

Eur^oAsia SPI²

2019 European System, Software & Service
Process Improvement & Innovation

What is Usability Engineering? What is Human Factors?

Presenter:

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What is Human Factors? What is Usability Engineering?

<https://www.youtube.com/watch?v=zSSoYmQS6Ng>

<https://www.youtube.com/watch?v=WqB0fOMX9hM>

What is Human Factors? What is Usability Engineering?

Human factors is the –

“DISCIPLINE OF APPLYING KNOWLEDGE OF HUMAN BEHAVIOUR, METHODS FOR ANALYSIS, TEST AND EVALUATION TECHNIQUES THAT LEAD TO OUTCOMES INCLUDING USABILITY, EASE OF USE, AND SAFE OPERATION WITHIN THE CAPABILITIES AND LIMITS OF THE HUMAN OPERATOR.”

- ☐ *Human factors engineering* is the term used for applying a human factors method to engineering and development of a product – in this case, a medical device, system, platform, process or health-consumer product.
- ☐ Human factors engineering originated in the aerospace industry.
- ☐ It has been included in medical device design processes since it aims to focus upon the human elements that affect safe operation.
- ☐ Human factors engineering processes interact very closely with risk management processes since the primary focus is use safety.
- ☐ It is very obviously focused around human beings!

What is Human Factors? What is Usability Engineering?

Usability Engineering is the –

“APPLICATION OF KNOWLEDGE ABOUT HUMAN BEHAVIOUR, ABILITIES, LIMITATIONS, AND OTHER CHARACTERISTICS TO THE DESIGN OF MEDICAL DEVICES (INCLUDING SOFTWARE), SYSTEMS AND TASKS TO ACHIEVE ADEQUATE USABILITY.”

IEC 62366-1:2015, SECTION 3.17

- ❑ *Usability Engineering* is comparable to *Human Factors Engineering* in its process – most regulators combine both into one process.
- ❑ Usability engineering originated in the consumer industry.
- ❑ It focuses on validating the process of user interaction.



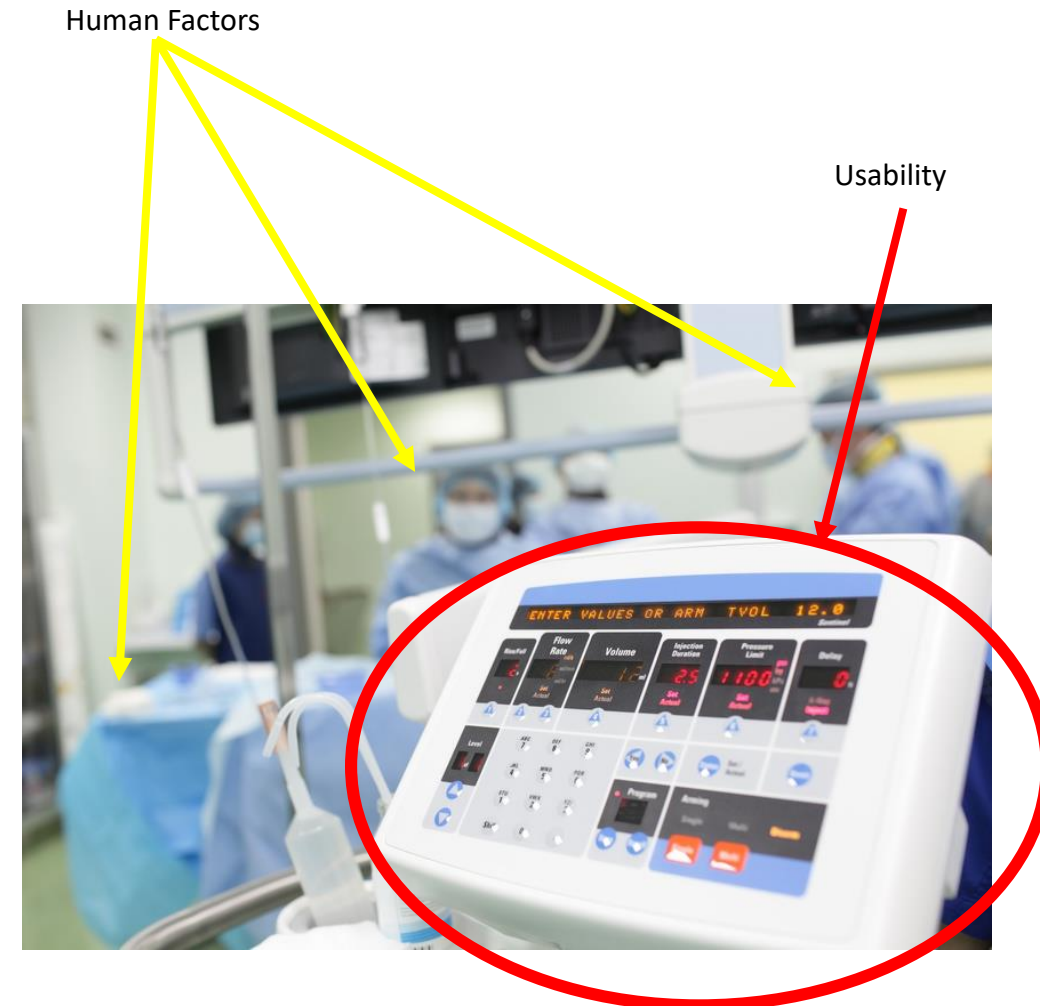
What is Human Factors? What is Usability Engineering?

