FDA Perspectives on Human Factors in Device Development

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Understanding Regulatory Requirements for Human Factors Usability Testing

RAPS Webinar – June 7, 2012

Overview

- **What are human factors & usability?**

- **Relevant regulations and standards**

- **FDA's human factors guidance**

- **Final words**

What are Human Factors? Usability?

- **Human factors:** "…the application of knowledge about <u>human capabilities</u> (physical, sensory, emotional, and intellectual) <u>and limitations</u> to the design and development of tools, devices, systems, environments, and organizations…." (ANSI/AAMI HE75:2009, Introduction)

- **Usability:** "Characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction" (ISO/IEC 62366:2007, Definition 3.17)
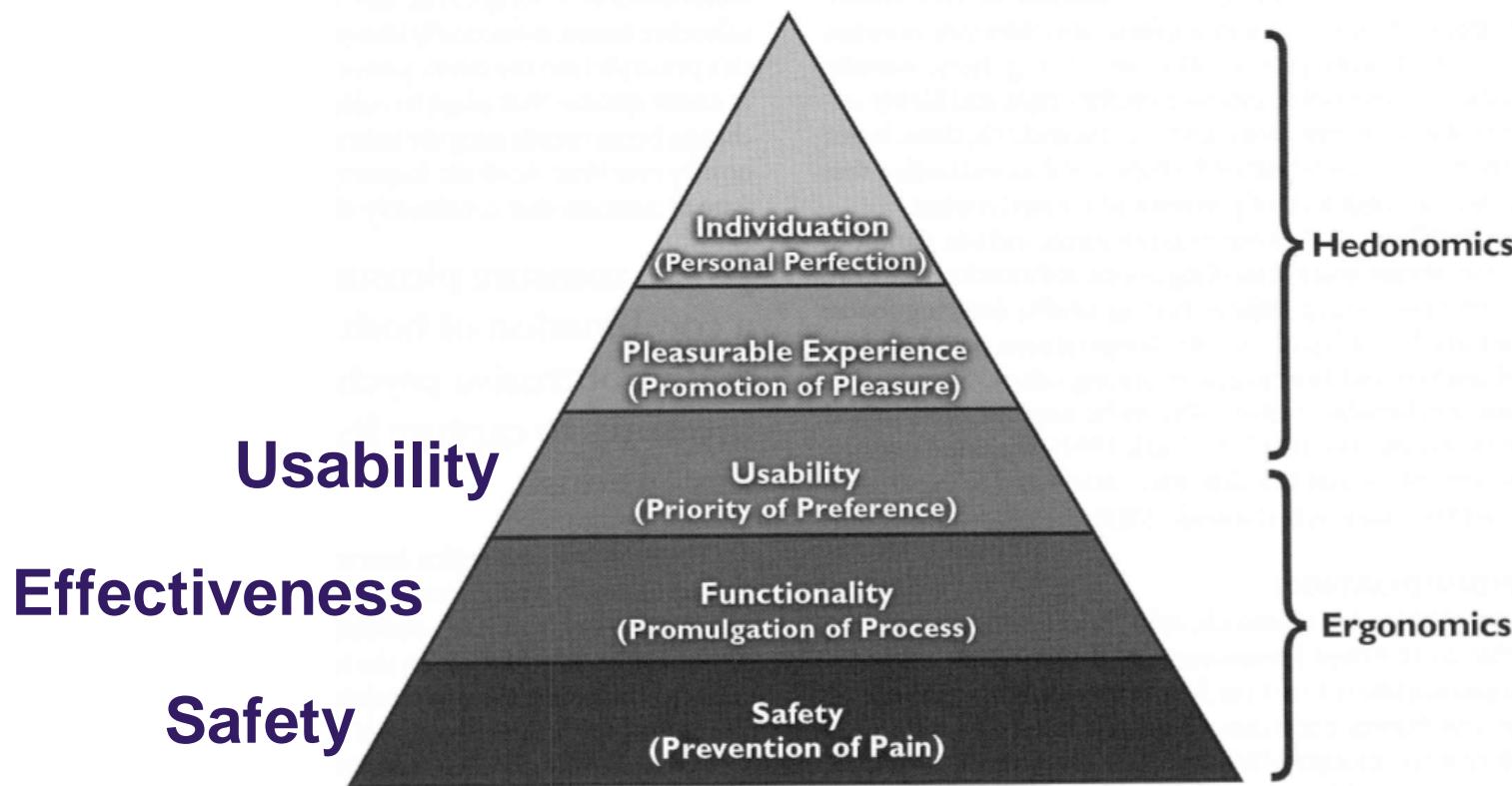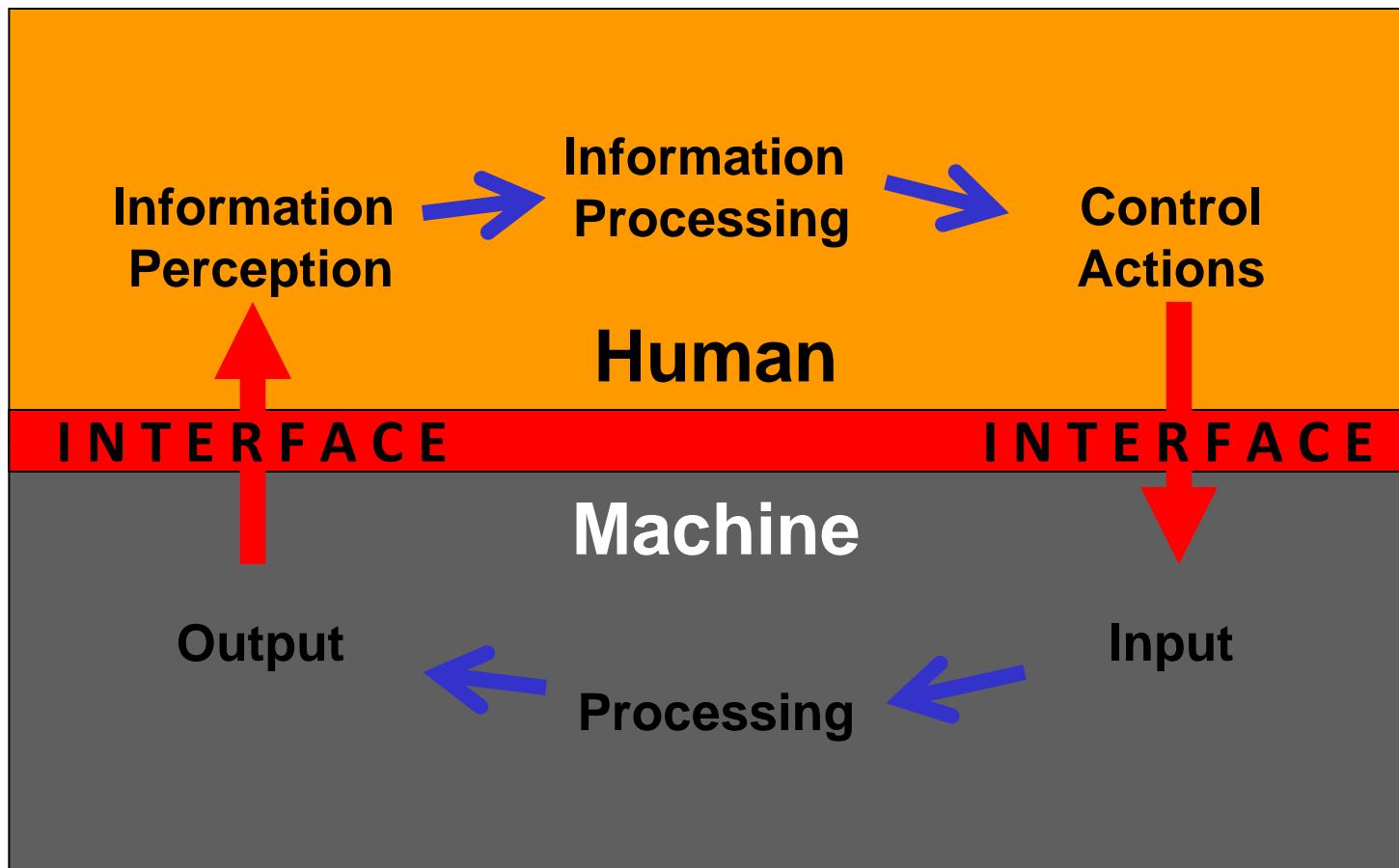
Why is FDA Concerned about HF?

