Safety and usability

Dr Leandro Pecchia

WARWICK

Medical Equipment Design
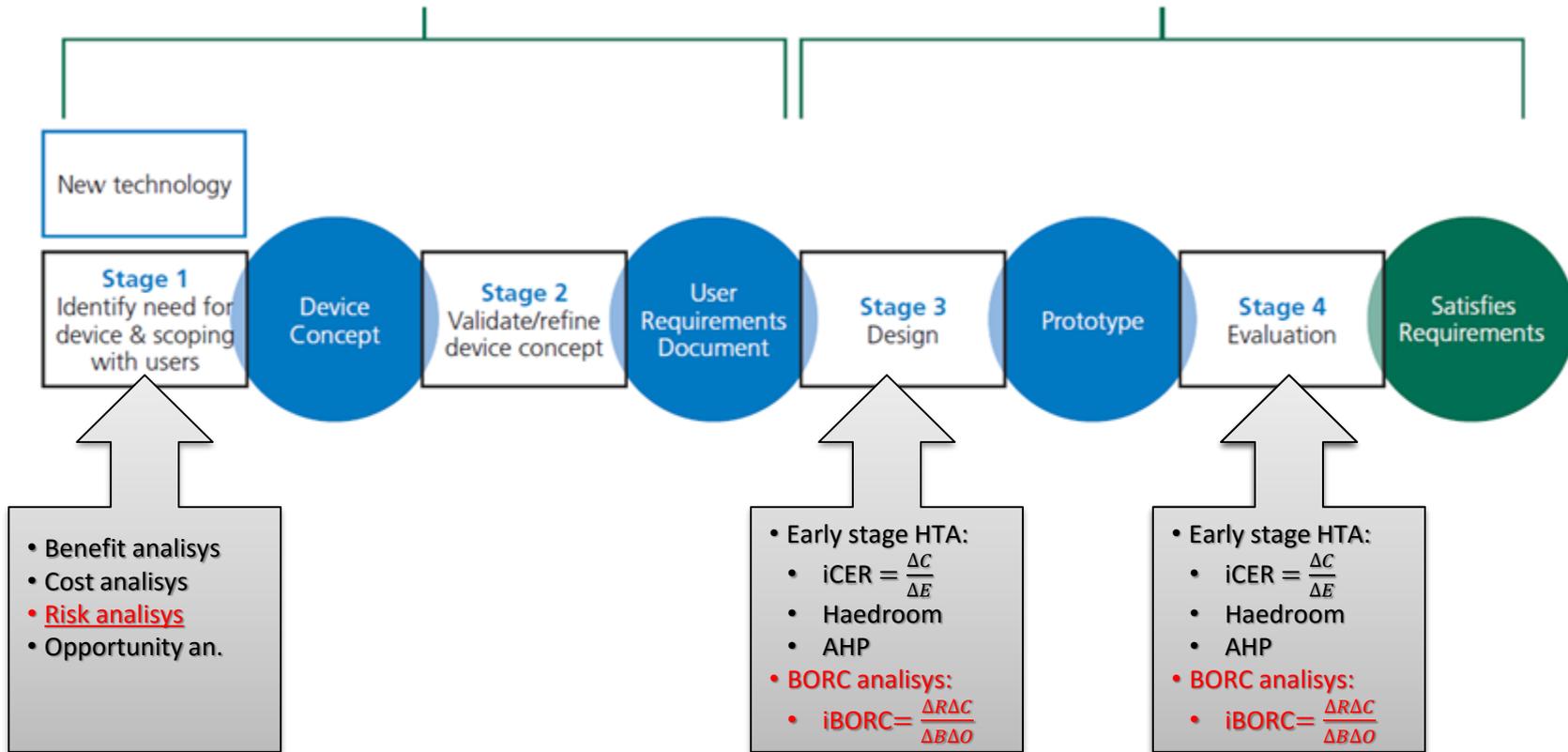## *Design process and user needs*