Points to note:

- ❑ The term “Human Factors (Engineering)” is widely used in the USA.
- ❑ The term “Usability (Engineering)” is widely used elsewhere.

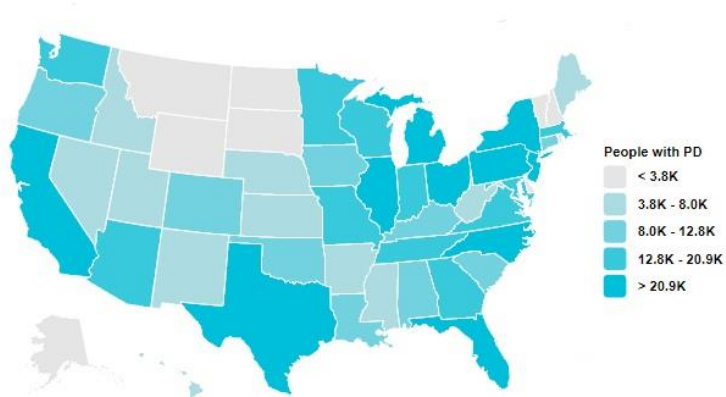
“Which is the correct term to use?”

- ❑ Use “human factors” in design, in development and in post-clinical feedback.
- ❑ Use “usability” when assessing **performance**.
- ❑ Usability engineering is the process of developing a product focused on **user interaction** only.
- ❑ Human factors engineering is often seen as having a **wider scope**, as it encompasses more elements.

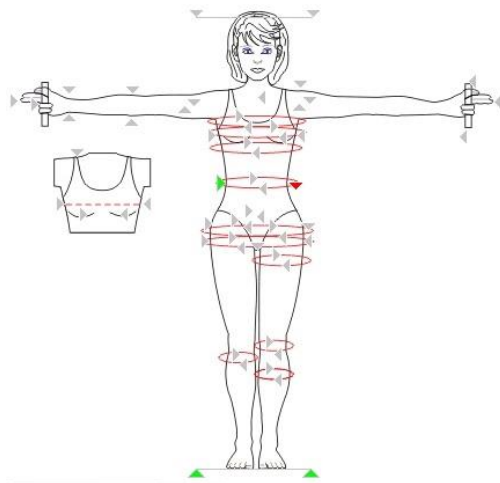


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What are "human factors"?



In more depth...