- **Device safety**

- **Device effectiveness**

Ergonomics and "Hedonomics"

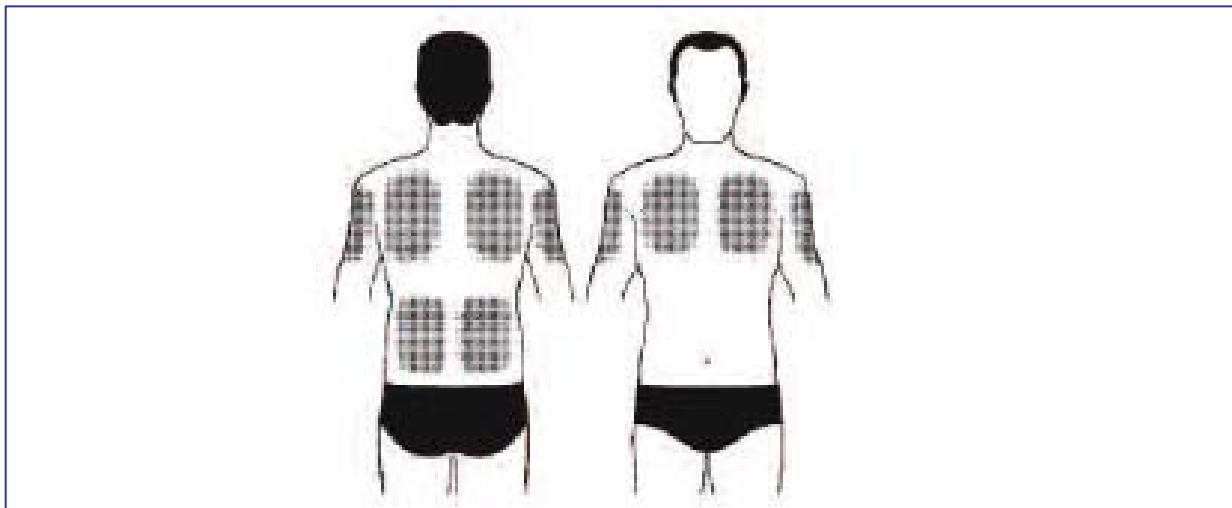**Source:** Hancock, Pepe & Murphy (2005), *Ergonomics in Design,* 13 (1), 8-14

Device-User Interface

Human Factors   Regulations & Standards   FDA's HF Guidance   Final Words   RAPS.org

Device Use Errors

Transdermal Patch Products

- **Original user instructions: where to apply patch**
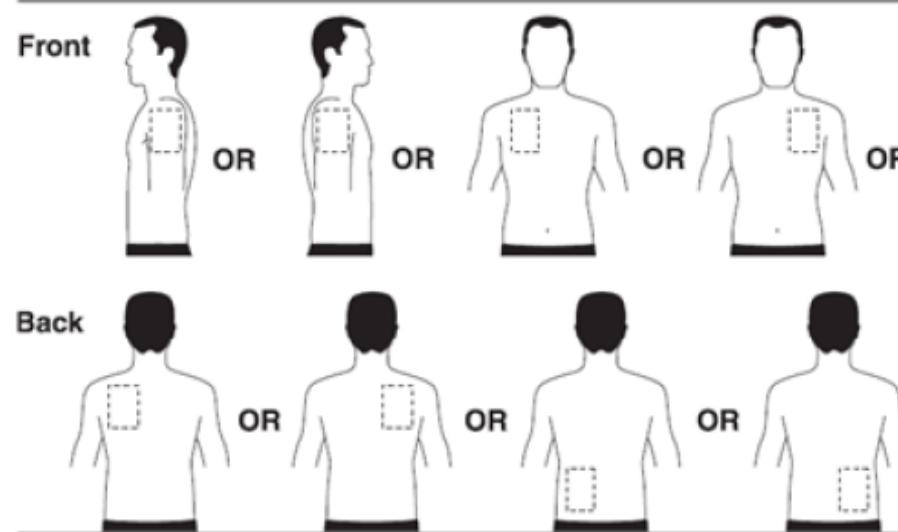

Source: Carlos M. Mena-Grillasca, FDA / CDER / OMEPRM

Device Use Errors

Transdermal Patch Products

• **Revised user instructions: where to apply patch**

Figure A:
Apply one patch to ONLY ONE of the following possible sites each day.

