DESIGNING MEDICAL DEVICES FOR THE LAY USER

Bryant Foster, MS + Maya Gonczi
Research Collective | Tempe, AZ

WHO WE ARE

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ABOUT

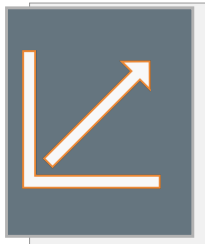
RESEARCH COLLECTIVE

Research Collective is a Human Factors and User Experience research and design consultancy located in Tempe, Arizona.

We partner with top medical device manufacturers and pharmaceutical companies to help them improve the usability and safety of their products.

Our network of human factors experts and user experience professionals help companies make their products easy to learn, efficient to work with, and desirable to use.

WEBINAR OVERVIEW



Why non-professional medical device use is on the rise

Human factors design considerations for medical devices intended for lay users

How to implement the principles of human factors at every phase of development

TOPIC 1

NON-PROFESSIONAL

MEDICAL DEVICE USE IS ON THE RISE

NON-PROFESSIONAL MEDICAL DEVICE USE

Non-Professional medical device

- Device intended for someone without relevant specialized training

Also referred to as devices intended for:

- The layperson
- The lay user
- Non-clinical user
- Home Use

NON-PROFESSIONAL MEDICAL DEVICE USE

THE U.S. POPULATION IS AGING

The elderly are more likely to live with chronic diseases that require daily medical care at home

INDIVIDUALS WITH CHRONIC ILLNESS ARE LIVING LONGER

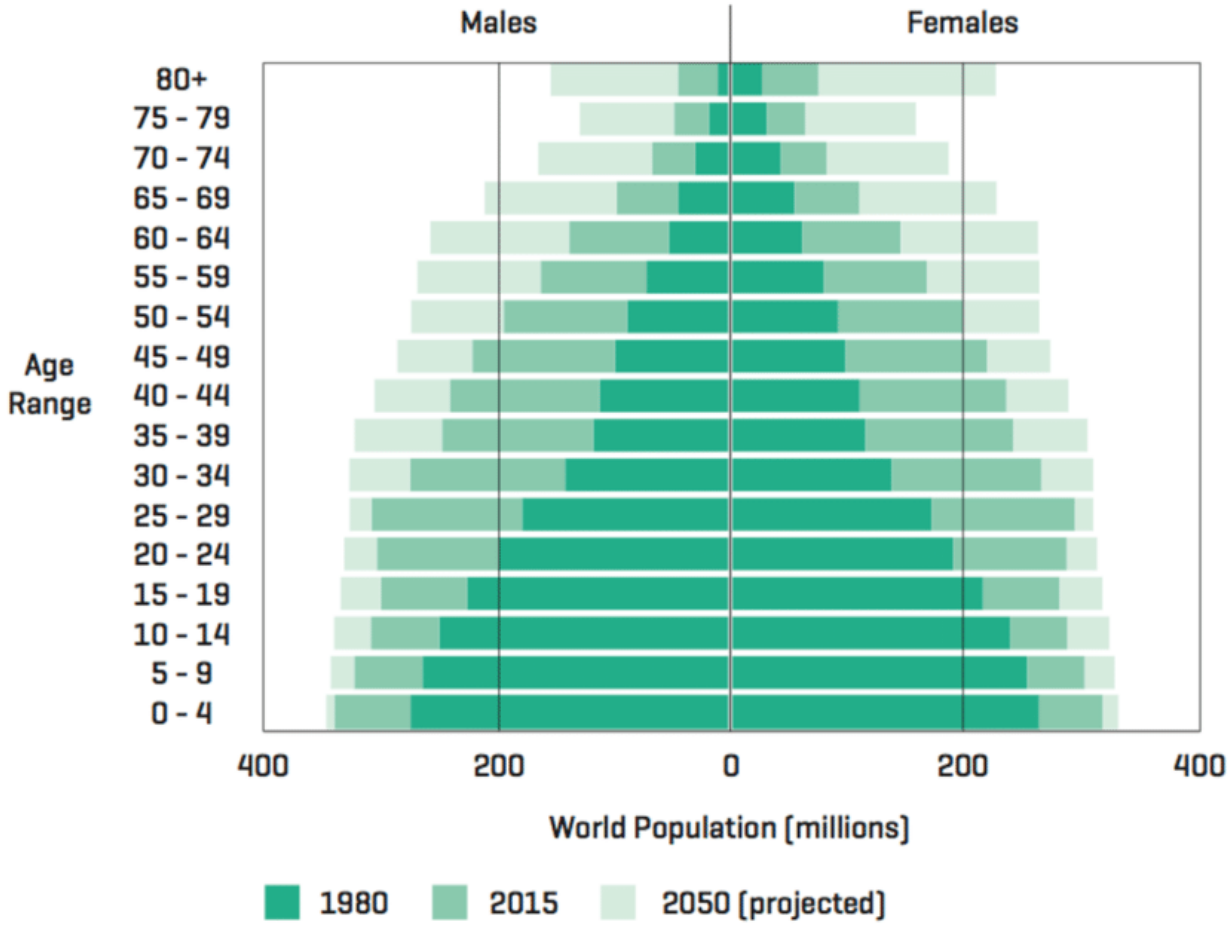
Due to medical advancements, many individuals with chronic diseases are living longer but are dependent on home medical care.

THERE IS AN INCREASING FOCUS ON REDUCING THE COST OF HEALTHCARE

Spurring the growth of the home health care market.