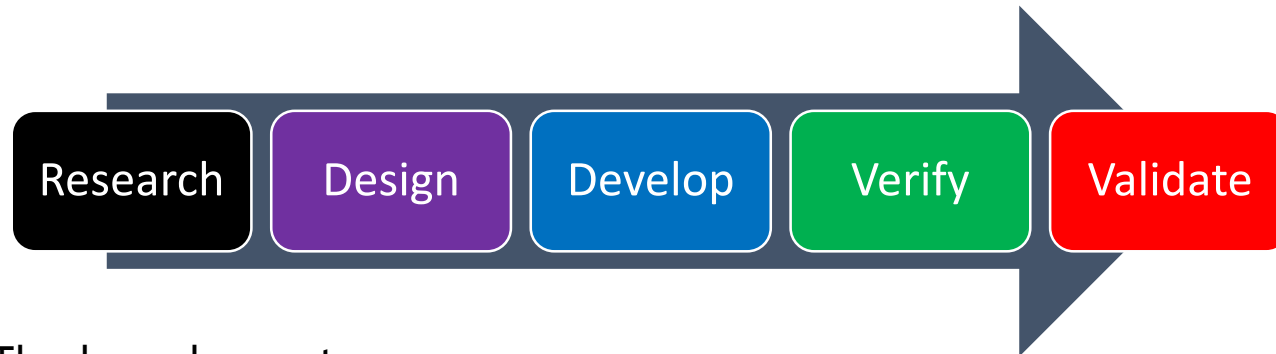


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Regulations

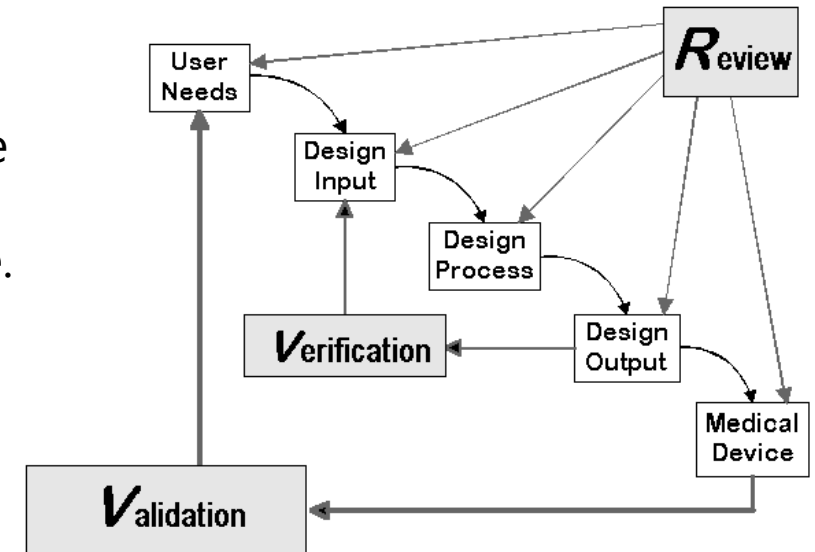
For medical device developments, the most commonly used 'design' method = the US FDA method.

For most medical device developers, compliance to International Regulations such as the **European Medical Device Regulation** (MDR) and the US-based **FDA Design Controls Guidance** (CFR Title 21, Section 820), and to country specific regulations are the most common routes to ensure the development of a *safe* medical device.



The key elements are:

- **User** research.
- Risk Management of **use-based** risks.
- Development and the design of **User Interfaces**.
- Verification and Validation of the medical device with intended **users**, in the intended **use environments**.



The US FDA regulated "Waterfall" design method.
Title 21, CFR, Section 820.

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The Human Factors Engineering and Usability Engineering processes are dependent on the regulation compliance is required for.