Use-Related Risks: Infusion Pumps

Hazard (samples)	Corresponding Risk(s) to Health	Use-Related Cause(s) (samples)
Infusion stopped prematurely	•Underdose •Delay of therapy	The user forgets to resume the pump after suspending it User is unaware of battery capacity
The user fails to detect or understand pump notifications	•Overdose •Underdose •Delay of therapy •Incorrect therapy	Background noise or nuisance alarms cause user to fail to detect/ignore them User muffles pump's speaker/audio, either intentionally or unintentionally
Wrong medication or concentration is delivered	•Incorrect therapy •Delay of therapy	User selects and sets up pump with incorrect medication or concentration Medication is correct but user selects incorrect concentration or delivery rate

FDA Regulations Relevant to HF

Quality System regulation:

21 CFR 820.30, Design Controls

– *The need for human factors is implied:*

c) **Design input** – includes "needs of the user and patient"

f) **Design verification** – performance criteria met

g) **Design validation –** "… devices conform to **defined user needs and intended uses** and shall include **testing of production units** under **actual or simulated use conditions.** Design validation shall include **software validation** and **risk analysis**…." [incl. use-related risks]

820.30(c) Design Input

- **User and Patient Needs**
  - **Relative to device *safety***
    - Users can operate the device without injury or negative clinical consequences to either the user or the patient
  - **Relative to device *effectiveness***
    - Users can operate the device successfully for the intended uses

- Potential use errors and failures have been eliminated or limited to the extent possible through appropriate application of human factors methods

820.30(f) & (g) Design Verif. & Valid.

- **Design Verification:**
  - *Did I make the product right?*

- **Design Validation:**
  - *Did I make the right product?*

Human Factors Standards

AAMI/ANSI HE75:2009

- **General considerations and principles**
  - Managing the risk of use error
  - Usability testing

- **Design elements**
  - Controls
  - Software

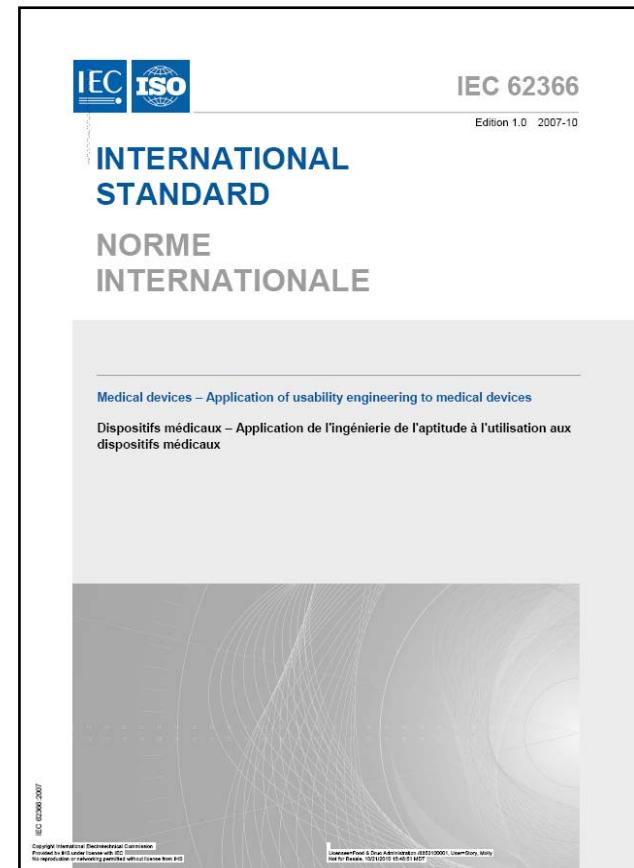- **Integrated solutions**
  - Mobile medical devices
  - Home health care

American National Standard

ANSI/AAMI HE75:2009

Human factors engineering – Design of medical devices

AAMI
Association for the Advancement of Medical Instrumentation

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Human Factors Standards

ISO/IEC 62366:2007

Medical devices – Application of usability engineering to medical devices

- **Usability engineering process**

- **Accompanying document**

- **Training**

  – *Note: Currently undergoing revision*

Human Factors   Regulations & Standards   FDA's HF Guidance   Final Words

Human Factors Standards

ANSI/AAMI/ISO 14971:2007

Medical devices – Application of risk management to medical devices

- **Risk management**
- **Risk analysis**
- **Risk evaluation**
- **Evaluation of overall residual risk acceptability**

American National Standard

ANSI/AAMI/ISO 14971:2007/(R)2010
(Corrected 4 October 2007)

Medical devices—Application of risk management to medical devices

AAMI
Association for the Advancement of Medical Instrumentation

FDA HF Guidance

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

http://www.fda.gov/ MedicalDevices/ DeviceRegulationand Guidance/ GuidanceDocuments/ ucm094460.htm

- *NOTE: Issued in 2000*

Guidance for Industry and FDA Premarket and Design Control Reviewers

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management

Document issued on July 18, 2000

This document replaces the draft guidance document of August 3, 1999, entitled *Device Use Safety: Incorporating Human Factors in Risk Management.*

