



TALK SERIES

Medical Device Evaluation: Integrating a Human Factors Approach

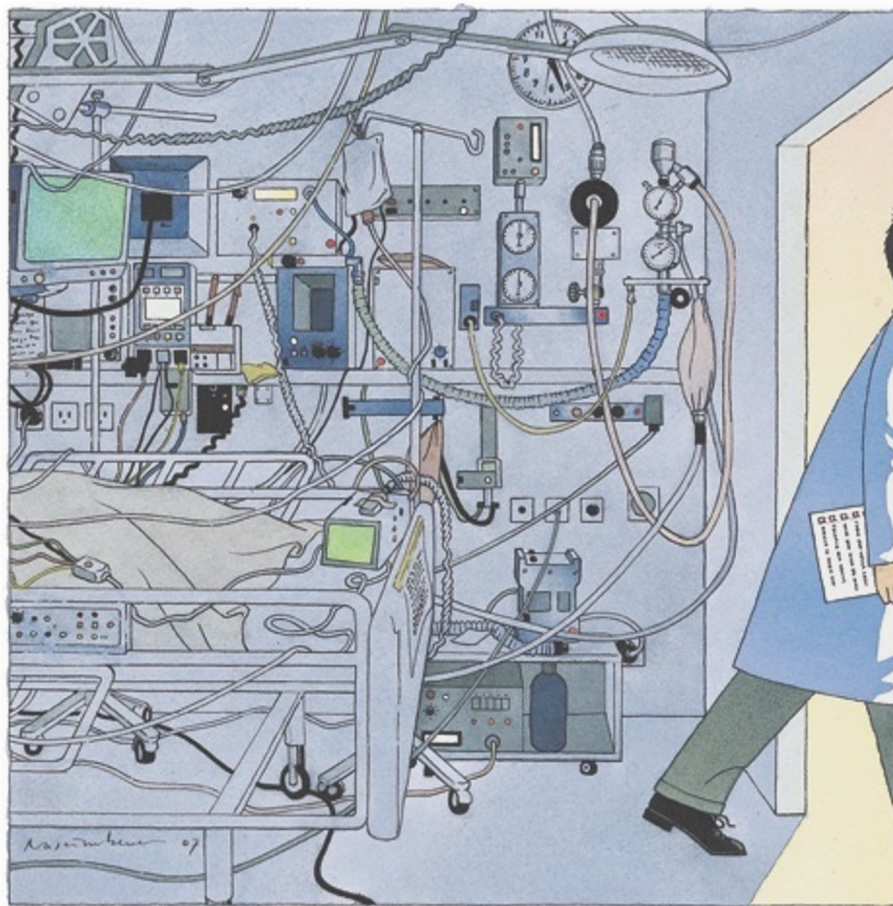
Patricia Trbovich, PhD and Sonia Pinkney PEng