The differences are small but all have the same outcome: **mitigation and evidence** to support a rationale of use safety, to ensure the clinical benefit of the medical device outweighs the inherent risks of use. There are 4 common routes:

IEC
62366-1

- ❑ **IEC 62366-1:2015** – *Medical Devices – Part 1: Application of usability engineering to medical devices.*
- ❑ **IEC 62366-2:2016** – *Medical Devices – Part 2: Guidance on the application of usability engineering to medical devices.*

FDA

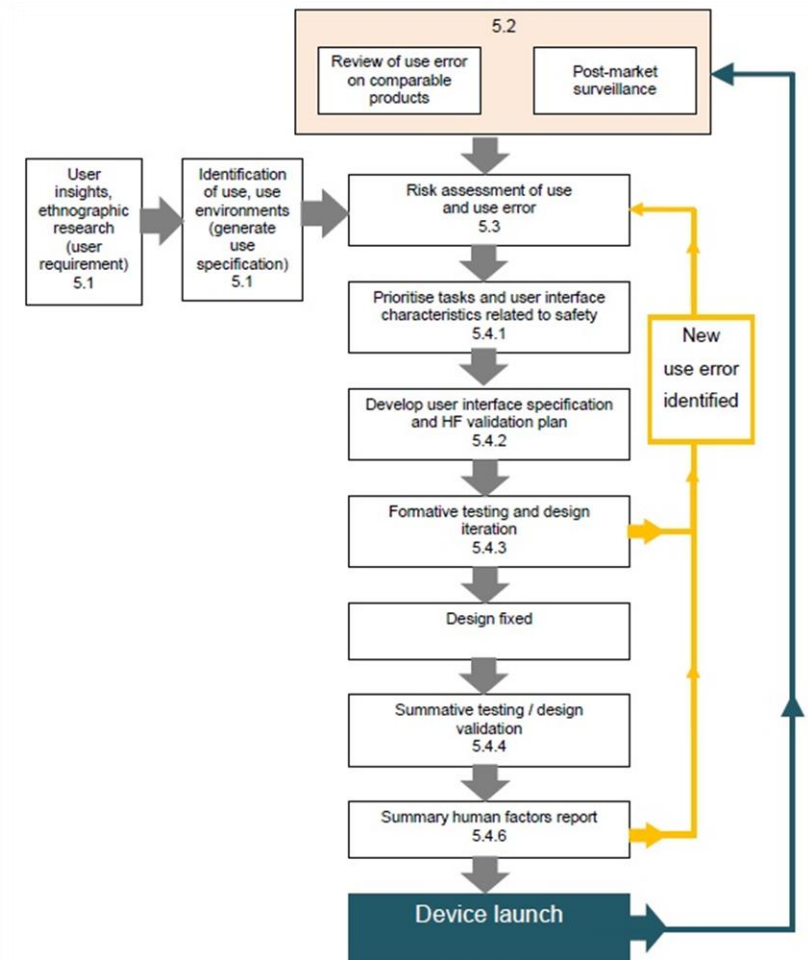
- ❑ **FDA UCM259760:** *Applying Human Factors and Usability Engineering to medical devices – Guidance for Industry and Food and Drug Administration Staff, Feb 2016.*

MHRA

- ❑ **MHRA** *Human Factors and Usability Engineering – Guidance for medical devices including drug device combination products, Sept 2017.*

He-75

- ❑ **(AAMI He-75:2009 R (2013) – Human Factors Engineering: Design of Medical Devices.)**



The MHRA Human Factors and Usability method.

Source: Human Factors and Usability Engineering – Guidance for medical devices including drug device combination products.