NON-PROFESSIONAL MEDICAL DEVICE USE

THE U.S. POPULATION IS AGING



NON-PROFESSIONAL MEDICAL DEVICE USE

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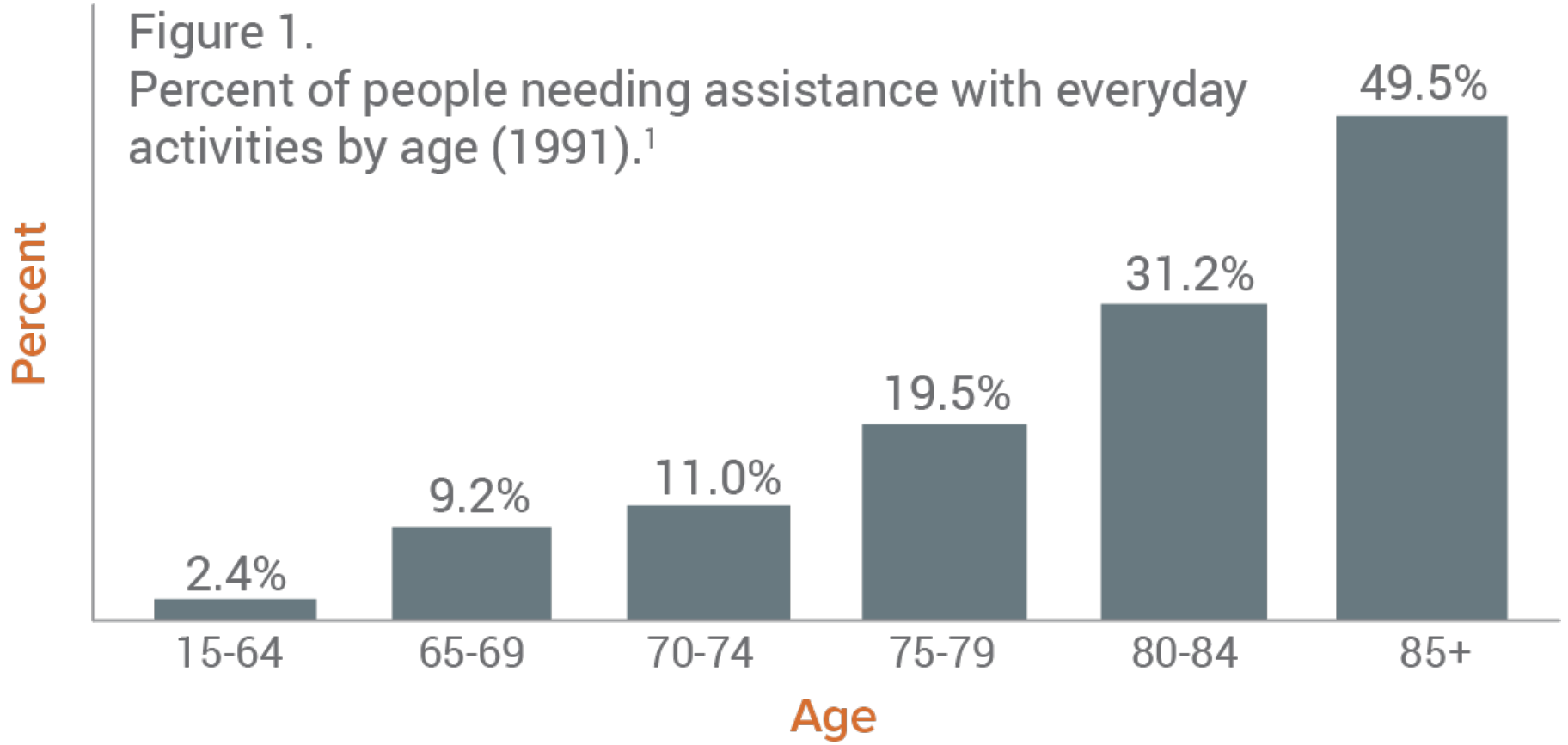

