

Human Factors:

A Methodology for Managing Risks of Use Error
in Device Design

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Introduction

Who We Are

- Bob North, PhD, Chief Scientist
 - Honeywell – Aerospace, Industrial Controls
 - Medtronic – Cardiac Rhythm Management
- Kate Peterson, Human Factors Engineer
 - Mitchell Madison Group: Process Engineering, Systems & Software Design
 - Software Manufacturing: HFE strategy

The Problem As We See It

- Use error is on the rise, poorly documented or understood, and adverse patient outcomes are the result
- Device complexity is on the rise, competitive positions depend on maximizing ease of use, reducing training, and eliminating unnecessary service

Presentation Objectives

1. Define human factors (recap) & describe the regulatory position
2. Introduce use problem risk management technique
3. Show how we've used this successfully in industry and education
4. Resources available today

**I. What is human factors
& what is the FDA
regulatory position?**

Human factors defined

- Discipline that optimizes the relationship between people and machines
- History in aerospace, military, nuclear energy

820.30(c): Design inputs

Perform human factors in the beginning...

Ensure that the device design requirements are appropriate and address the intended use of the device, **including the needs of the user and patient**

820.30(g): Design validation

...before you put your product on the market...

Ensure that the device conforms to defined user needs and intended uses and **shall include testing under actual or simulated use conditions**

820.100: Corrective & Preventative Action

*Patient death or injury caused by “user error”
is an unacceptably high risk and
nonconformity*

“...because human factors and other similar
tools should have been considered during the
design phase of the device”

K. Trautman, *The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices*, 1997, pages 151-152.

What is FDA doing today?

- Human factors experts to review device submissions for innovative and new products
- Expertise in adverse event investigations
- Encouraging all device makers to start talking with them about human factors plans & program (proactive & outreach)

2. Use Problem Risk Management Technique

UPCARE is...

A human factors analysis,
description and educational
tool for medical device use
problems

Why UPCARE was developed

- Traditional “human error” classification schemes are informative, but not directly applicable to design or effective response to problems.
- New interviews, centered on questions regarding perceptual, cognitive, and behavioral (action) device issues produced better, more contextual stories.
- Developed descriptive domains of user: Perception, Cognition, and Action
- Added descriptive domains for context (User’s Unmet Need), risk (Result), and follow-up (Evaluation)

UPCARE Domains

U - Unmet user need

P - Perception

C - Cognition

A - Action/behavioral

R - Result

E - Evaluation strategy

Using UPCARE

- A use problem scenario from actual medical device reports and our interviews with nurses
- Analyze the problem

3. Applying UPCARE in Device Design Risk Management

Roadmap for an HFE program: case study

“I’m losing data every day on the usability of device, so I need to capture usability data in a more structured/formal way”

“I don’t want these use problems to be reproduced in the next generation of my product, so...

- Where do I need to refine my existing product development process?
- What human factors tools can I implement today? Tomorrow?

Practical use in device design/development

- Why this device maker contacted us
- A medical device maker had conducted in-depth user acceptance surveys on a new product
- We suspected that user comments would indicate remaining use problems
- We analyzed the user comments by filtering them through UPCARE

First steps

- We assigned each user comment a designation of Perceptual, Cognitive, or Action/Behavioral to indicate what appeared to be the source of the problem, and then identified the unmet user need
- We discussed the potential or real clinical risk linked to each unmet user need
- Assigned a level of criticality to each clinical risk

The issues related to human performance & safety criticality

<i>Issue category/ Deg. of criticality</i>	Low	Medium	High
Perceptual	9%	3%	1%
Cognitive	27%	9%	17%
Action/ Behavioral	27%	4%	3%

n = 77 issue occurrences

Next steps

- We developed a human factors evaluation strategy for each class of use problems by level of safety criticality
- Analyzed the relationships between the type of use problem (PCA), the level of criticality, and the human factors techniques that address each of these best