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HumanEra

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

-Atul Gawande, The Checklist Manifesto, 2009



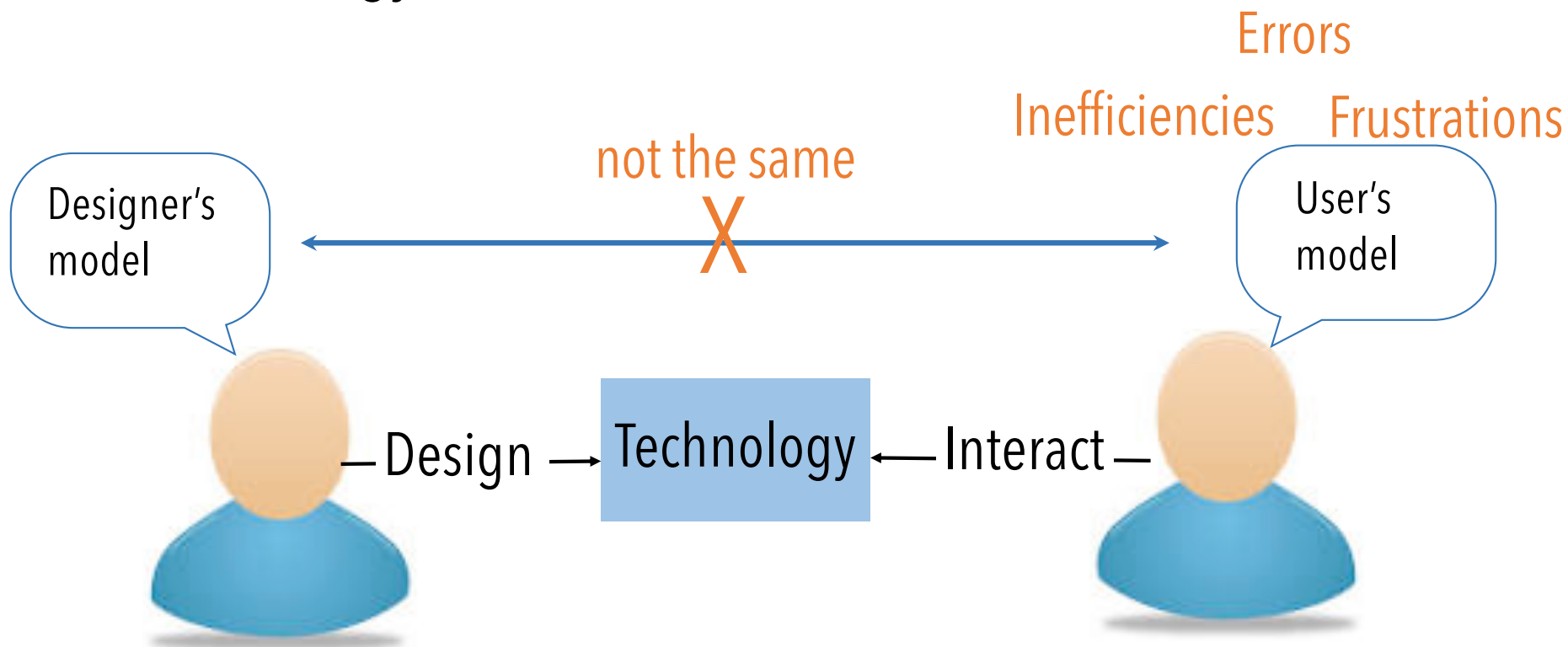