CDRH
Center for Devices and Radiological Health

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Device User Programs and Systems Analysis
Office of Health and Industry Programs

Draft Guidance

http://www.fda.gov/ MedicalDevices/ DeviceRegulationand Guidance/ GuidanceDocuments/ ucm259748.htm

– *NOTE: Issued in 2011 – **not yet in effect** but reflects FDA-CDRH's current thinking and approach to human factors.*

Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Applying Human Factors and Usability Engineering to Optimize Medical Device Design

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management
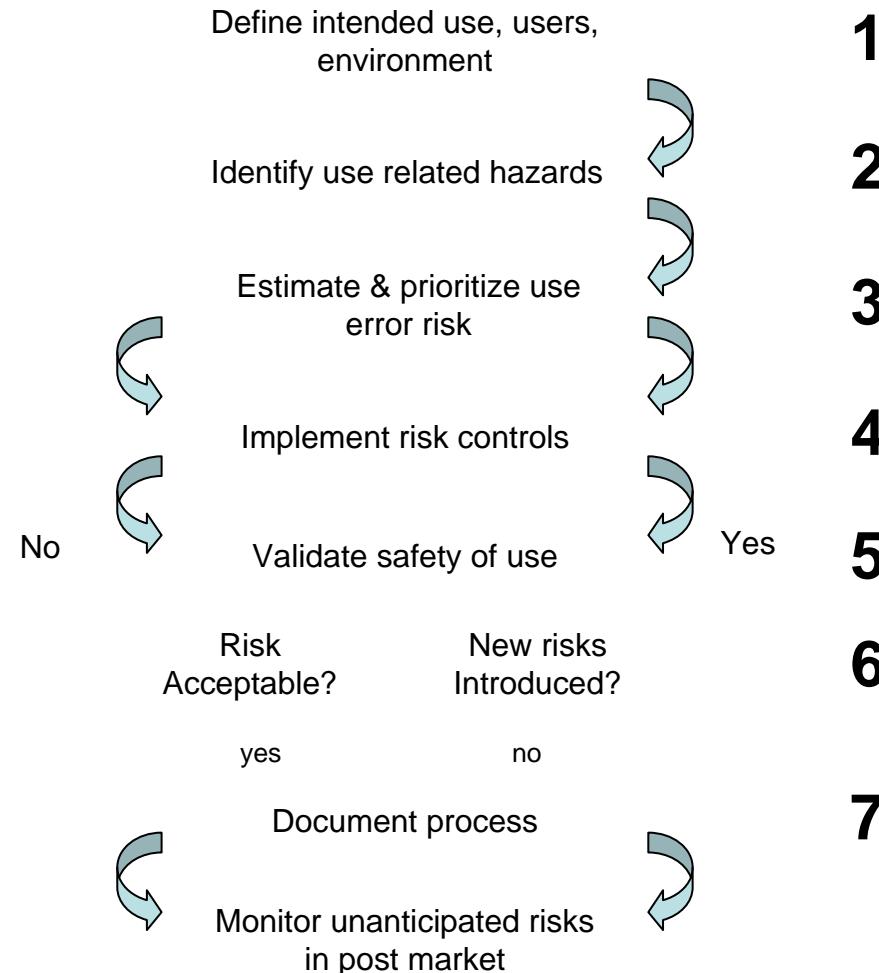*(Issued July 18, 2000).*