Identifying requirements

Ensuring device meets requirements

New technology

Stage 1 Identify need for device & scoping with users

Device Concept

Stage 2 Validate/refine device concept

User Requirements Document

Stage 3 Design

Prototype

Stage 4 Evaluation

Satisfies User Requirements

- Focus groups
- Ethnography
- Contextual inquiry
- Task analysis
- Questionnaires
- Interviews
- Usability tests

- Focus groups
- Interviews
- Questionnaires
- Delphi technique
- Contextual inquiry
- Task analysis

- Scenarios
- Personas

- Usability tests
- Cognitive walkthrough
- Heuristics
- Focus groups
- Questionnaires
- Interviews

Key: ☐ Stage of development ● Target/outcome ⬆ Recommended methods

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NHS
National Patient Safety Agency

Medical Equipment Design

Design process and safety

Identifying requirements

Ensuring device meets requirements

New technology

| Stage 1 Identify need for device & scoping with users | Device Concept | Stage 2 Validate/refine device concept | User Requirements Document | Stage 3 Design | Prototype | Stage 4 Evaluation | Satisfies Requirements |

- Benefit analisys
- Cost analisys
- Risk analisys
- Opportunity an.

- Early stage HTA:
  - iCER $= \frac{\Delta C}{\Delta E}$
  - Haedroom
  - AHP
- BORC analisys:
  - iBORC $= \frac{\Delta R \Delta C}{\Delta B \Delta O}$

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Medical Equipment: peculiarities

Devices	Drug
Principal action	
Other than principally drugs	Pharmaco./Immunologic/Metabolic
Mechanical/Electromagnetic/Materials	Chemical based
Product life cycle	
Short life cycle	Long life cycle
Constantly evolving components/parts	Unchanging compound
Clinical evaluation	
Difficult to blind (no placebo)	Easy to blind
Multiple end users	Usually one end users
Long learning curve	Short learning curve
Strongly dependent by settings/users	Less dependent by settings/users
Complex to standardize for RCT	Easy to standardize for RCT
Use issues	
User-dependent efficacy	Efficacy is less user-dependent
Often require intensive training	Usually do not require training
Complication decrease with use	Complication increase with use
Diversity	
Mainly small companies/few large co.	Mainly large multinationals
Diagnostic or therapeutic	Therapeutic
Costs	
Varying overheads/slow return	High overheads with quicker return
Higher distribution costs	Lower distribution costs
Higher maintenance/installation costs	No maintenance/installation

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Medical Equipment: design process
A systems approach: The Onion model of Healthcare

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A systems approach: The Onion model of Healthcare

Groups/fun

- Nurses/
- Drs /dia
- Patients
- Family/t
- Carers /
- Pharma
- Technic
- Cleaner
- Porters/

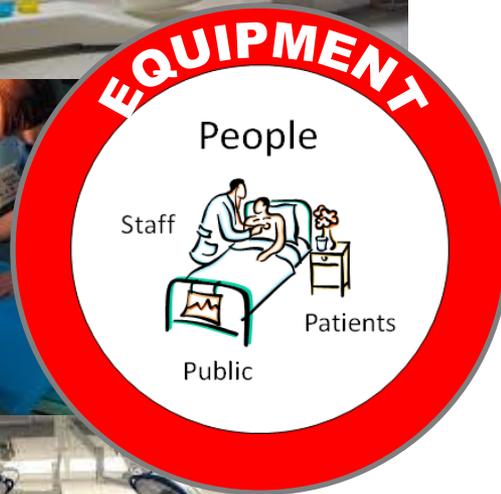© 2000 Randy Glasbergen.
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"THE COMPUTER SAYS I NEED TO UPGRADE MY BRAIN
TO BE COMPATIBLE WITH ITS NEW SOFTWARE."

Medical Equipment: design process
A systems approach: The Onion model of Healthcare

- Compatibility

- Multi-functionality

- Non-standard equipment

- Adaptations / Modifications

- Consumables

- Parts (batteries, etc)

- Portable equipment

- …

Medical Equipment: design process
A systems approach: The Onion model of Healthcare

- Prognosis
- Diagnosis
- Medical Therapy
- Surgery Therapy
- Monitoring
- Follow-up
- Rehabilitation

Medical Equipment: design process
A systems approach: The Onion model of Healthcare

WORKSPACE
TASK & JOBS
EQUIPMENT

People

Staff

Patients

Public

- Admission

- Outpatient ambulatory

- Ward

- Emergency Unit

    - Storage

- Surgery theatre (which kind?)