Human-Technology Interaction



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



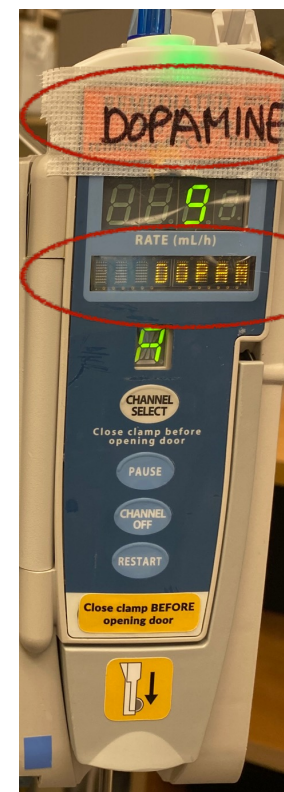
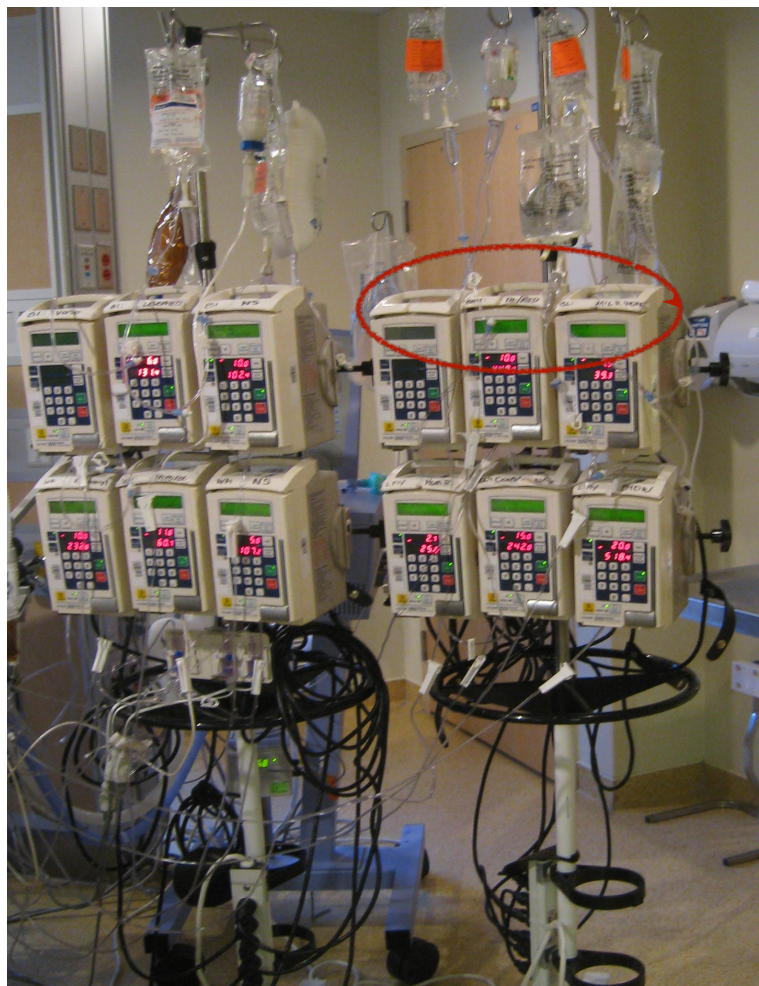
Work as Imagined

