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Applying Human Factors to Usability Engineering

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Usability Assessment / Human Factors Engineering – ABIA Perspective

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Rob Ngungu, RAC

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AUSTEN BioInnovation INSTITUTE IN AKRON

Additional Disclosure

- Mr. Rob Ngungu has served in a dual role – oversight of programs at the Austen BioInnovation Institute in Akron, as well as transitioning into a full time role as Chief Operating Officer for Quest Medical Imaging, North America, based out of Akron Ohio

Presentation Outline

- Presentation Objectives
- Human Factors / Usability definition(s)
- Regulatory Background / Relevance
- Key Terminology
- HF / Usability Model – Theory and Practice
- HF / Usability Program Considerations
- Common Pitfalls
- Summary

Presentation Objectives

- Provide practical hints / tips in understanding, developing, and implementing a human factors engineering program that is designed to yield organizational value.
  - Do not implement to fulfill a regulatory obligation only
- We will not spend too much time around standards, theory, etc., but rather on what we believe are key considerations not adequately covered in current publications and what ABIA has learnt from clients / client programs over the past 2 or so years

Regulatory Background

- Almost half of device failures tied to design issues that led to user error
- Design Controls as outlined in 21CFR Part 820.30 starts off with user requirements ultimately leading to design validation (design validation defined as meeting user expectation)

Notable History

- 1996 – Design Controls as part of the QSR
- 1999 – IOM Report, to err is human; 98,000 hospital deaths due to errors. 5th Largest cause of death, exceeding auto accidents, breast cancer and aids, annual cost 29 billion
- 2000 – CDRH releases Human Factors Guidance as part of risk analysis
- 2001 – ANSI/AAMI HE 74 – Human Factors Design Process for Medical Devices
- 2006 – IEC 60601-1-6, Collateral Standards: Usability of Medical Electrical Devices
- 2007 – HF Team in FDA's ODE. IEC 62366, Application of Usability to Medical Devices
- 2010 – ANSI/AAMI HE75:2009 Human Factors Engineering – Design of Medical Devices
- 2013 – Review of Usability in Medical Device Submissions

What is “Usability” or Human Factors Engineering

- Various definitions are offered, however, the following elements are common:
- Human Factors Engineering is a multi disciplinary science of equipment design to reduce risk, improve usability.
  - Reduce operator / user error
  - Human Factors
    - Perception (visual, auditory, tactile)
    - Cognition (interpreting meaning, decision making, recalling information)
    - Actions (physical interactions, what users will do and won’t do)
  - Non Human Factors
    - Use Environment, e.g. noise, workload
    - User interface

Human Factors and Usability

- **What are Human Factors? Usability?**
- **Human factors:** "…the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations…." (ANSI/AAMI HE75:2009, Introduction)
- **Usability:** "Characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction" (ISO/IEC 62366:2007, Definition 3.17)

Clinical Trial vs HF / Usability Evaluation

- ICH Definition of clinical trial, versus global definition of usability
  - Usability / HF addresses user expectations
- Clinical trial focus is on device effectiveness and safety
  - Clinical effect, as opposed to user friendliness
- Study design and type of data collected
  - Does it meet clinical data definition?
- Could a test plan / protocol be designed to meet both?
  - Design Validation by definition in design controls can meet both

Bioethical Considerations

- Consenting subjects in a usability study
  - Could be a matter of policy, but double edged!
- Issues around confidentiality of study data
- Target subjects versus users (healthcare provider versus patient data issues)
- Records retention policies, use of photography
- Institutional policy versus sponsor requirements

Key / Common Terminology

- Formative Evaluations – inform the development process
- Cognitive walk-through – guided walk thru on use of device during development, includes subjective input
- Summative Evaluation – similar to validation testing
- Heuristics – de facto rules, accepted standards, methods
- Human factors
  - Perception – visual auditory tactile etc.
  - Cognition – interpreting meaning, recalling information, decision making, expectations etc.
  - Actions – what user will or wont do
- Non human factors – use environment, noise, workload
- Residual Risk – can be acceptable if reasonably limited, difficult to reduce and outweighed by device benefit