    - Accessibility

- Reanimation Space

- Store Access to Consumables, batteries, etc.

- Implants:

    - Access to Electricity / Gas

    - Water

    - Portable equipment

    - Electricity (eq. node?)

    - Air conditioning/filtering

Medical Equipment: design process
A systems approach: The Onion model of Healthcare

- Lighting, reflections, glare
- Noise
- Air changes & filtering
- Thermal comfort
- Infection Control

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Medical Equipment: design process
A systems approach: The Onion model of Healthcare

- Culture
- Leadership
- Team working
- Training
- Support

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Application of Usability Engineering
to Medical Devices
ISO EN 62366

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MM4MDR Medical Device Regulation

Medical Devices & Safety

- 2007: 3% of reported incidents to NHS related to medical devices (25,000 incidents)

- Many due to faulty or unavailable equipment

- But...many due **to poor usability and user errors**:

  - Equipment not set up correctly

  - Equipment not operating as intended

  - Compatibility problems

  - Equipment not used correctly

- FDA: 45-50% of all medical device recalls are due to poor product design

Usability Requirements: EU

From the EU Medical Device Directive Essential Requirement 1

- "The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients..."

- ... "This shall include **reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety)**, and consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)."

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What are the relevant regulations?

IEC/ISO 62366: Application of Usability Engineering to Medical Devices

ANSI/AAMI HE75: Human Factors Engineering - Design of Medical Devices.

IEC/ISO 14971: Risk Management.

These standards have been developed to ensure that MDD is inclusive of...

- **Safe use**
- **Effective use**
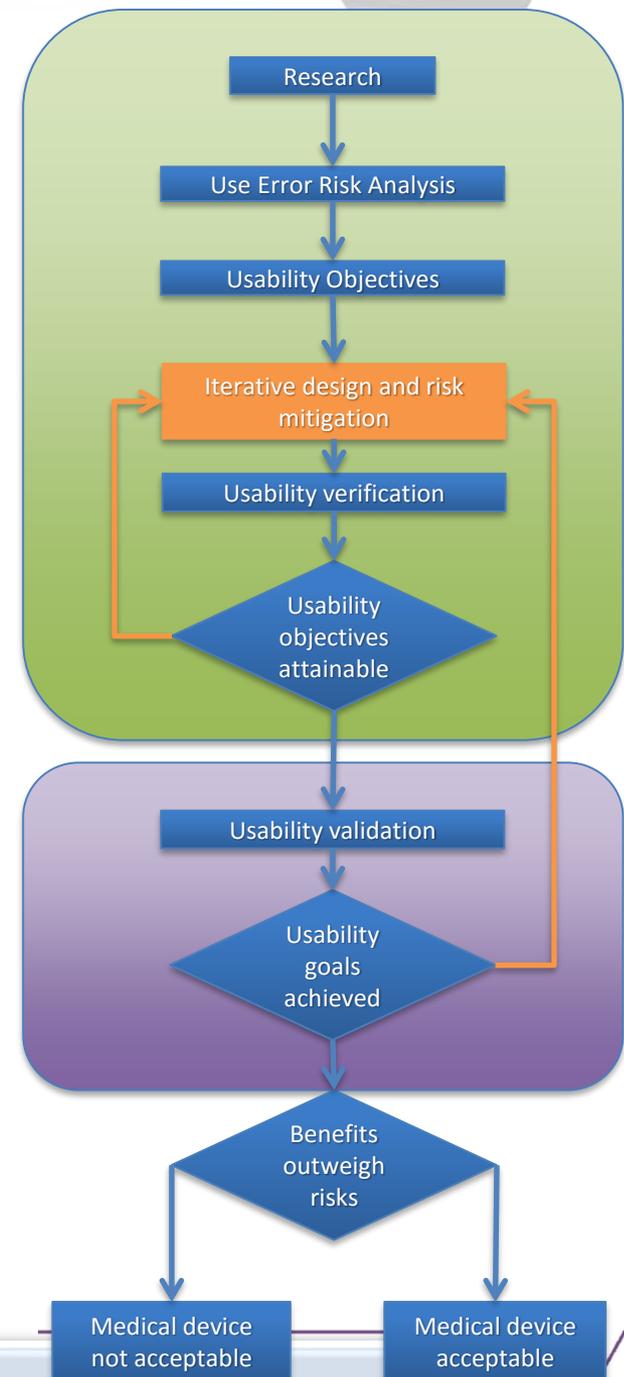- **Mitigates for potential use errors**