Problem with asking users directly is...

"What people **say**,
what people **do**,
and what they **say they do**
are entirely different things"

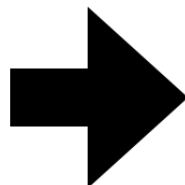
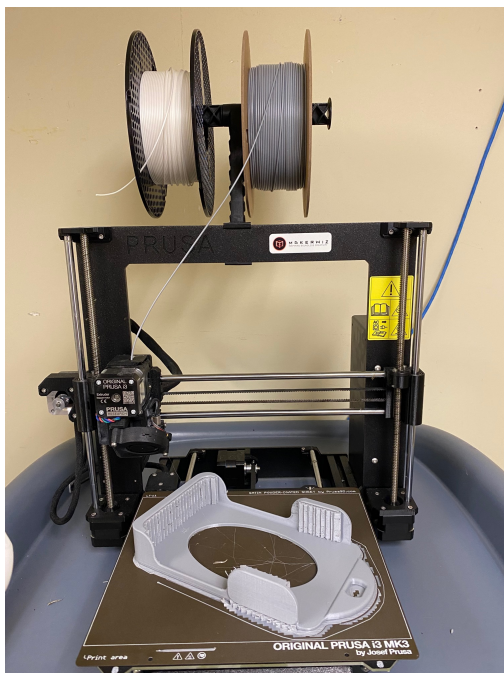
Margaret Mead, anthropologist

- Multitasks they perform
 - Interruptions they deal with
 - Workarounds they cope with
 - Struggles they encounter
- = Opportunities for innovation





Design: Technology → in-house



OR BLACK BOX®



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Medical Device Market is Growing

Surgical Equipment

Dialysis Machines X-Rays

Pet Scans Health IT Ventilators

Ehealth

Infusion Pumps

Medical devices with AI

Nature of Human-Device Interaction is Changing

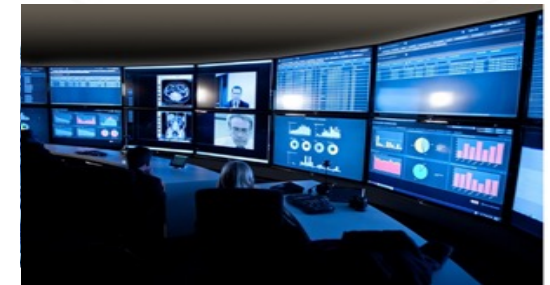
Skills



Rules



Knowledge



Automation
Design behaviour

Augmented Intelligence
Monitor activity

Rasmussen, J. IEEE Transactions on Systems, Man and Cybernetics (SMC-13)3:257-266, 1983.

