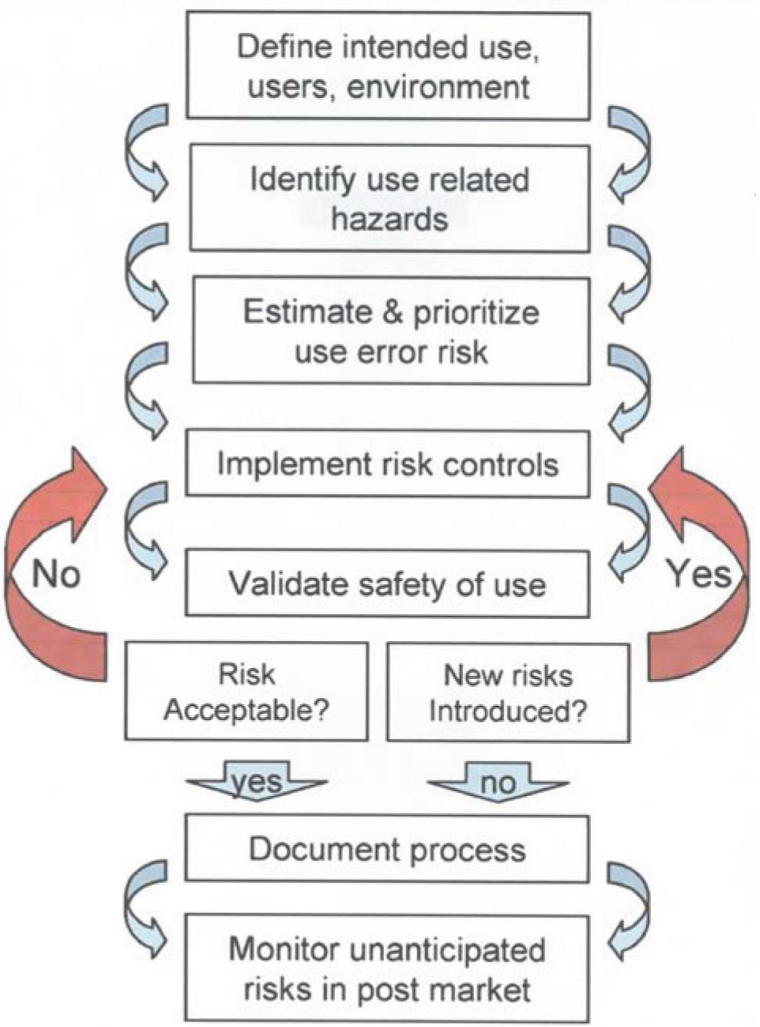
Hazard

- A key concept in risk management is hazard
  - a potential source of harm
- Examples of harm
  - Degradation of quality of health care
  - Injury to patient
  - Injury to device user

Risk (R), as defined by multiple sources, is the product of the quantified severity of an identified *hazard* (H) and its *probability* (or likelihood) of occurring (P):

$$R = H \times P$$

Risk Management Process



Intended use

- A description of the device's intended use in terms of its clinical applications (the conditions or diseases to be screened, monitored, treated, diagnosed, or prevented)
- A description of potential future uses if the functionality of the device could be changed because of market shift (e.g., hospital to home) or operating conditions (e.g., stationary to ambulatory or mobile)
  - When possible
- Example:
  - Hemodialysis: removal of excess unwanted metabolites and water from the body

User

- Develop and document user profiles
  - Describe the skills and the physical, perceptual, and cognitive abilities of individuals making up the distinct user groups for the device
  - Any special circumstances that could affect device use, including variability of abilities among the anticipated user population, should be described, as well as any special training needed and the level of this training.
- Employ user profiles in the design process.
- Support the analytical process of identifying potential use-related hazards by anticipating situations in which device users could have difficulties.
- Develop a user interface that properly accounts for user abilities.
- Guide the selection of representative (or critical) users for usability testing.