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The process
(IEC-ISO 62366)

Learning about your users (formative research & testing)

Continual refinement of the design of the device based on user research findings

Making sure your device is effective, safe and that use-errors are designed out as much as possible (summative testing and validation)

Research

Use Error Risk Analysis

Usability Objectives

Iterative design and risk mitigation

Usability verification

Usability objectives attainable

Usability validation

Usability goals achieved

Benefits outweigh risks

Medical device not acceptable

Medical device acceptable

Pre-prototype research (Formative Research)

Aim: to learn about your users and how your device will be used. This helps to identify the Usability Objectives.

- Who will be using be using your device? (user population)
- What are they using it for? (medical function)
- How will they be using it? (task identification)
- Where will they be using it? (context of use)

Methods:
- Ethnography
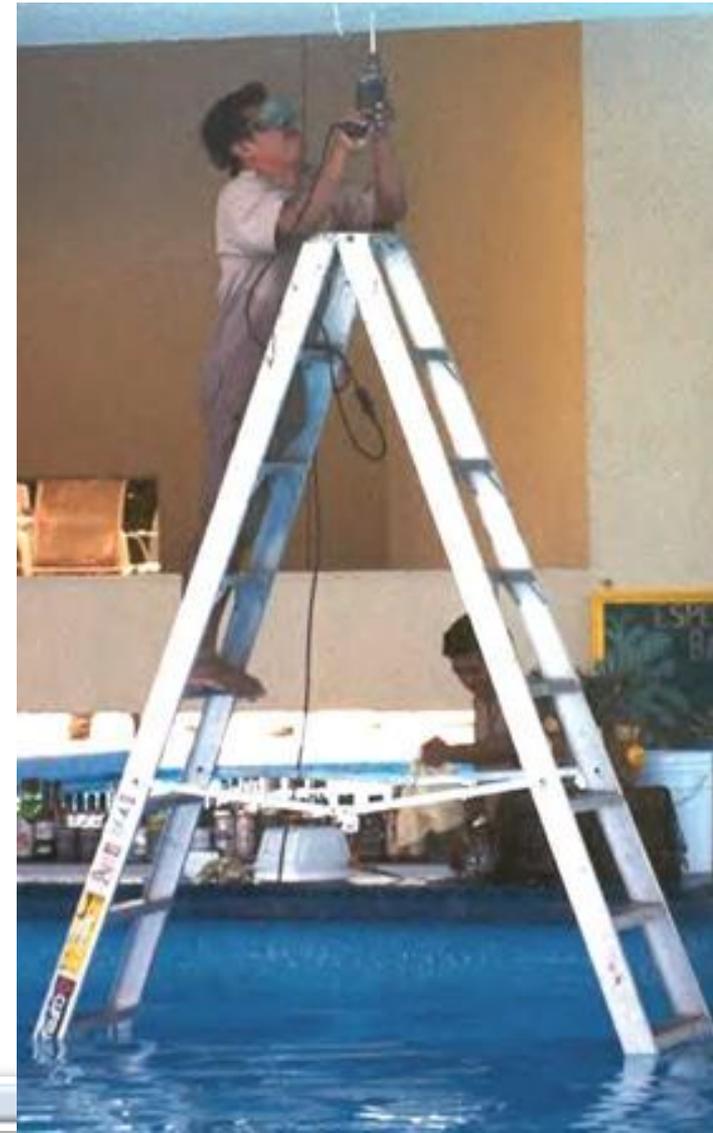- Task Analysis
- User Interviews
- Contextual Inquiry
- AHP