NON-PROFESSIONAL MEDICAL DEVICE USE

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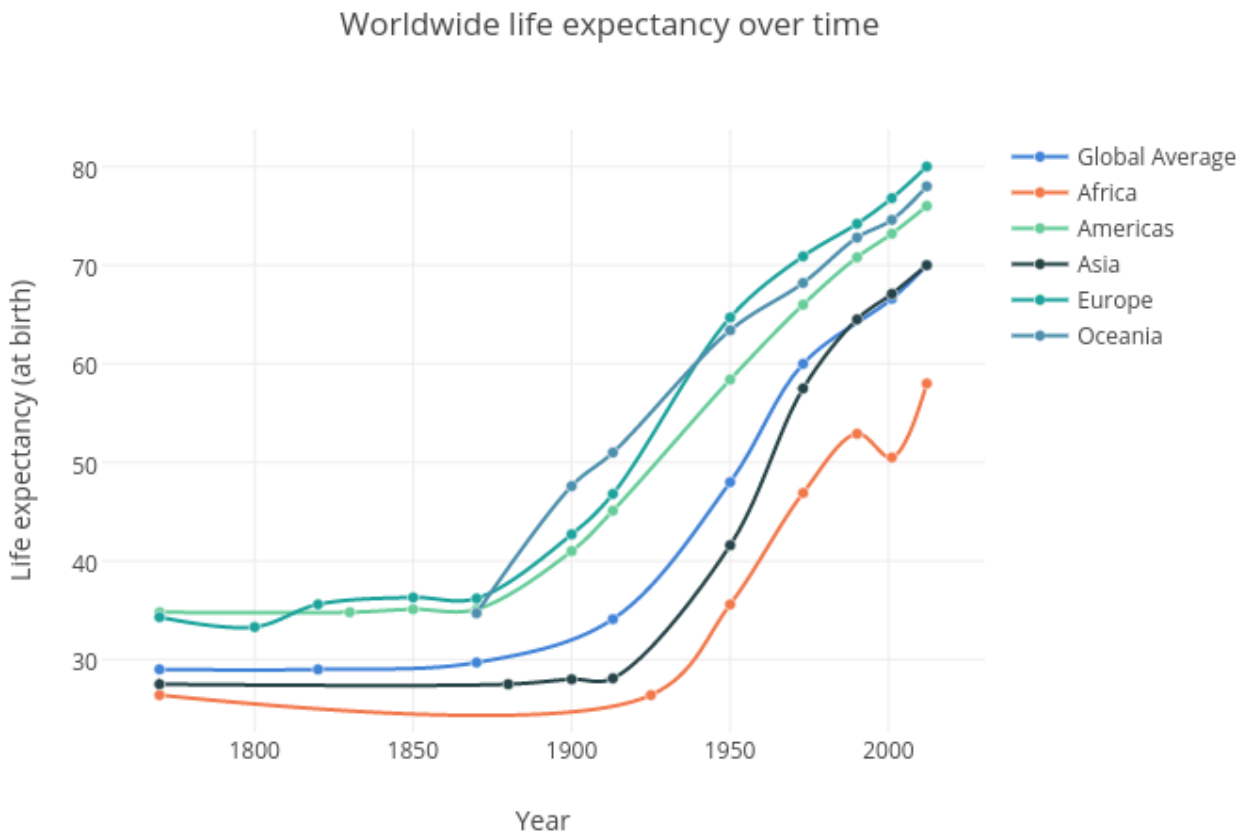
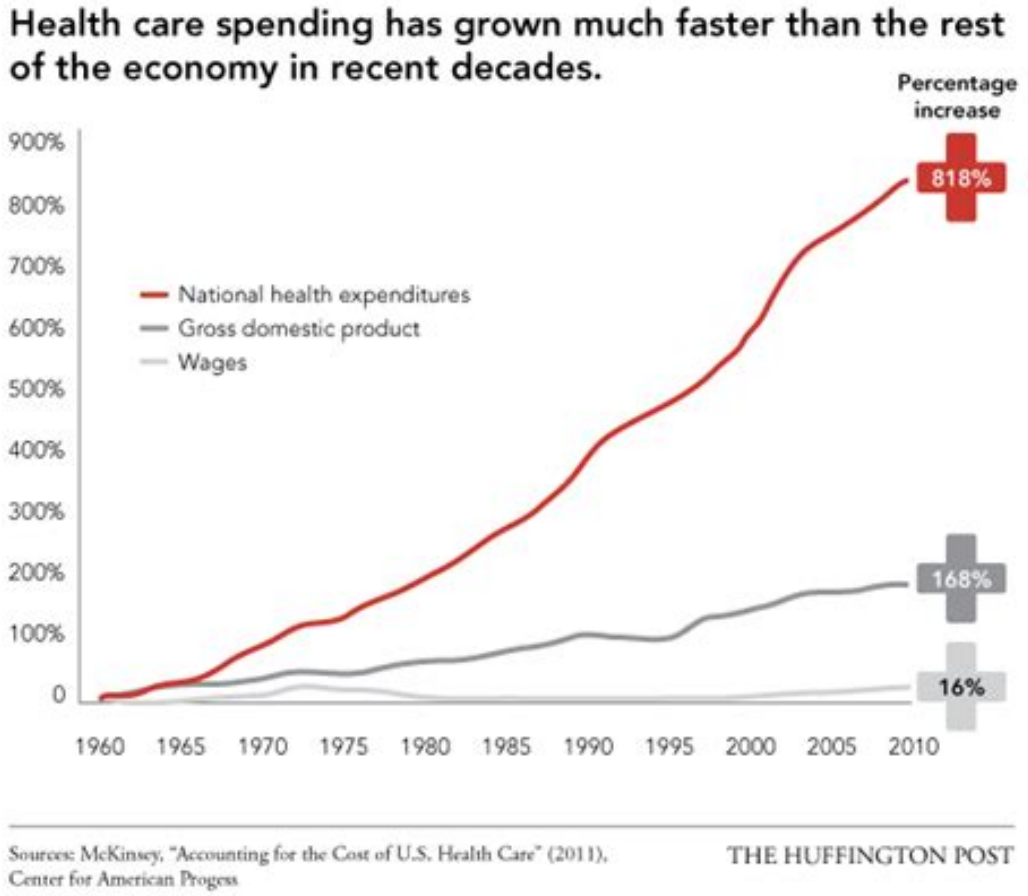