Nature of Device Evaluation is Evolving

Skills

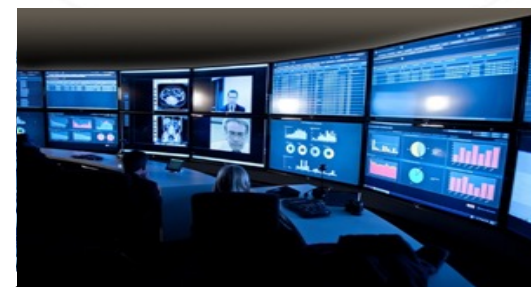


Rules



- Technical failures
- Use issues

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



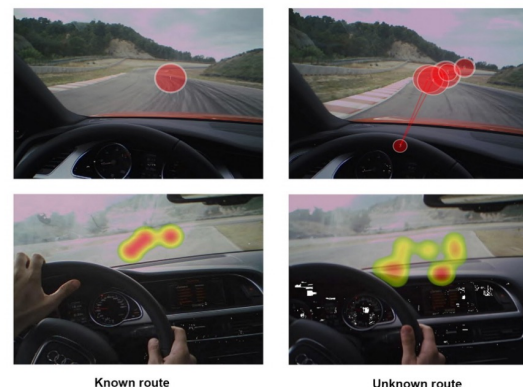
Black box decision making: a system's predictions are not open to inspection or interpretation and can only be judged as correct based on the final outcome

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



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

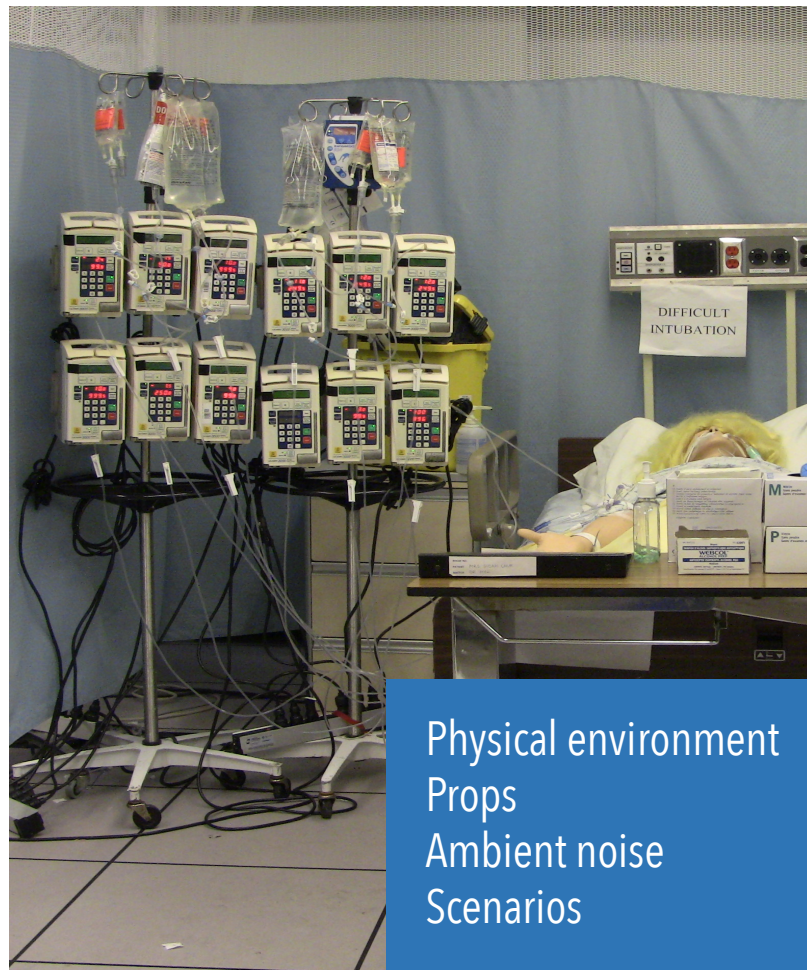
Lab Simulation Testing

Lab Simulation Testing



Evaluates an intervention by having representative users perform representative tasks