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Early research (pre-prototype)

Aim: to learn about how the device will be used

Using a range of research methods: not just interviews

Important to find out how people behave:

- Difficult to remember and describe details of tasks
- Users may not report poor/unusual practice
- People may not realise that they are using equipment incorrectly or taking risks (O_2 therapy)
- Users may not divulge all violations (even those made for good/ operational reasons)
- **<u>What are the critical tasks?</u>**

Shortcuts & workarounds are commonplace... and soon become standard and unquestioned practice

Prototype Development – how to design in safety and usability and design out error?

Making it easy to do the right thing

Mental models

How can we design in safety and usability?

Making it easy to do the right thing

Affordance

How can we design in safety and usability?
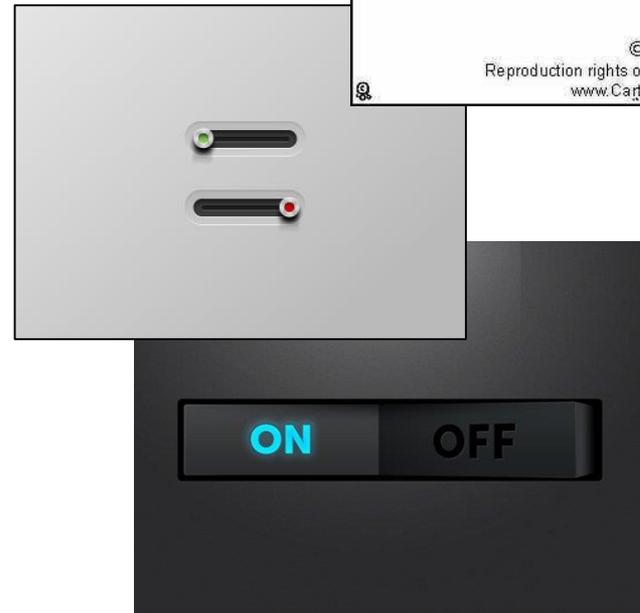
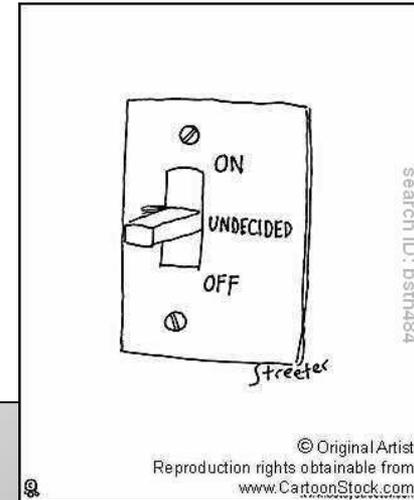

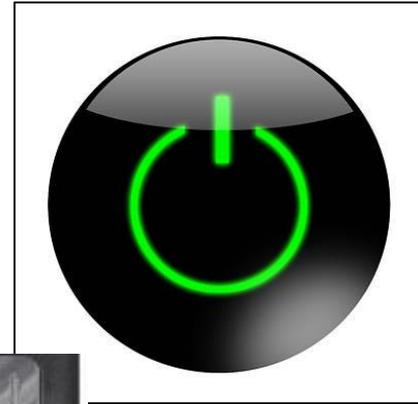Using design to reduce use errors

Standardisation

**On?
or
Off?**

Design Rules of Thumb: Examples[*]

- Always **keep users informed** about current device status.

- Make sure that **controls provide tactile feedback**.

- **Provide immediate and clear feedback** following entries.

- **Give users recourse in the case of an error**.

- **Consider the wide spectrum of operating environments** when designing and testing alarms, including other equipment in simultaneous use.

- **Design control buttons and switches so that they correspond to the conventions of the user population**

  (e.g. turning a dial to the right = increase/high)

[*] Sawyer, D. Do it by design – an introduction to human factors in medical devices. US Food and Drug Administration. (1996)

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