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Enhanced ergonomics

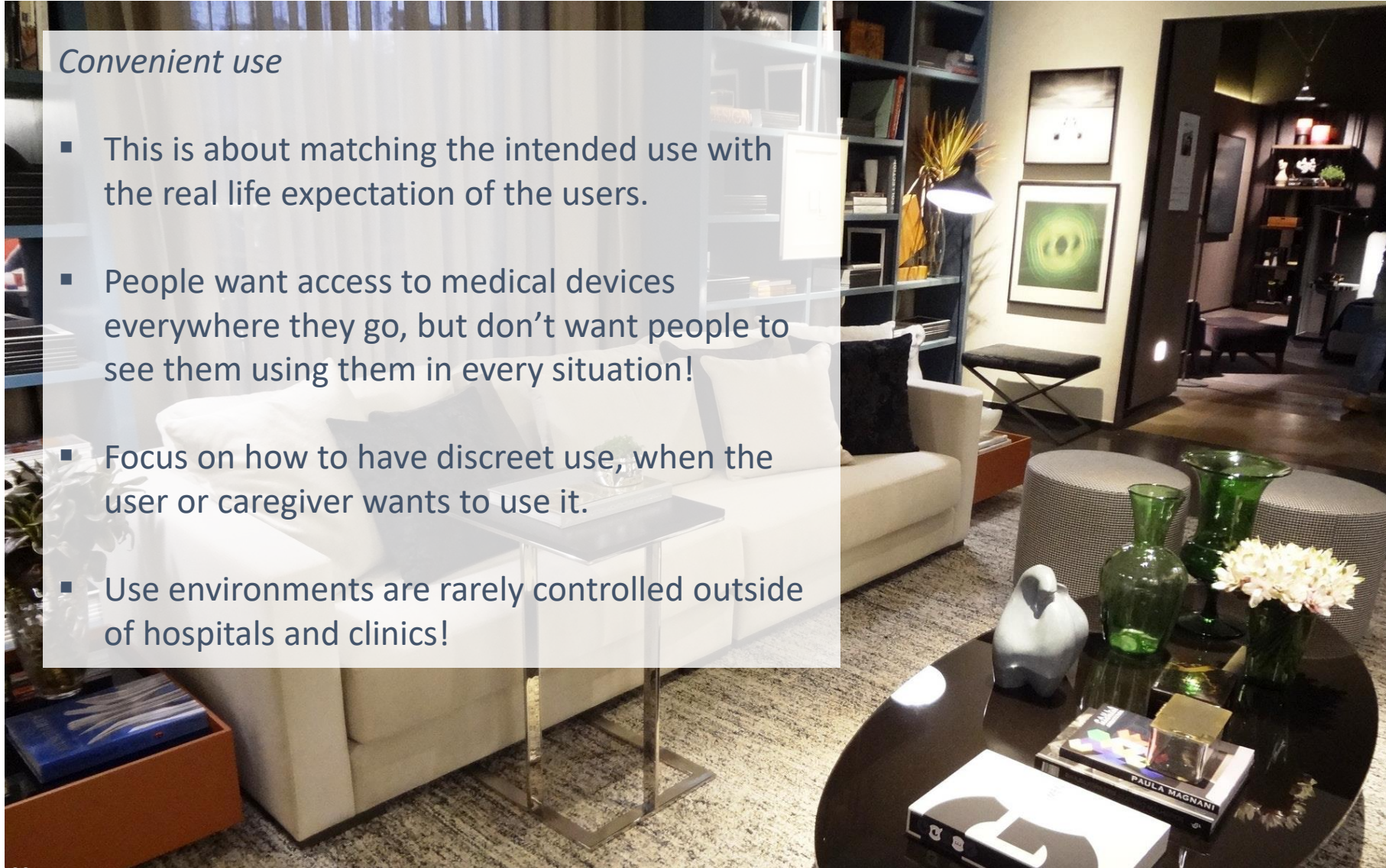
- Really understand global variability in the biomechanics and anthropometric capabilities of the users, caregivers and patients.
- Make medical devices stylish as well as ergonomic - focus on consumer-led aesthetics.
- Prioritise information the user needs to see on the medical device.
- Reduce preparation, activation and retirement tasks for patient users.