Use environment

- Identify environment-of-use characteristics.
  - Should be included in preliminary design and use-error risk management assessment.
  - Environment in which a device is used (e.g., OR, hospital bed, home) can affect the actual use of the device because of variations in conditions such as noise, lighting, and temperature
- Consider dynamic ambient conditions.
  - Conditions of use can change in a given use environment according to time of day, patient load, and type of care given in the environment.
  - Example: readability of displays in low lighting of a patient room at night might differ from that in the same room in bright daylight
  - Accessibility of critical display information or controls in a busy emergency room could be vastly different from that in a patient room on the hospital floor.
  - Dynamics of patient load in the use environment can also create periods of stress and high workload that could increase the likelihood of use errors
- Consider worst-case use environments.
  - If errors are more likely under certain use conditions, those conditions should, to the extent possible, be considered carefully or simulated in user-based testing

Identification of use-related hazards

- Analysis of predecessor and similar devices
  - Internal "customer complaint" and customer experience data and problem reports
  - Adverse-event-report databases such as FDA's medical device reporting (MDR) database, MAUDE, and MedSun
  - Published articles on use-related problems with the device or device family
  - compilations of particular device problem reports at FDA's Center for Devices and Radiological Health website (http://www.fda.gov/cdrh)

Identification of use-related hazards

- Analysis of device use tasks
  - Identify a high-level set of user–device interaction functions
  - Identify tasks for those high-level functions
  - Identify interaction steps
  - Identify user requirements
  - Identify potential failures for each user requirement
  - Identify potential use errors and consequences
- Application of best practice for user-interface design
- Consideration of user workload in device use
  - Task load, task demand, and time pressure

Estimation and prioritization of risk of use-related hazards

- Risk analysis approaches, such as failure modes effects analysis (FMEA), fault tree analysis (FTA), and usability testing, can be used for this purpose
- For use-related risks, these techniques are applied to components of device use rather than, more typically, to device failure hazards
  - unless the failure is associated with how the device is used
- Pitfalls
  - Do not limit prioritization to simple or obvious use-related hazards.
  - Avoid underestimating the risk of low-frequency events.

Estimation and prioritization of risk of use-related hazards

- Failure mode effects analysis (FMEA)
  - Most successful when performed by a team consisting of people from a variety of relevant specialty areas
  - FMEA team "brainstorms" possible use scenarios and identifies and describes use hazards and estimates the anticipated likelihood and harm associated with each
  - Risks are calculated mathematically by multiplying the severity of each hazard by its probability
  - "Bottom-up" approach
- Fault tree analysis (FTA)
  - Top-level hazards first – "Top down" approach
  - builds a comprehensive fault tree that covers all aspects of user–device interaction

Estimation and prioritization of risk of use-related hazards

- Usability Testing
  - Appropriate test methods
  - Focus on user interactions relative to anticipated risk level
  - Unanticipated errors
  - Subjective assessments
  - Extent of testing effort
  - Appropriate test participants
  - Training prior to testing
  - Helping test participants
  - Appropriate sample size

Implementation of risk controls

- Most preferred use-related hazard mitigation strategies
  - Design modification
  - Safeguards
- Less preferred use-related hazard mitigation strategies
  - Modification of intended use
  - Training
  - Warnings and labeling

Validation of safety of use (effectiveness of risk controls)

- Validating specific design modifications
  - When design modifications have been introduced to control use-error risk, their effectiveness should be validated to ensure that no new risks have been introduced by those changes
  - Summative usability testing, which evaluates user performance across the complete range of possible device interactions, is well suited for these types of validation
- Validating overall device use safety
  - comprehensive effort intended to demonstrate that intended users in realistic work environments can use the device safely
  - A final (or nearly final) version of the device should be used

Risk Management Final Steps

- Decision on whether risks are acceptable
- Determination of whether new risks were introduced
- Documentation of the use-related risk management process
  - Use error analysis (e.g., FMEA)
  - Usability test reports
  - Any preventative measures related to use-error mitigation
- Monitoring, identification, and control of use-related issues post-marketing
  - Identify and anticipate post-market use-error potential
  - Interview training personnel
  - Track incidents of user complaints and device returns
  - Combine analysis of device reports with user interviews

Covered Material

- Chapter 5