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

Center for Devices and Radiological Health
CDRH

2011 *Draft* Human Factors Guidance

- **Regulations, Guidance, Standards**

- **Considerations: Device Users, Use Environments and User Interfaces**

- **Preliminary Analyses and Hands-On Studies**

- **Risk Control and Design Iteration**

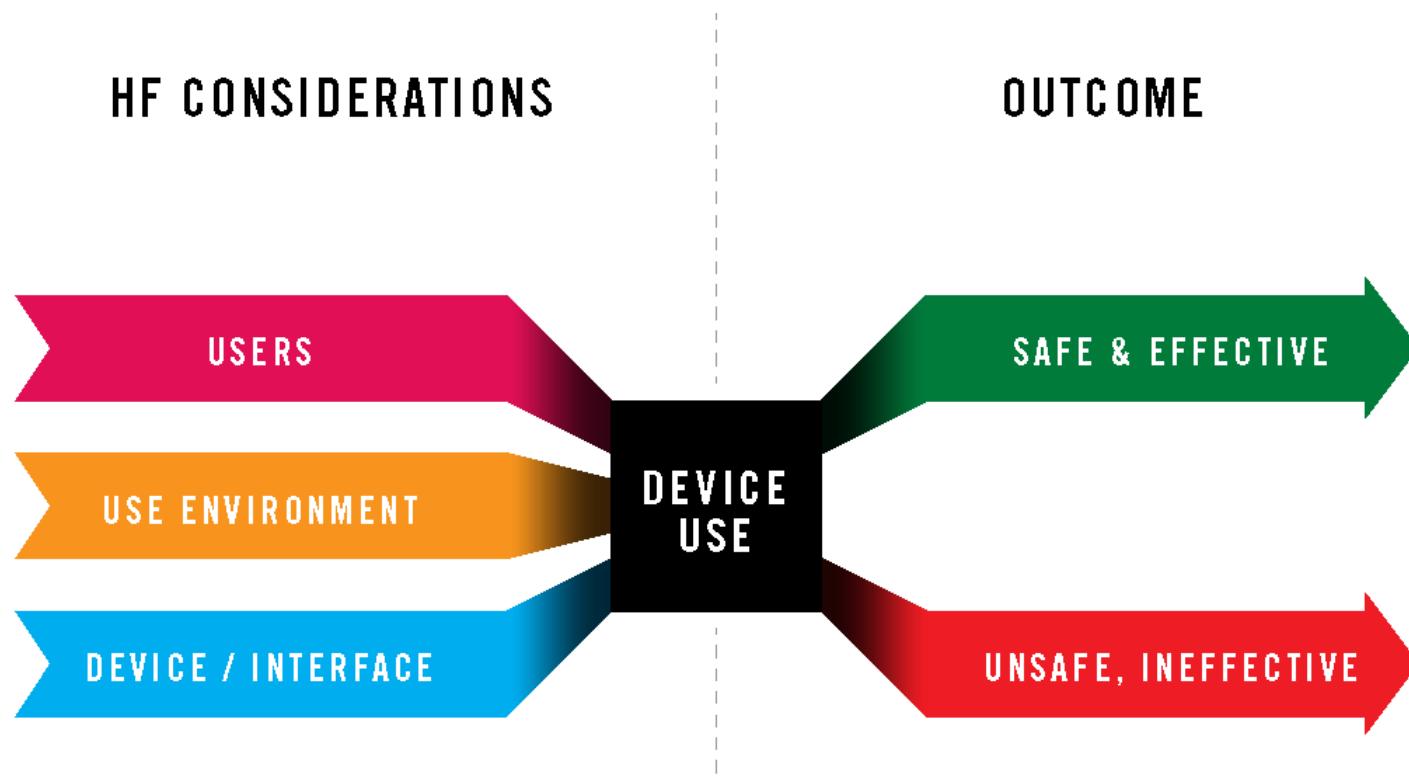- **Human Factors Validation Studies**

Define intended use, users, environment **1**
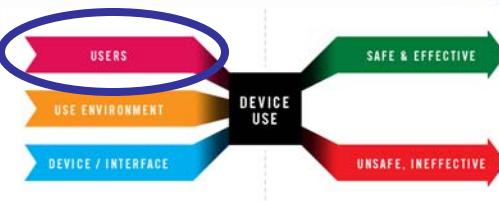
Identify use related hazards **2**

Estimate & prioritize use error risk **3**

Implement risk controls **4**

No   Validate safety of use   Yes **5**

Risk Acceptable?   New risks Introduced? **6**

yes   no

Document process **7**

Source: ANSI/AAMI HE75:2009

Monitor unanticipated risks in post market

Human Factors of Device Use

Define intended use,
users, environment

1
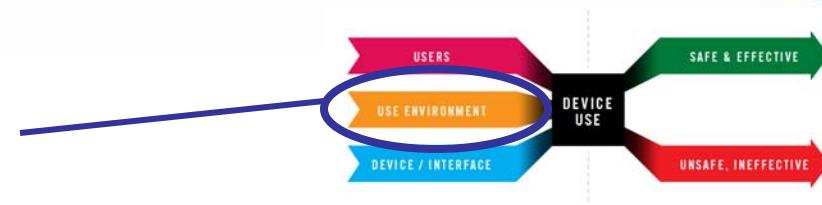
Users
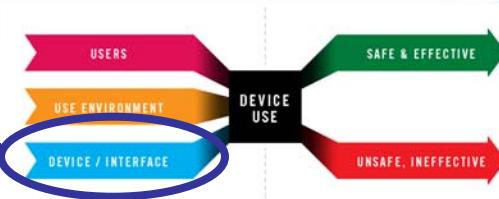
- **Professional or non-professional**