NON-PROFESSIONAL MEDICAL DEVICE USE

THERE IS AN INCREASING FOCUS ON REDUCING THE COST OF HEALTHCARE

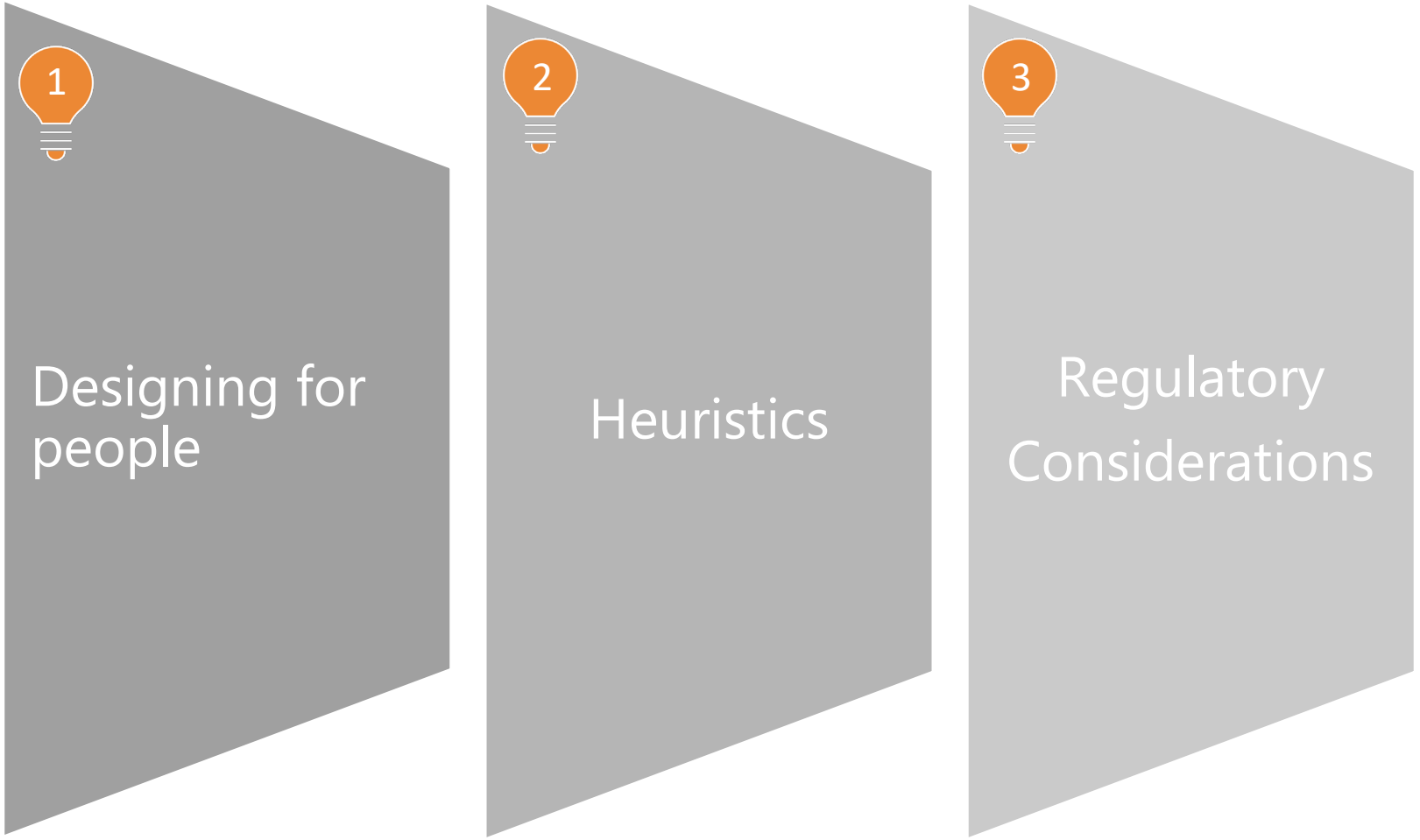


TOPIC 2

HUMAN FACTORS

DESIGN CONSIDERATIONS FOR MEDICAL DEVICES INTENDED FOR LAY USERS

HUMAN FACTORS DESIGN CONSIDERATIONNS



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NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE

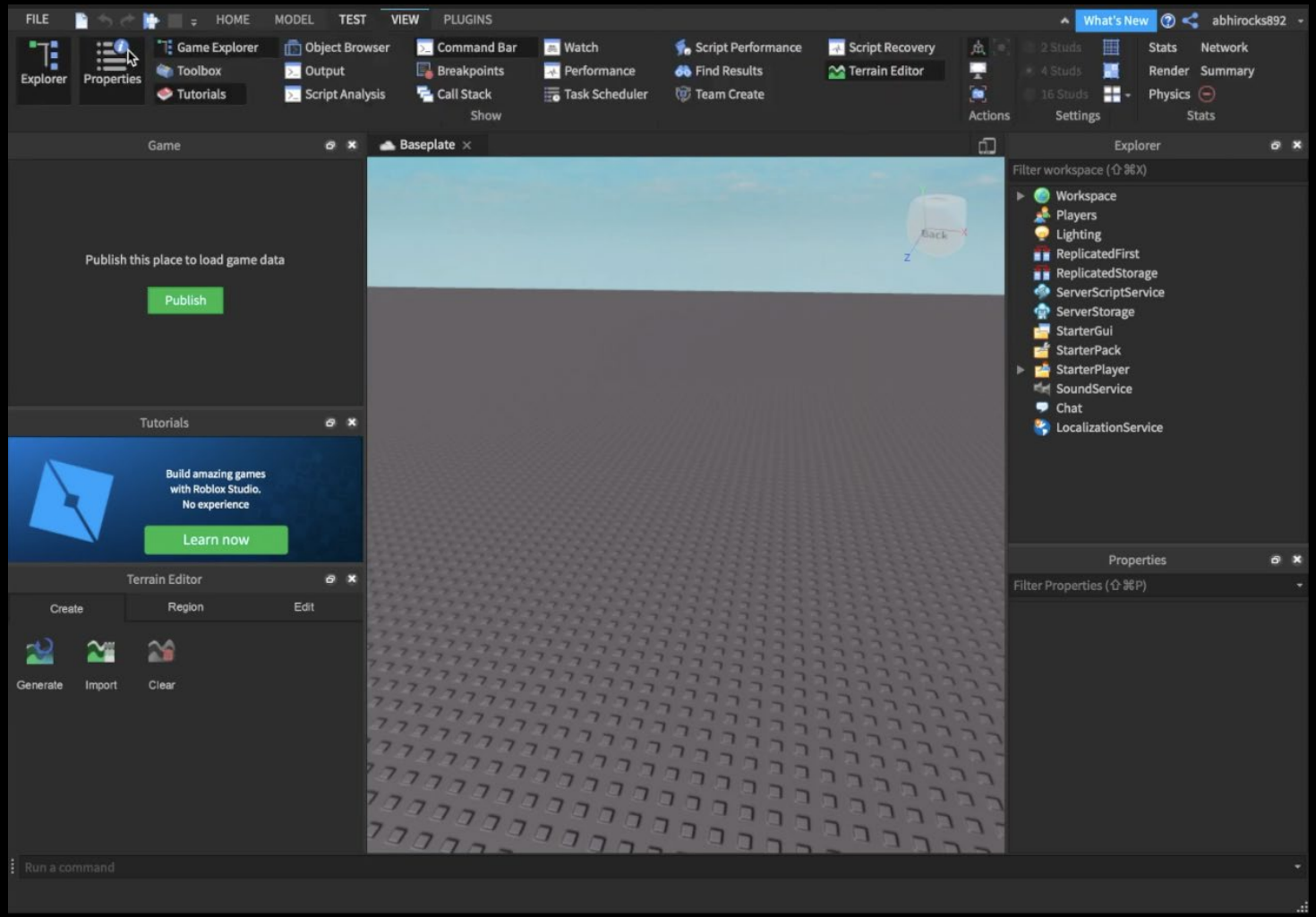
ROBLOX

ROBLOX STUDIO

1

NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE



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NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE

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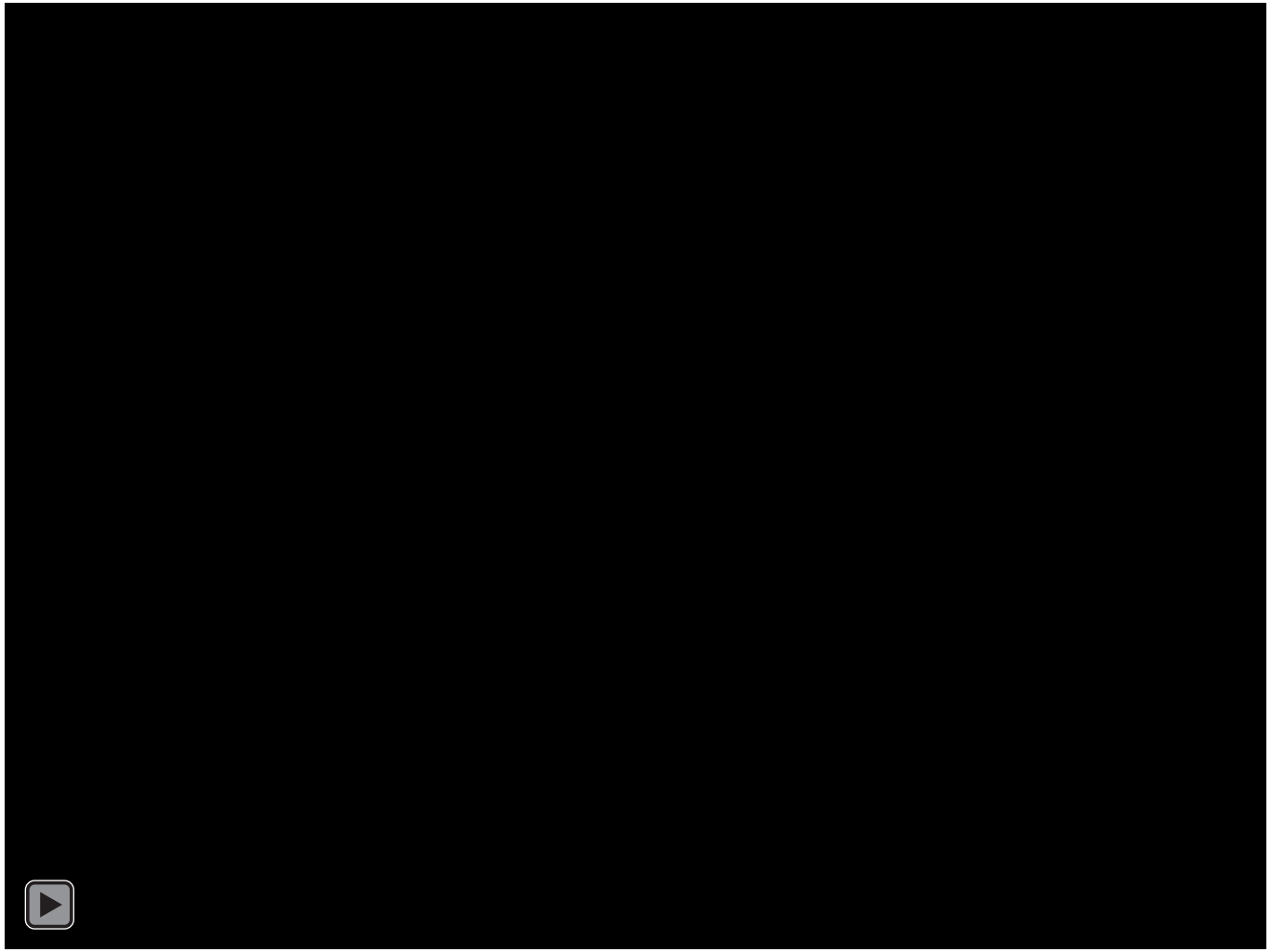
NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE



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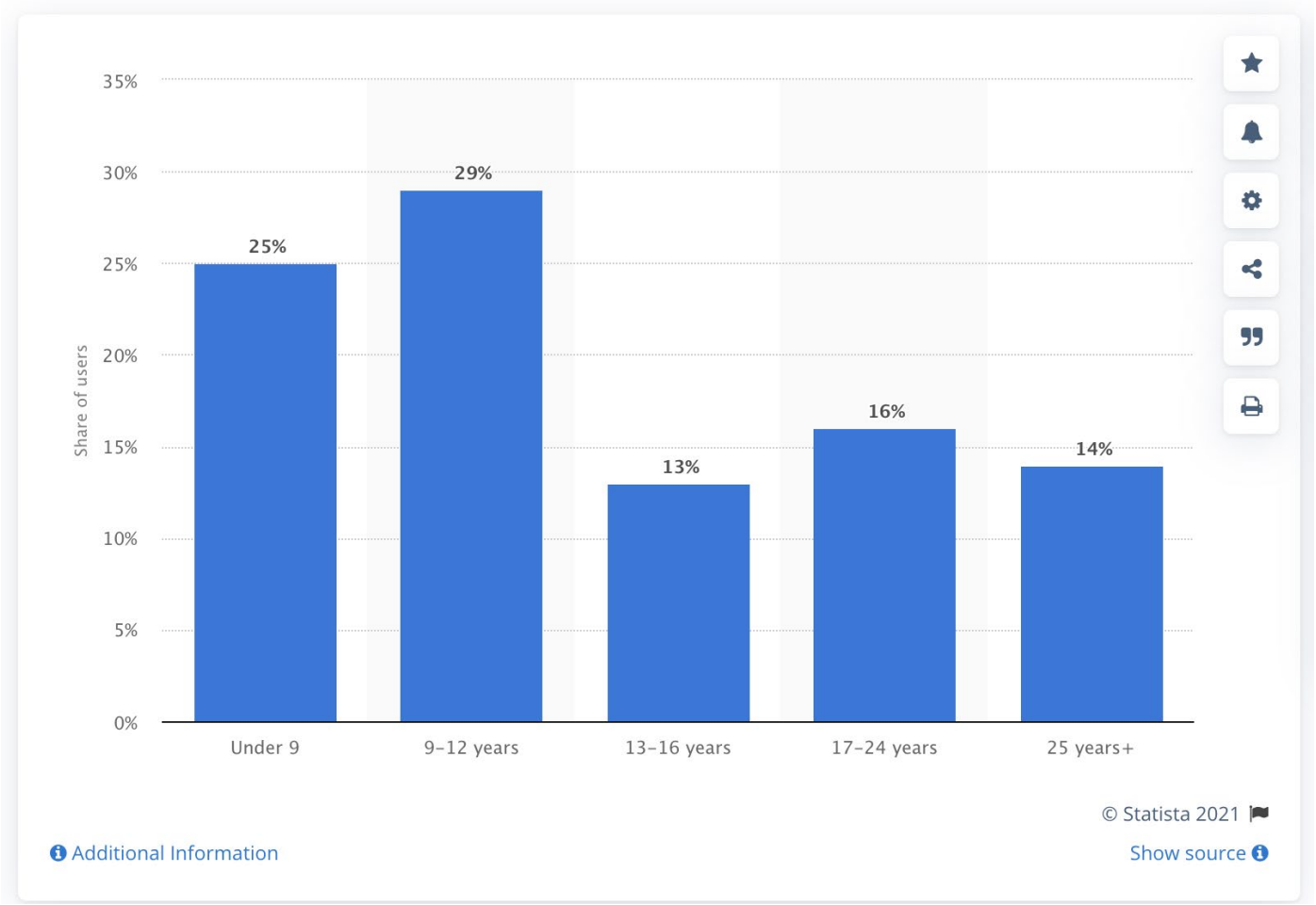
NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE

Distribution of Roblox games users worldwide as of September 2020, by age



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NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE

ANNALS OF MEDICINE NOVEMBER 12, 2018 ISSUE

WHY DOCTORS HATE THEIR COMPUTERS

Digitization promises to make medical care easier and more efficient. But are screens coming between doctors and patients?