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Convenient use

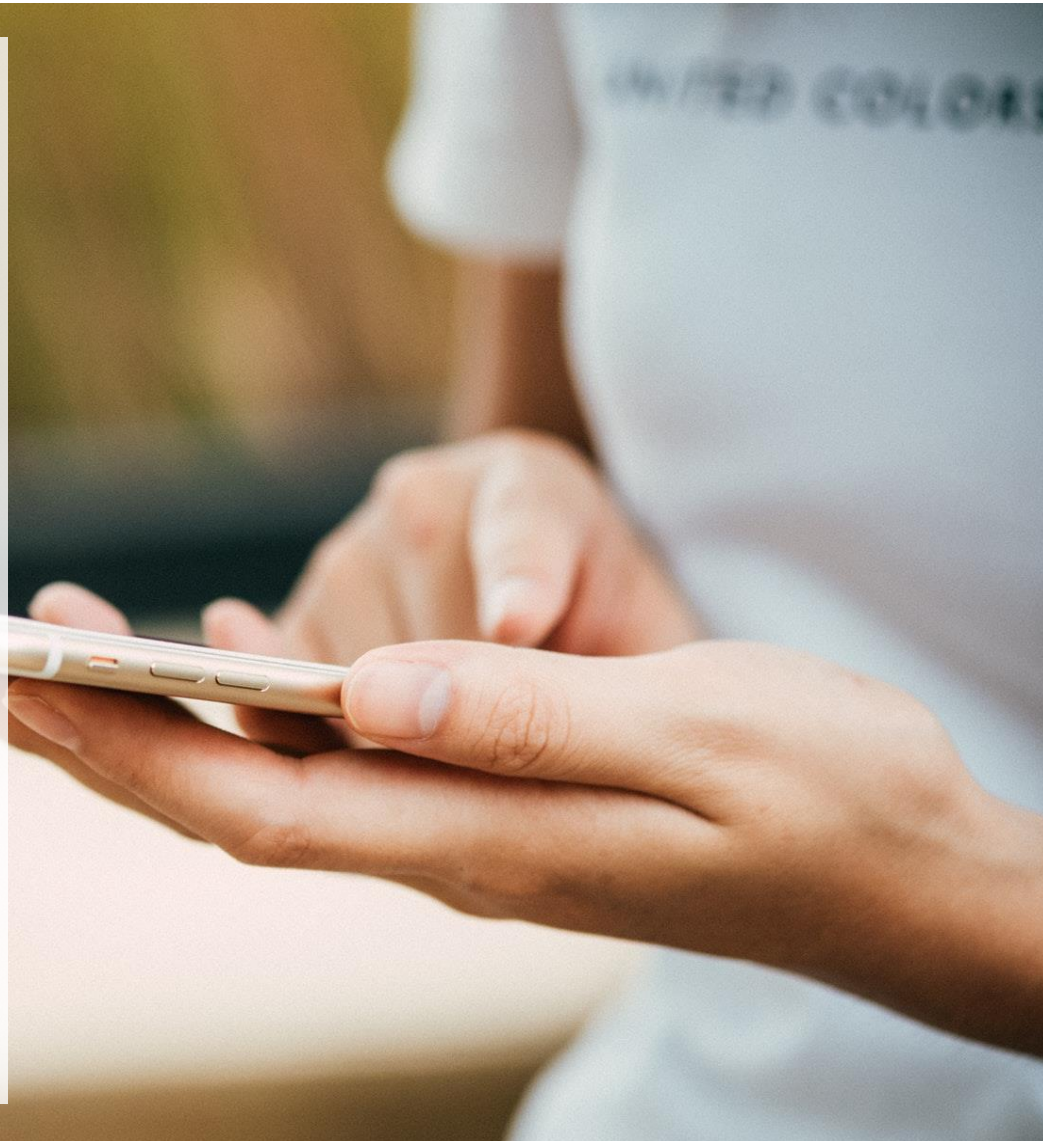
- This is about matching the intended use with the real life expectation of the users.
- People want access to medical devices everywhere they go, but don't want people to see them using them in every situation!
- Focus on how to have discreet use, when the user or caregiver wants to use it.
- Use environments are rarely controlled outside of hospitals and clinics!



