Medical Device Evaluation: Integrating a Human Factors Approach

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“Medicine has become the act of managing extreme complexity - and a test of whether such complexity can, in fact, be humanely mastered”

Human-Technology Interaction

Designer’s model → Technology ← Interact

not the same

Errors
Inefficiencies
Frustrations

User’s model
What is Human Factors?
“We cannot change the human condition, but we can change the conditions under which humans work”

James Reason
Observations
Work as Done

Work as Imagined
Problem with asking users directly is...

“What people say, what people do, and what they say they do are entirely different things”

Margaret Mead, anthropologist
• Multitasks they perform
• Interruptions they deal with
• Workarounds they cope with
• Struggles they encounter

= Opportunities for innovation
Design: Technology ➔ in-house
Medical Device Market is Growing

- Surgical Equipment
- Dialysis Machines
- Pet Scans
- X-Rays
- Health IT
- Ventilators
- Ehealth
- Infusion Pumps
- Medical devices with AI
Nature of Human-Device Interaction is Changing

Skills

Rules

Knowledge

Automation
Design behaviour

Augmented Intelligence
Monitor activity

Nature of Device Evaluation is Evolving

**Skills**
- Technical failures
- Use issues

**Rules**

**Knowledge**
- Alarm/data fatigue
- Decision making errors
- Automation complacency
- Black box decision making
In 737 Max Crashes, Boeing Pointed to Pilot Error — Despite a Fatal Design Flaw

EXCLUSIVE: SURVEILLANCE FOOTAGE OF TESLA CRASH ON SF’S BAY BRIDGE HOURS AFTER ELON MUSK ANNOUNCES “SELF-DRIVING” FEATURE

Maneuvering Characteristics Augmentation System (MCAS)

Black box decision making: a system’s predictions are not open to inspection or interpretation and can only be judged as correct based on the final outcome

Automation complacency: a system’s predictions are given more weight than they deserve as the system is seen as infallible or confirming initial assumptions
Test the Design
Action
over
Evidence
Evidence over Action
Methods for Evaluating Medical Devices

Traditional

• Physical Inspection
• Specification/calibration testing
• Review logs, service history, and databases

• Do not fully capture human-device interaction and contextual issues (e.g. no fault found)
• Limited intervention identification

Human Factors

Lab Simulations
In-Situ Simulations
OR Black Box

• Can identify new risks
• Help identify and test interventions for prevention
Lab Simulation Testing
Lab Simulation Testing

Evaluates an intervention by having representative users perform representative tasks
Physical environment
Props
Ambient noise
Scenarios
Skills

Rules

Knowledge
Ask questions and think aloud
Document performance
Preference vs Performance
Preference vs Performance
Lab Simulation Testing: Inform procurement and design evaluations
Handling the device
In-Situ Simulation Testing
Human Factors for Health Technology Safety:
Evaluating & Improving the use of Health Technology in the Real World
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Thank you!