The issues related to human factors strategy & safety criticality of issue

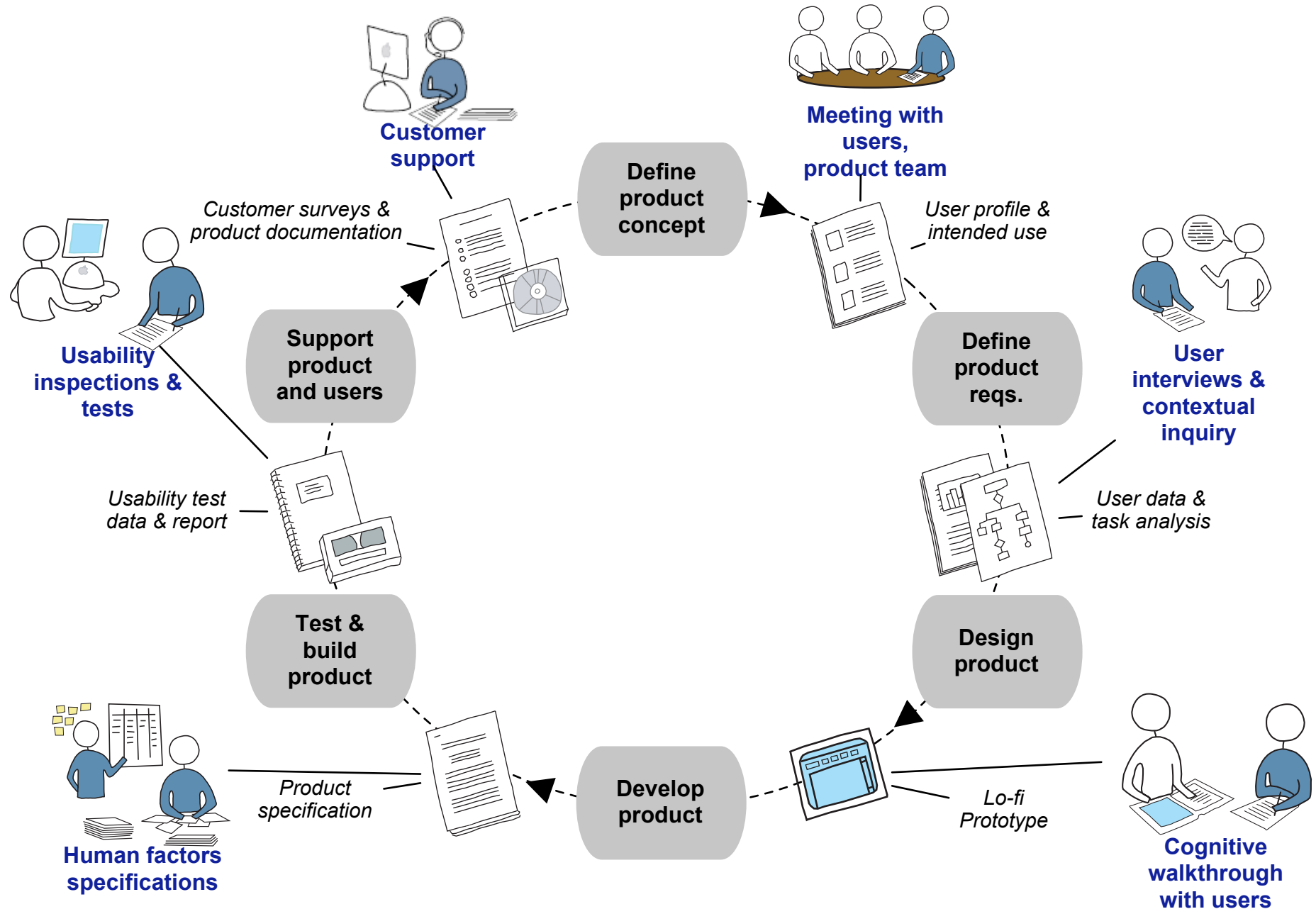
<i>Human factors approach/ Deg. of criticality</i>		Low	Medium	High
Perceptual	Formal usability testing	9%	3%	1%
Cognitive	User interviews & field observation	8%	8%	6%
	Task analysis & walkthroughs	19%	1%	4%
	Formal usability testing	-	-	6%
Action/ Behavioral	Formal usability testing	27%	4%	3%

n = 77 issue occurrences

What next?

- Create a multi-year plan to integrate a “full-lifecycle” human factors engineering process into existing device research, development, and customer support processes
- Train product teams and product support staff in human factors “best practices”

Suggested Human Factors Plan



4. Available Human Factors Resources

FDA Resources

Human Factors at FDA Center for Devices & Radiological Health (CDRH):

<http://www.fda.gov/cdrh/humanfactors/>

- Ron Kaye & Jay Crowley, “Medical Device Use – Safety: Incorporating Human Factors Engineering into Risk Management
- Office of Health and Industry Programs, “Human Factors Points to Consider for IDE Devices
- Dick Sawyer, “Do It By Design: An Introduction to Human Factors in Medical Devices”

Industry Resources

AAMI Publications: Standards Collections:

<http://www.aami.org/publications/standards/>

- AAMI HE48:1993, Human factors engineering guidelines and preferred practices for the design of medical devices
- ANSI/AAMI HE74:2001, Human factors design process for medical devices
- AAMI HE75\Ed.3, Human factors engineering – Design of medical devices

Questions & Comments

Thank you!