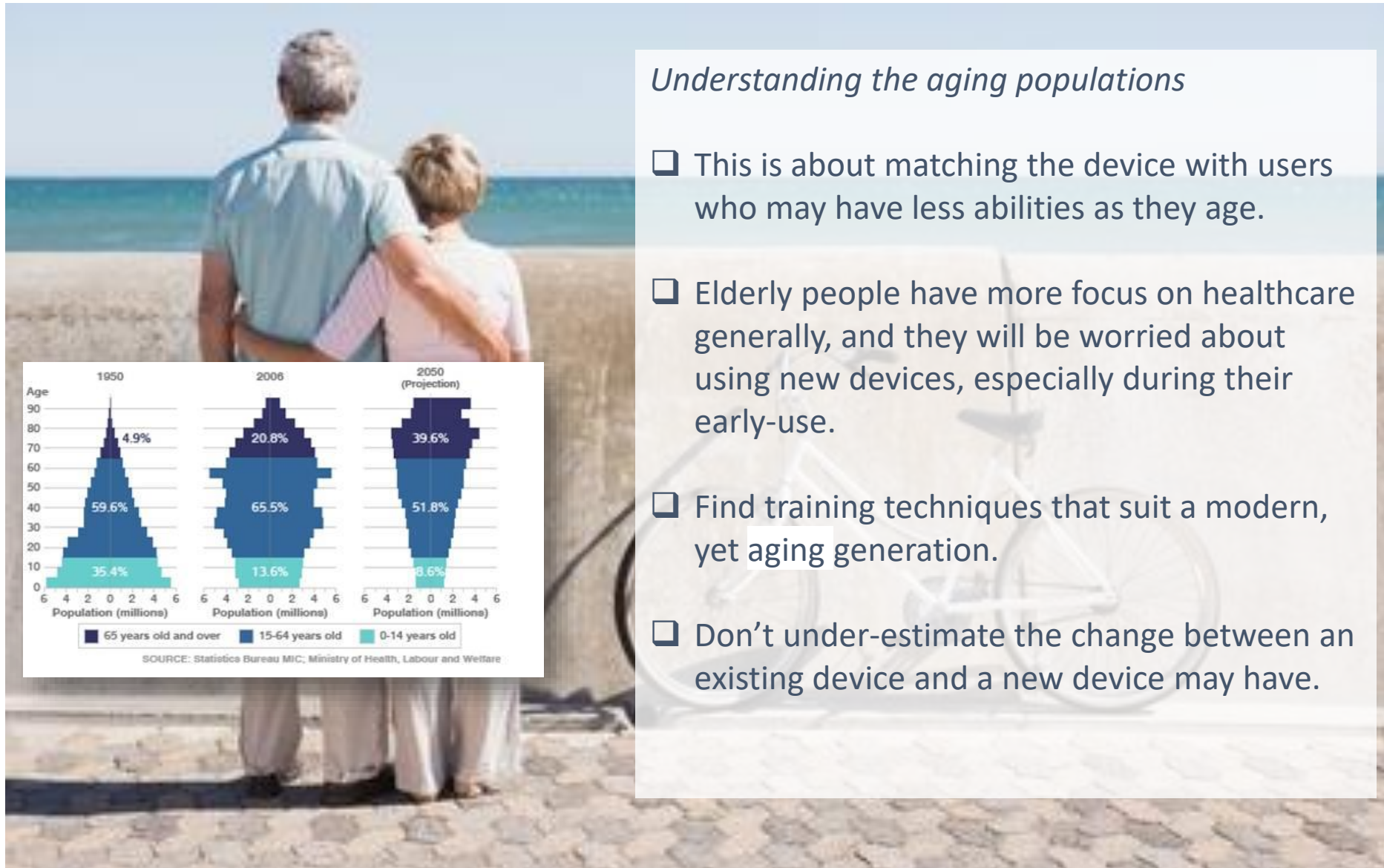
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Apps and Connected devices

- Not all users will want to use an app or a Smart device to collect data, monitor use or use for reminding them to use a medical device. But some do!
- Target specific user types if technology is going to be used to assist with compliance and control.
- Medical apps often have a short life – this should be considered
- The FDA has separate guidance for Healthcare Applications.



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Understanding the aging populations

- ☐ This is about matching the device with users who may have less abilities as they age.
- ☐ Elderly people have more focus on healthcare generally, and they will be worried about using new devices, especially during their early-use.
- ☐ Find training techniques that suit a modern, yet aging generation.
- ☐ Don't under-estimate the change between an existing device and a new device may have.