  – Job title and responsibilities

- **Knowledge and experience levels**

- **Age and functional capabilities**

  – Physical, sensory/perceptual, cognitive/intellectual

- **Mental and emotional condition**

Use Environment
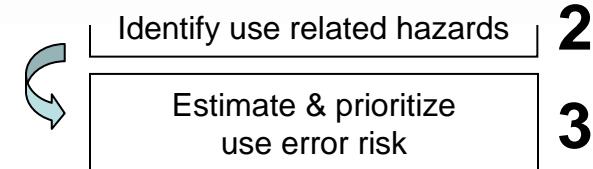
- **Clinical environment**
  - Hospital, clinic, etc.

- **Transitional care environment**
  - Rehabilitation, assisted living, long-term care, etc.

- **Home environment**
  - House, mobile home, townhouse, apartment, etc.

- **Community setting**
  - Office, school, retail, outdoors, etc.

- **Mobile environment**
  - Car, plane, train, bus, ambulance, medevac, etc.

User Interface

- **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.

Preliminary Studies

Identify use related hazards	**2**
Estimate & prioritize use error risk	**3**

- **Identify and analyze: intended users, use environments, expected use scenarios**

- **Develop initial product concepts and prototypes**

- **Identify and explore potential device use-related hazards and risks and their potential clinical consequences**

- **Explore different design alternatives and identify the trade-offs between them**

Preliminary HF Analyses

- **Study use of current devices**
  - Contextual inquiry
  - Focus groups and interviews
- **Study use of device under development**
  - Function and task analyses, failure mode and effects analyses, etc.
  - Heuristic analyses
  - Expert reviews

Preliminary Hands-On Studies

- **Identify issues not findable through application of analytical techniques, e.g.:**
  - The use environment has negative effects
  - The demands associated with use of the device exceed the user's capabilities
  - Aspects of device use are inconsistent with the user's expectations or intuition
  - The device is used in unexpected ways
  - The device is used in inappropriate but foreseeable ways, for which adequate controls were not applied

Preliminary Hands-On Studies

- **Done while the device is under development**
  - Testing can involve simple product mock-ups or early prototypes, or even partial designs (e.g., components) operating in simulated-use modes
  - Test participants should be representative of the intended user population(s)
  - At early stages, use-related problems can be addressed more easily and less expensively
  - Conduct studies iteratively to optimize the device design and ensure the human factors/usability validation testing results will be successful

Preliminary Hands-On Studies

- **Conduct separate studies on labeling and training (recommended):**

  – Assess the clarity and effectiveness of all labeling (e.g., instructions for use, other documentation, packaging)

  – Determine the format and complexity of training that will be necessary (if any)

Risk Control

Implement risk controls | **4**

- **Develop risk mitigation strategies as needed:**
  - Modify the interface design, user instructions, and/or training to address the problems found

- **Re-test to assess whether mitigation strategies:**
  - Effectively reduced the known risks and
  - Did not introduce any new risks

- **Residual risk can be acceptable if it is:**
  - Reasonably limited, difficult to eliminate or further reduce, and outweighed by the device's benefits

Human Factors Validation

Validate safety of use | 5

- **Demonstrates and provides evidence that a medical device, as designed, can be used safely and effectively:**

  – By people who are representative of the intended users

  – Under expected use conditions

  – For essential and critical (high-risk) tasks

Test Populations

- **All intended user populations – e.g.:**
  - Healthcare professionals, pharmacists, engineers/technicians, home health care aides, family caregivers, patients
  - Pediatric and geriatric populations need careful consideration

- **Not company employees**

- **Representative of U.S. population**

Device Testing Conditions

- **Use finalized device design and labeling**

- **Present within typical context of use**

- **Incorporate expected use conditions**
  - E.g., lighting, sound, and activity (distraction) levels

- **Allow realistic device-user interactions**
  - Provide participants with device as they would receive it (e.g., in its original packaging, with all documentation)
  - Allow participants to use the device as they normally would (e.g., without interference from test facilitator)

Selection of Tasks Tested

- **Tasks tested in validation do not necessarily include everything in the instructions for use**

  - Include *essential tasks* – i.e., tasks necessary for successful use of the device for its intended purpose

  - Include *safety-critical tasks* – i.e., tasks on which users could make errors or could fail to complete, which would have negative clinical impact