By Atul Gawande

November 5, 2018

EHR fatigue has frustrated doctors looking to cut clinical hours

New AMA report finds the weight of technology and administrative burdens is creeping into time physicians need for patient care.

By **Jeff Lagasse** | November 01, 2017 | 11:40 AM

Sep 11, 2014, 01:25pm EDT

5 Things Preventing Technology Adoption In Health Care

Robert Pearl, M.D. Contributor ⓘ
Healthcare

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This article is more than 7 years old.

The Stanford Medicine X conference is one of the most publicized events in health care. Its hashtag #MedX was a top-

It’s easy to
make
things difficult,

but it’s difficult
to make
things easy.

- Alphonse Chapanis

NON-PROFESSIONAL MEDICAL DEVICE USE

DESIGNING FOR PEOPLE

Who are *the people*?

- How much education do they have?
- Do they have any specialized training?
- Do they have any physical limitations?
- Do they have any cognitive limitations?
- What is their emotional state when using the device?

NON-PROFESSIONAL MEDICAL DEVICE USE

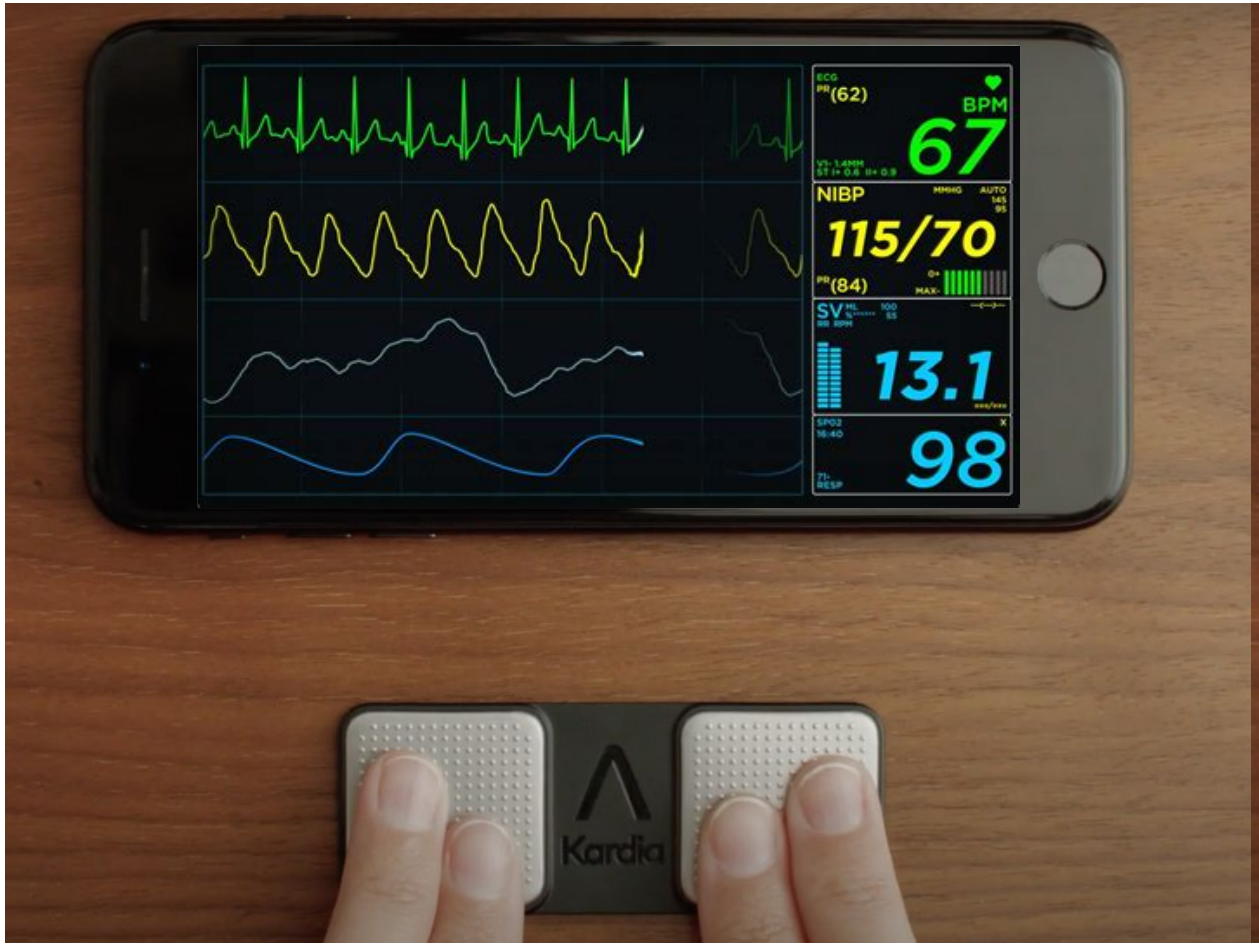
HEURISTICS

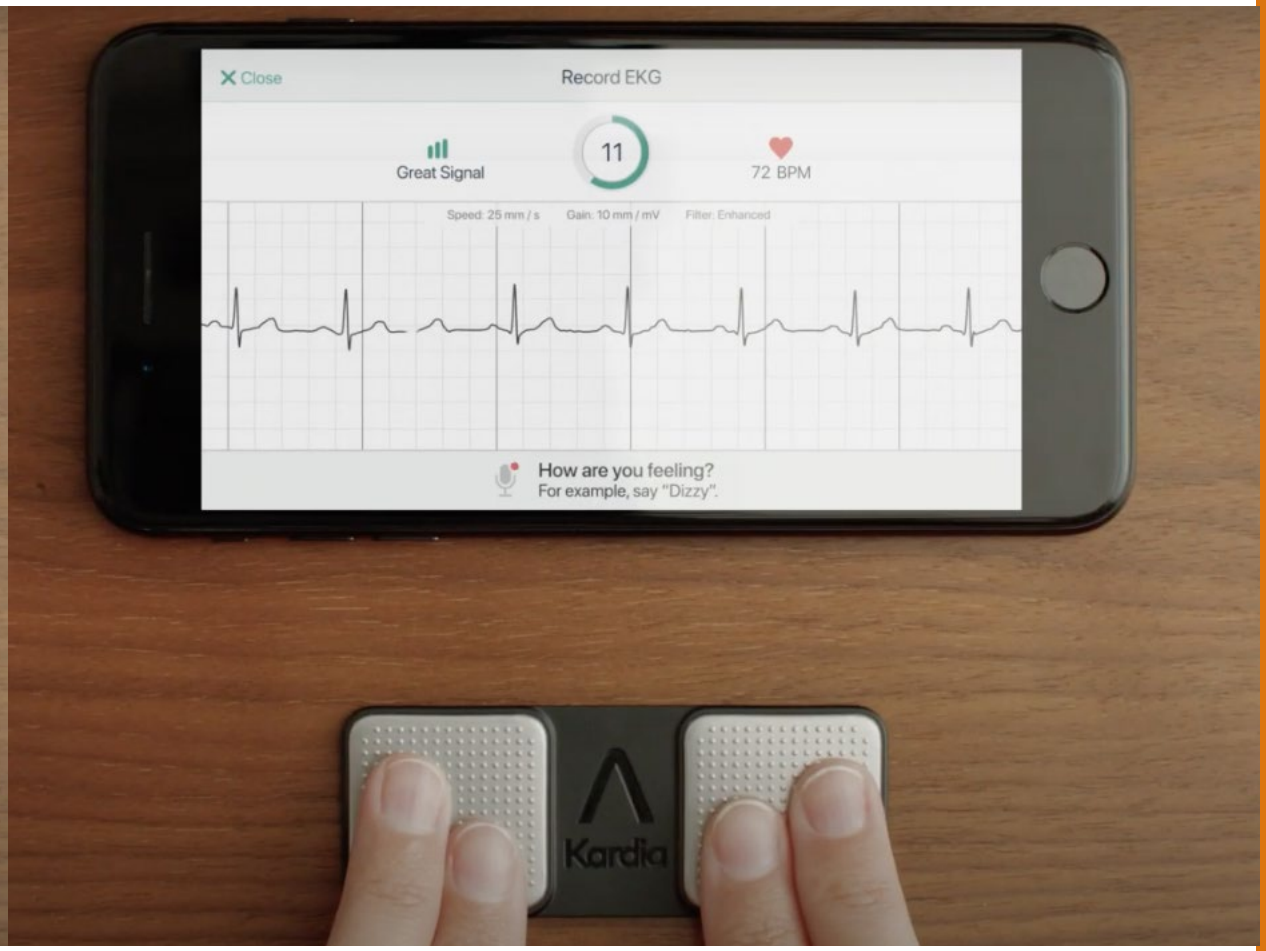
1. Consistency
2. Visibility
3. Match
4. Minimalist
5. Memory
6. Feedback
7. Flexibility
8. Message
9. Errors
10. Closure
11. Undo
12. Language
13. Control
14. Document

2

NON-PROFESSIONAL MEDICAL DEVICE USE

HEURISTICS – VISIBILITY, MATCH





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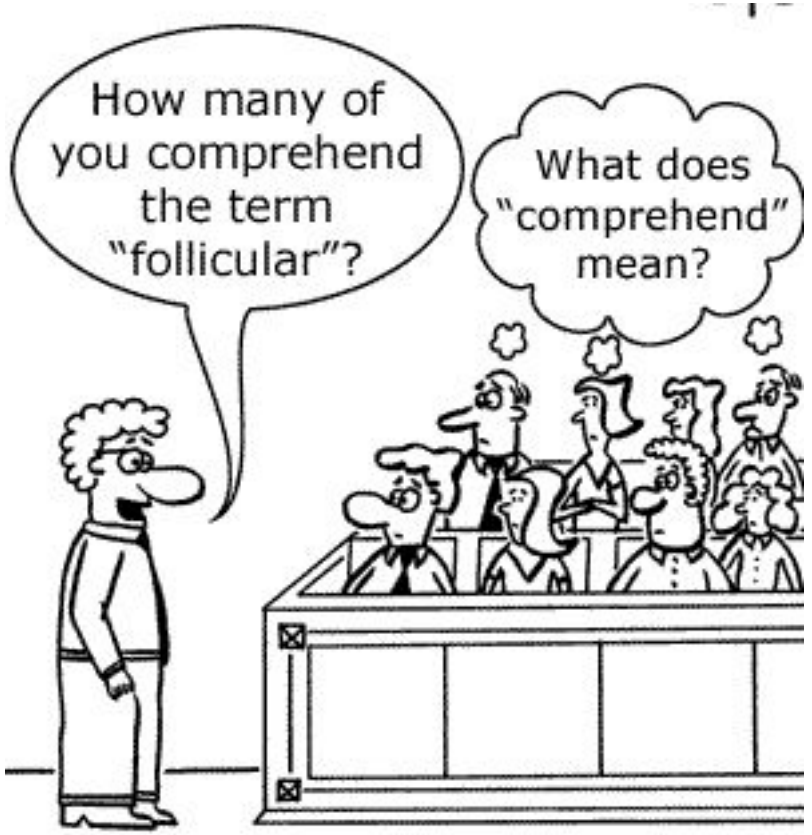
NON-PROFESSIONAL MEDICAL DEVICE USE

HEURISTICS - LANGUAGE



NON-PROFESSIONAL MEDICAL DEVICE USE

REGULATORY CONSIDERATIONS

FDA launched the Medical Device Home Use Initiative in 2010

1. Guidance document
2. Labeling repository
3. Increase awareness

NON-PROFESSIONAL MEDICAL DEVICE USE

REGULATORY CONSIDERATIONS

Design Considerations for Devices Intended for Home Use (FDA)

- Environmental considerations
- User considerations
- Design considerations
  - Lock-out mechanisms
  - Calibration
  - Mechanical
  - Electrical
- Human Factors testing
- Labeling
- Post Market