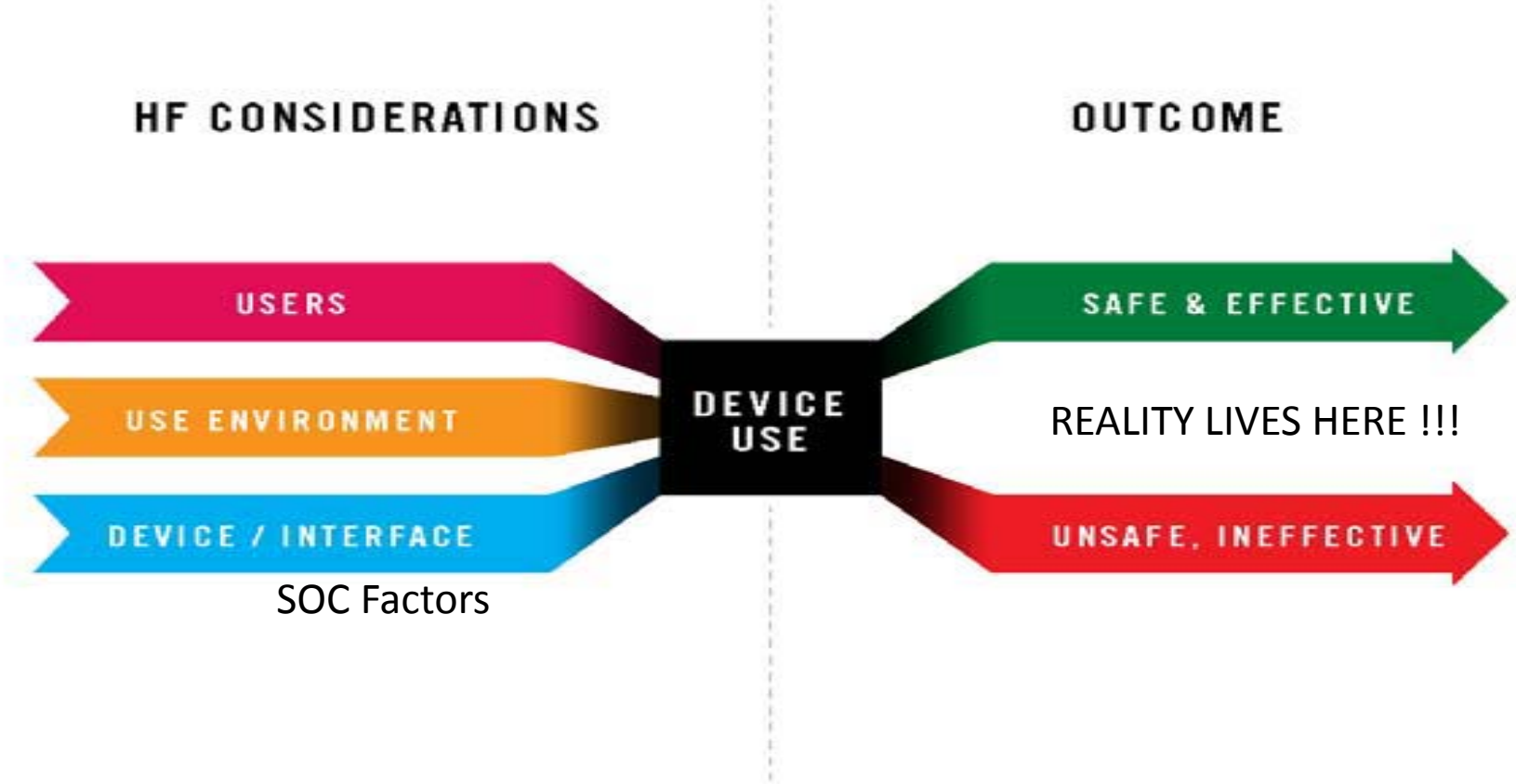
Common Confusion

- **Design Verification: *Did I make the product right?***
- **Design Validation: *Did I make the right product?***

When is HF Evaluation conducted

- During design – first prototypes, for design optimization and improvement. Can be an iterative process.
- Design Verification Phase – to ensure that the design requirements were met.
- Design Validation Phase – to ensure that the design performs as intended in the actual use environment (clinical studies as well)
- Post Marketing – validate significant design changes and for competitive intelligence / marketing

User / Device Interaction Model



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Considerations in Human Factors / UE

- User
  - Who is the user (patient, nurse, doctor)?
  - How skilled is the user
  - How important to safe use are the user's vision, hearing, dexterity, strength
- Environment
  - How complex is the environment?
  - How busy is the environment
- Workflow / Standard of Care
- *Target subject (defining patient parameters)
- Can user error result in serious injury or death?