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Websites & Social Media use

- This is where people will look for information more and more!
- Understand what people want to use before embarking on a format with the medical device. Users may want more than one format – website, app, Facebook group, Twitter feed, download etc.
- Users turn to websites when there is confusion – use the human factors engineering process to determine where this confusion may lie, and action it!

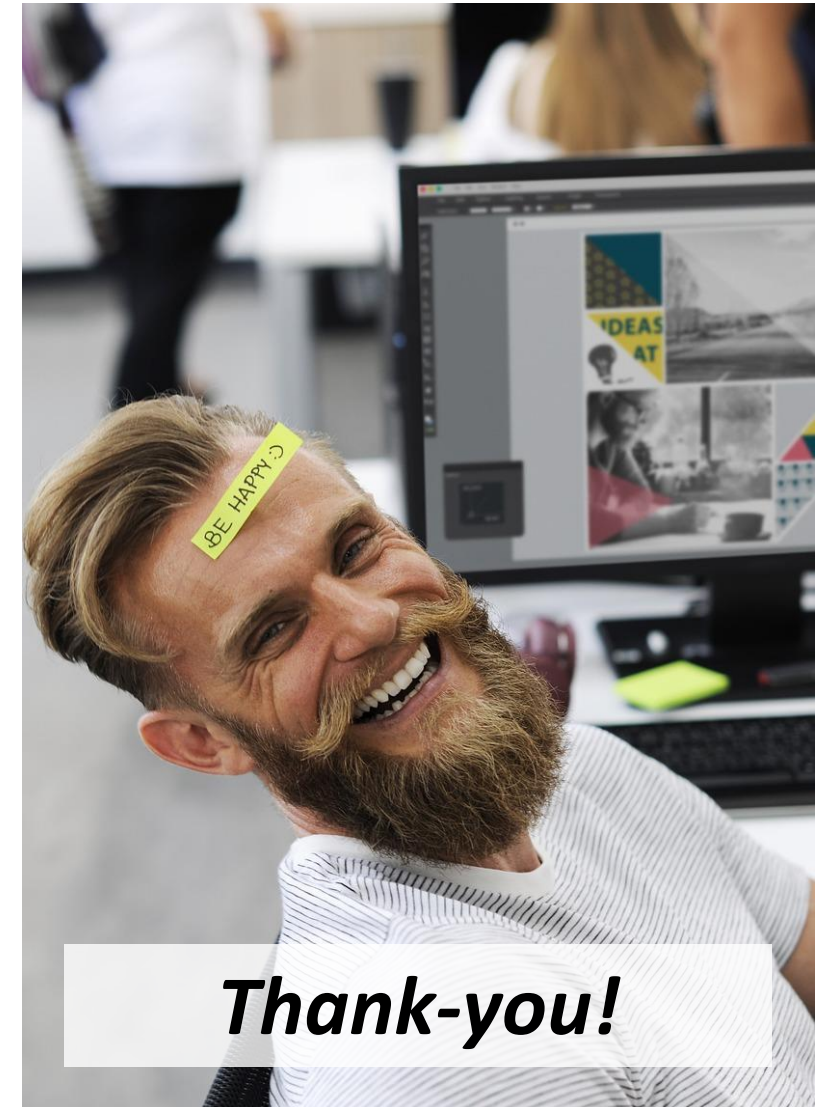
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Including Usability and Human Factors (Engineering) into the development of a medical device can only enhance it and make it suited to its intended users, use environments and scenarios of intended use.

Usability and human factors incorporated into a medical device:

- ❑ Can improve the **use-safety** inherent in the *design* of the medical device.
- ❑ Can aid the long-term **compliance** of using the medical device (very important for expensive devices, or for medicine / drug adherence).
- ❑ Can show an **economic benefit** in using the medical device against existing medical devices.
- ❑ Can be clinically more **effective** and efficient than existing technologies.
- ❑ Can enable a higher **acceptance** of the medical devices when launched and used for the first time.
- ❑ Can determine a higher level of **ease of use** than predicate medical devices.
- ❑ Can enable a better **user experience** than with existing technologies.



Thank-you!