Physical environment
Props
Ambient noise
Scenarios

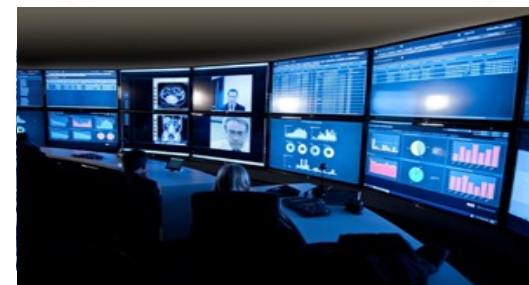
Skills



Rules



Knowledge

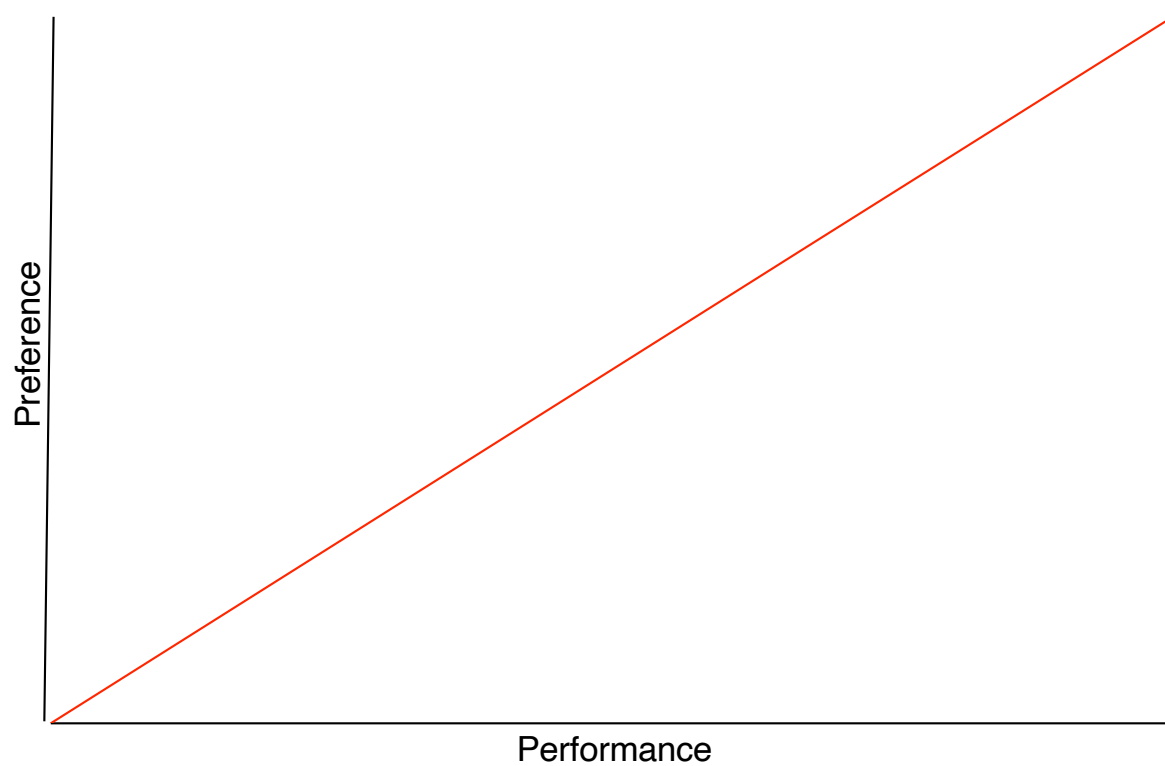


Ask questions and think
aloud
Document performance

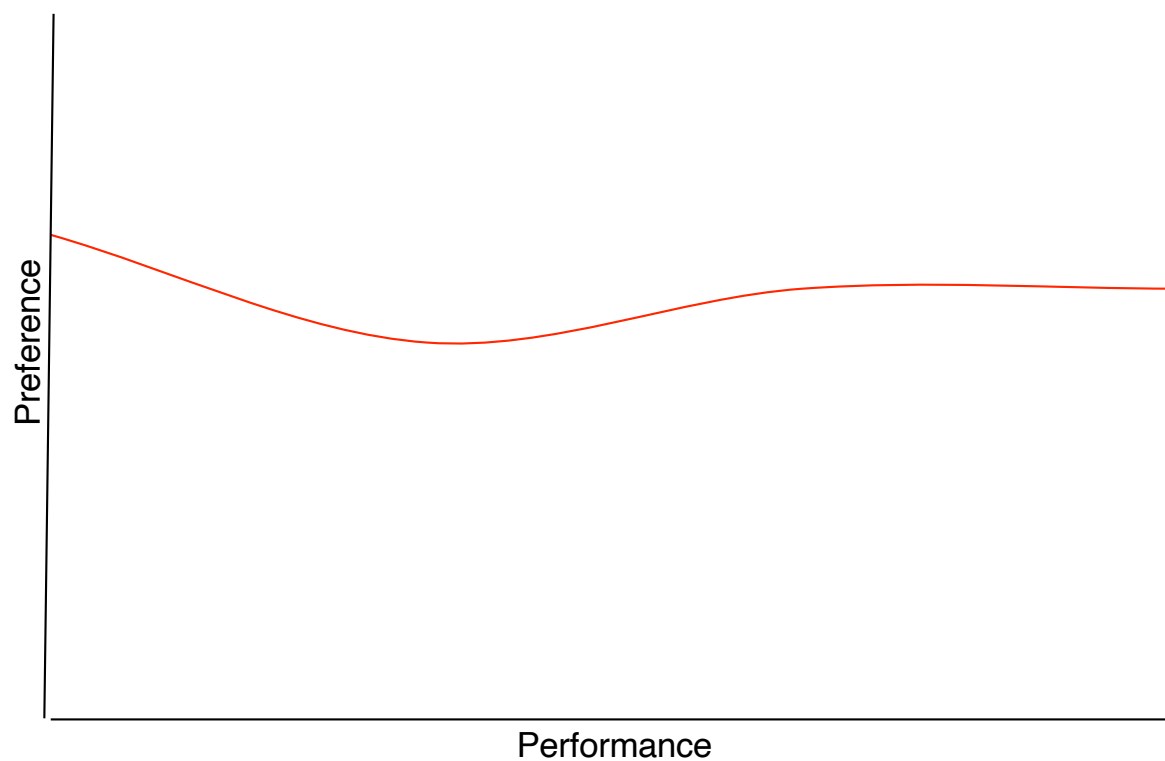




Preference vs Performance



Preference vs Performance



Lab Simulation Testing:

Inform procurement and design evaluations

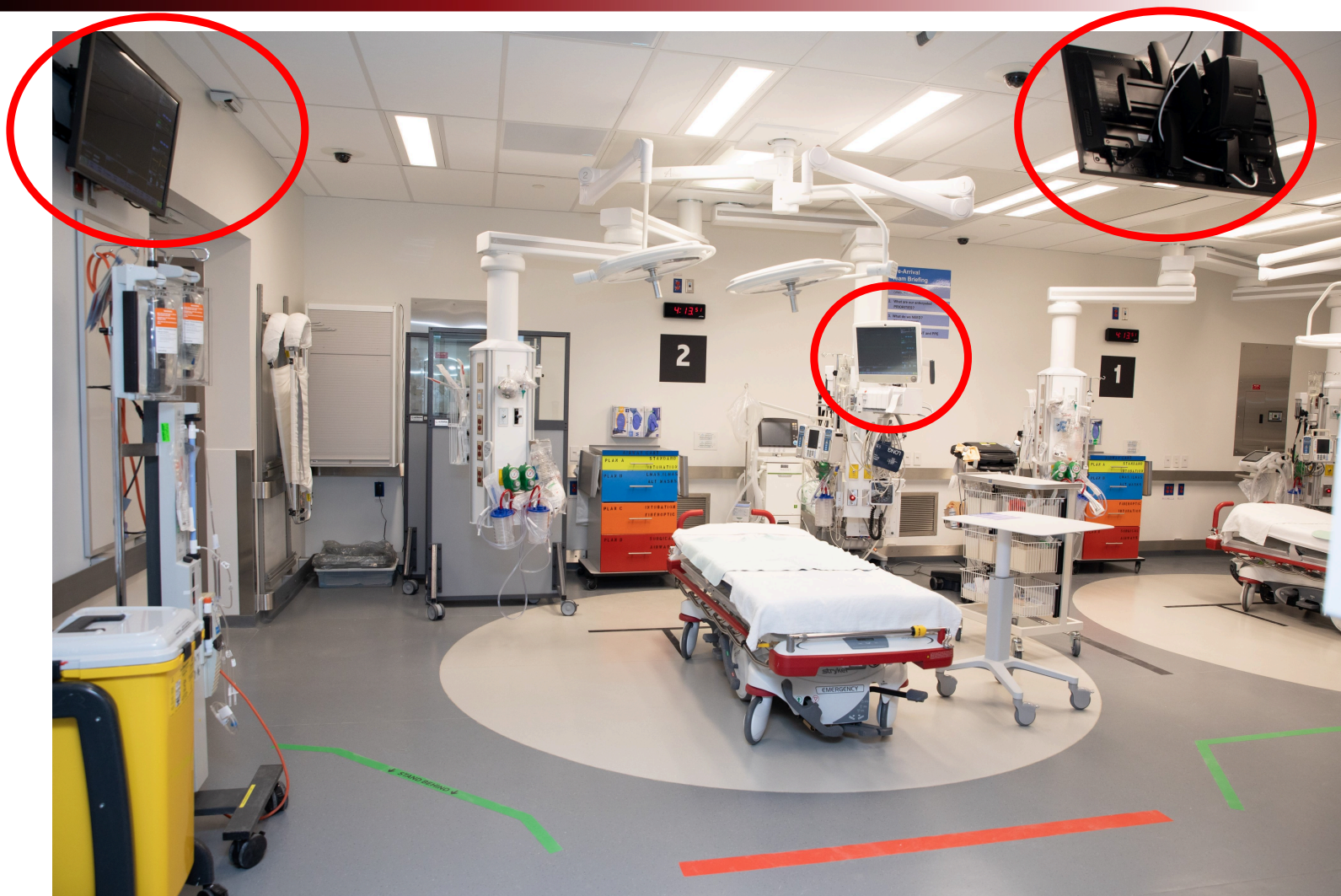
Handling the device

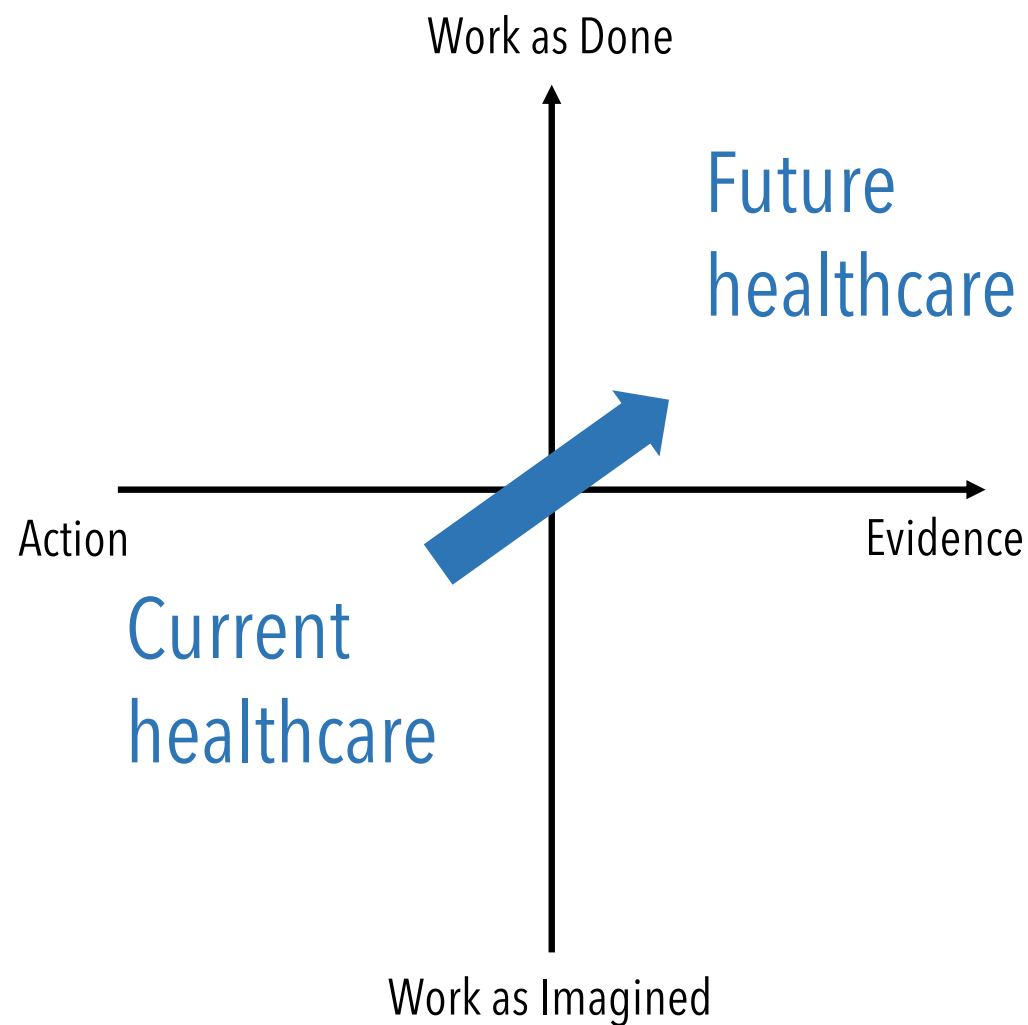


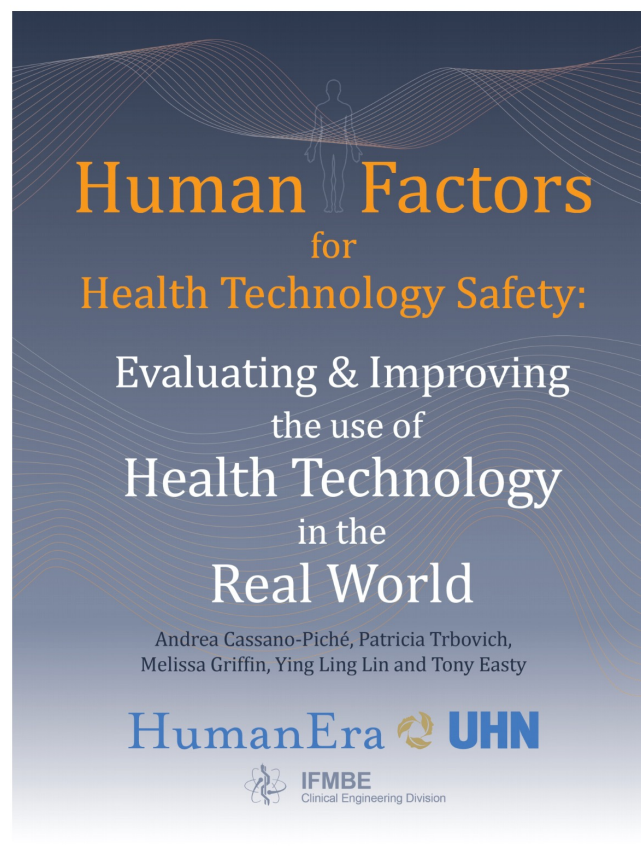
In-Situ Simulation Testing











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Thank you!



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