HF / Usability Program Considerations
Areas of weakness – ABIA Experience

- Device focus – lack of overall context
- Process / work flow definition
- Labeling - intent versus practical hospital environment
- Device complexity and role of software
- Pre-defined acceptance criteria
- Risk assessment role
- Global considerations
- Sample size
- Fault tolerancing

Human Factor Process Flow

Intended use, users, environment

Identify use related hazards

Estimate and prioritize user error risk

Implement risk controls

Validate safety of use

Risk Acceptable — Yes

New Risks Introduced — No

Document Process

Monitor unanticipated risks in post market phase

Importance of Human Factors Engineering

- Allows developers to use resources more efficiently
- Provides a historical benchmark for future designs and product improvements
- Minimizes risk and increases user acceptance
- Mitigate product liability claims
- Helps gain a competitive advantage
  - Increases revenue, profitability.
- Reduces potential for product recalls

Relevance of device issues to drugs or combination products

- Some drugs require devices for delivery
- User instructions can result in proper or improper use
- Consequences of improper drug use can result in serious injury or death
- Adherence or Compliance to drug user instructions critical
- Mental and emotional condition of patients should be considered

Common Pitfalls – ABIA Experience

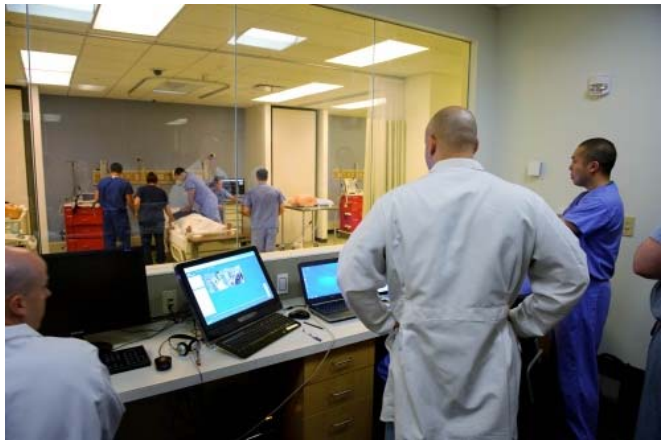
- Human Factors Engineering / Usability being inadvertently merged into clinical trial / clinical protocol programs
  - Consenting subjects, or not to consent
  - When does it become a clinical trial as opposed to a usability study
- The usability success is as good as its weakest link – role of accessories, such as drapes etc. on the usability of a device
- Failure to learn or understand role of traditional standard of care, or hospital workflow relating to the device
  - Often confused with “environmental factors”
- Underestimating significant contribution of accessories or simple devices

Common Pitfalls - continued

- Failure to create a robust user profile as well as target subject (patient) profile – immersion process / shadowing essential
  - Strength, weight, dexterity, target patient population factors
- Understanding the limitations of simulation versus actual use
- Over reliance on labeling, underplaying traditional practices or norms
- Engaging in a pivotal trial clinical protocol without prior usability assessment
  - Trials have failed to meet an endpoint due to usability not device failure per se

ABIA's Usability Facilities

- Mock Hospital including triage area, emergency room, maternity suite and fully operational surgical suite, to facilitate usability in a real life environment
- Eight Standardized Patient Rooms
- Nine Bay Bioskills Lab
- On staff expertise includes MDs, paramedics, healthcare educators, clinical researchers, and device developers
- Network of hospital and university partners
- Representative regional patient population



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HFE / UE Validation Report

- Intended device users, uses, environments and training
- Device User Interface
- Summary of known use problems
- User task selection, prioritization
- Summary of Formative Evaluations
- Validation Testing (Rationale for test design, simulated or clinical, test goal, technique for capturing errors, assessment of errors)
- Conclusions

Summary

- Human Factors / Usability should be approached from a business benefit perspective, while addressing regulatory requirements
- HF / Usability efforts / program critical to successful design efforts
- Human Factors Engineering is critical to ensure competitive advantage (drug exclusivity can be broken based on better usability)
- Injury lawsuits can be significant if HFE was not instituted
- HFE now a regulatory requirement for some devices
- HFE can be applicable to drugs or pharmaceuticals

Thank you!

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