    - All warnings and most caution statements in the device labeling imply safety-critical tasks

    - All tasks requiring responses to alarms are safety-critical

Selection of Tasks Tested

- **Include in the human factors validation study protocol and report a rationale for the tasks you choose to include in your testing**
  - Base task selection on results of preliminary analyses
    - E.g., task analyses and identification of use-related risks
  - Incorporate findings of preliminary hands-on studies
    - E.g., tasks found to be error-prone or difficult for users
  - Define criteria for task success prior to the test

Instructions and Training

- **Participant interaction with instructions should approximate reality**
  - Labeling used in device validation should be final versions
  - Availability of labeling should represent realistic situation
- **Provision of training should approximate reality**
  - Training used in device validation study should be comparable to the training that actual users will receive
  - Consider integrating period of time for learning gained through training to "decay" before conducting device validation study, depending on actual conditions of use

Human Factors/Usability Data

- **Objective (performance) data:**
  - Facilitator observes and notes all use errors, failures and difficulties, including details about performance, e.g.:
    - Task success or failure, use error, close call, reference to instructions for use, need for assistance, evidence of difficulty or confusion, unsolicited comments
  - Facilitator should not interfere with participant's independent and natural use of device
  - Measuring speed of task completion: only appropriate if it is clinically meaningful
  - Number of task attempts allowed: varies by type of device and context of use

Human Factors/Usability Data

- **Subjective (narrative comment) data:**
  - Discuss user performance after use, particularly regarding perceived reasons for any essential and critical task errors, failures and difficulties
  - Solicit participant feedback on design of device, labeling and training

- **Unacceptable methods and data:**
  - Use of "think aloud" technique: not natural
  - Forced-choice questionnaires: introduce bias
  - User opinions on rating scales: can introduce bias, usually does not demonstrate safety or effectiveness

Validation Data Analysis

| Risk Acceptable? | New risks Introduced? | 6 |

- **Analyze all use errors and failures**
  - Determine root cause and potential clinical consequences
  - Determine need to modify device, labeling, or training
  - Identify true residual risks
- **Use errors/failures are not of equal importance**
  - Some errors might be frequent but inconsequential
  - Some errors might be rare but reveal a hazardous design deficiency that was not previously recognized

Human Factors Report

Document process | 7

1. **Intended device users, uses, environments**

2. **Description and images of device user interface**

3. **Summary of known use problems**

4. **Use tasks: descriptions, risk priorities, success criteria**

5. **Summary of preliminary evaluations**

6. **Validation study protocol and results**

7. **Conclusion**

Status of *Draft* Guidance Document

- **Document issued June 22, 2011**
- **Comment period closed Sept. 19, 2011**
  - About 600 comments were submitted
- **We are reviewing the comments**
  - Some comments are minor and easy to address
  - Some comments are significant and require ODE to establish new policies
- **We hope to finalize the document soon…**

FDA Expectations for HF Data

- **Conduct a comprehensive risk assessment**
- **Identify and mitigate risks, including all use-related risks**
- **Conduct human factors/usability validation testing on any strategies implemented to mitigate *significant* use-related risks**
- **Document everything in the Design History File**

Advice: Consult FDA Early

- **Discuss product development plans with FDA before your design is finalized (and changes would be difficult)**
  - Through a pre-submission (e.g. "Pre-IDE") mechanism
  - Interact with experts in CDRH (and/or CDER/CBER) who have advice to share based on experience

- **FDA will review human factors/usability validation study protocols on request**
  - *Before implementation is recommended!*

CDRH "Pre-IDE" Meetings

- **Can be used to interact with FDA regarding any future submission or application**
  - Can request a face-to-face meeting or teleconference or simple written response
  - Quicker turnaround: FDA often responds within 60 days
  - Can be used to request review of human factors validation study protocols
    - We try to turn these around within 2-3 weeks
- ***Guidance on IDE Policies and Procedures:***
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm

FDA/CDRH Human Factors Program

http://www/fda.gov/ humanfactors

- Premarket Info
  - Design & Documentation

- Postmarket Info
  - Surveillance & Reporting

- Info for Consumers, Patients, Caregivers

- General Human Factors Info and Resources

New HFES-AAMI Web Site

http://
www.medicaldevice
humanfactors.org

- Resources

- Consultant Directory

- Organizations

- Events

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Questions

Molly Follette Story: **molly.story@fda.hhs.gov**

FDA/HF web site: **www/fda.gov/humanfactors**

RAPS.org