TOPIC 3

IMPLEMENTING

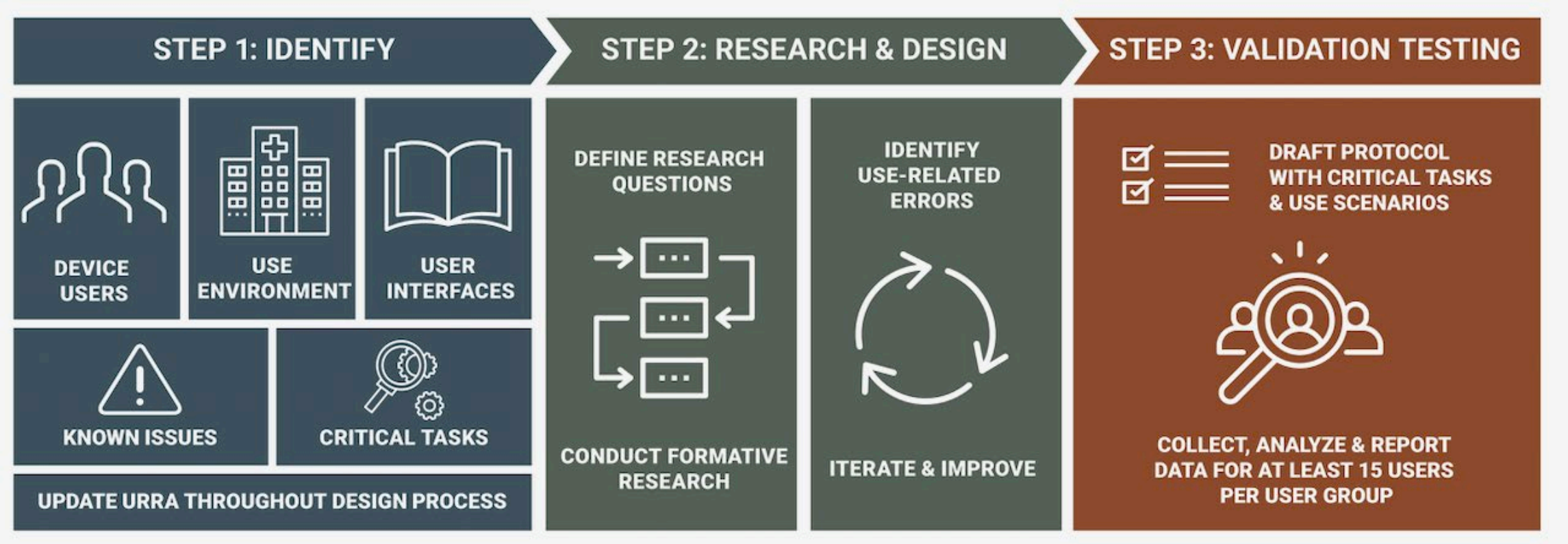
THE PRINCIPLES OF HUMAN FACTORS

IMPLEMENTING THE PRINCIPLES

1. Identify Users, Use Environments
2. Use Heuristics and Regulatory Guidance
3. Conduct research
4. Iterate, improve, test again

IMPLEMENTING THE PRINCIPLES

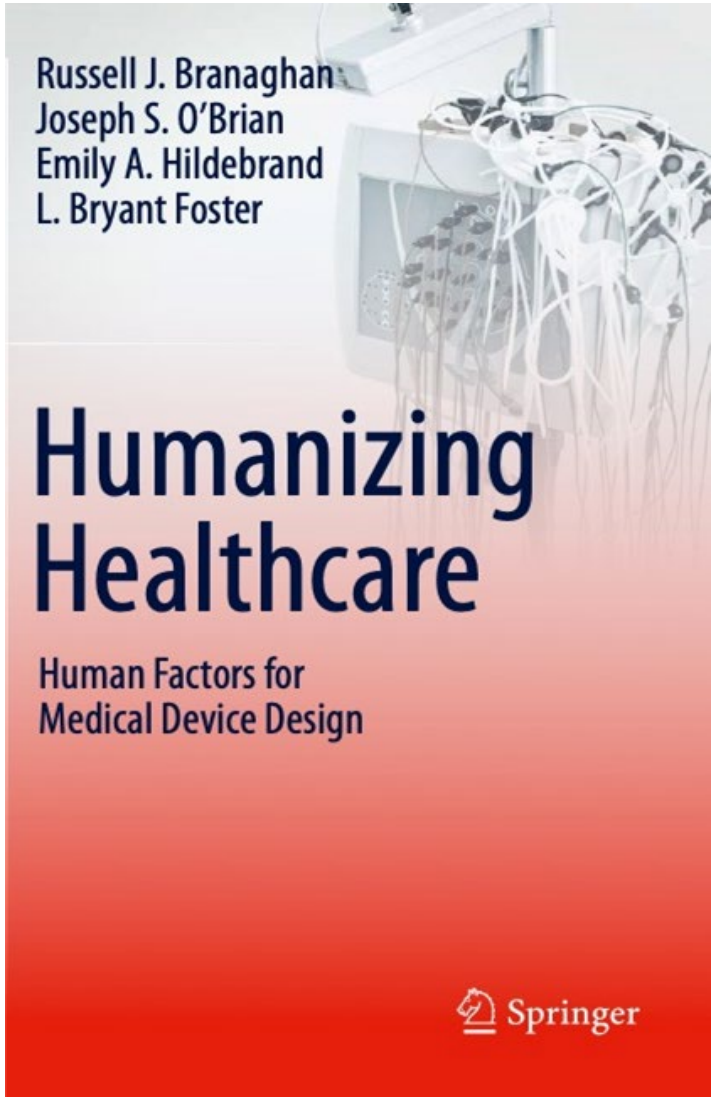
APPLYING HUMAN FACTORS AND USABILITY ENGINERFING TO MEDICAL DEVICES



IMPLEMENTING THE PRINCIPLES

OUR BOOK

- Russ Branaghan, Bryant Foster, Emily Hildebrand and Joe O'Brian, from our team, recently co-authored a book, Humanizing Healthcare
- A comprehensive guide to human factors engineering principles, guidelines, and design methods for medical device design



RESEARCH COLLECTIVE

THANK YOU

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