Incorporating Human Factors Engineering into Clinical Engineering Practice

Rani Gebara, MS, CSSBB
Senior Product & Human Factors Engineer
Beaumont Services Company
Clinical Engineers (Historical)

- Proliferation of new medical technologies
  - Need for engineering experts in medical instrumentation and devices

- Patient safety related activities
  - Need for more than the maintenance and repair of equipment
  - Incident investigator of equipment related injuries
  - Adherence to regulatory codes and standards
Clinical Engineers in Healthcare Today

“A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology\(^1\)”

- Project Management
- Technology Assessment
- Technology Management
- Risk Management
- Standards Compliance
- Training/Education

1. American College of Clinical Engineering, 1992
Driving Forces for Patient Safety

- It’s the right thing to do for our patients
- The IOM Reports and Recommendations
- JCAHO Standards
- National Patient Safety Goals
- Safe Medical Device Act
- Financial implications of errors
- Public awareness and concern

Rani Gebara, Beaumont Services Company
How can CE’s contribute to Patient Safety?

- Use Human Factors Engineering research to evaluate medical devices and investigate medical incidents

- Identify critical safety initiatives and provide a short term solutions

- Collect data for future planning and improvements aiming for optimal product design and quality
Human Factors Engineering

- An engineering discipline that looks to understand the relationship between people and the systems that surround them
- To understand and optimize how people use and interact with technology
  - Avoid reliance on memory
  - Use forcing functions
  - Avoid reliance on vigilance
  - Simplify key processes
  - Standardize work processes
  - Design systems with feedback and monitoring mechanisms
Human Factors Engineering

- Mitigates and reduces errors in multiple high reliability organizations (HRO)
- Predicts and provides an understanding of human performance in complex environments
- Discovers underlying systemic factors that lead to error
- Provides a framework for medical device evaluation
- Identifies areas to improve patient safety
High Reliability Organizations

- Nuclear Power Plants
- Air Traffic Controller
- Flight Deck on an Aircraft Carrier
  - Crew Resource Management
- Space Shuttle
- Hospitals
  - Emergency Departments
  - Operating Rooms
  - Intensive Care Units
  - Centralized Telemetry Units
Human Factors: Causal Factors

Environment

Use

Failures

Device

Culture
Device Limitations

- The inconsistency and complexity of design can lead to improper use of medical devices and subsequent errors.
- Common design flaws that can lead to error:
  - Lack of system indicators
  - Unclear messages
  - Non-intuitive programming requirements
  - No status of information
  - Ambiguous abbreviations or missing units
  - Disregard for anthropometrics

Muller-Lyer Illusion

Line Lengths

activate illusion

flash player required
The Ponzo Illusion

With linear perspective

Without linear perspective

--- figure 10.20 A version of the Ponzo illusion. The two horizontal lines are equal. (Revised by M. Ponzo in 1913.)
Use - *Human Capabilities*

- **Visual**
- **Auditory**
- **Tactile**
- **Physical**
- **Cognitive**

(Kaye R. and Crowley J., FDA)
Visual

- Eye is made of two types of photoreceptors
  - Rods- We have 120-130 million on each retina
    - Sensitivity to low light conditions
  - Cones- We have 6-8 million on each retina
    - Color sensitive and acuity

- Visual capacities decrease with age
  - Changes in the efficiency of the structures
    - Presbyopia – lens hardens, loses flexibility
      - Early 40’s to Mid 60’s

- Contrast Sensitivities
  - Some evidence suggests that older eyes require more light for similar tasks compared to younger eyes
Auditory

- Range of audible frequencies is 20 Hz to 20,000 Hz

- We are maximally sensitive to sounds around 3,000 Hz (Ex. Child screaming)

- 16% of adults have 25 dB loss or more

- New phone ring tone “Teen Buzz”
Cognition: Perception vs Attention

Only a Tiny Fraction of Perceivable Information is Attended To

Perceivable Information

Attended Information
Environmental Factors

- Light
- Noise
- Distraction
- Motion/Vibration
- Room layout

Culture

- Serves as a sense making device that can guide and shape an organization
- Values, beliefs, norms an organization shares
- Historical based evidence to justify why?
HFE Techniques

Failure Mode and Effects Analysis (FMEA)

- Identifies and prioritizes failures in a process
- Prioritization based on Severity, Occurrence and Detection
- Multi-disciplinary team is effective in identifying multiple causal factors contributing to the failure modes

Clinical Engineers are key stakeholders in this process

- Experience in investigations and technology assessments
  - Review of the FDA’s MAUDE, ECRI’s Health Device Alerts, ISMP, JCAHO NSPG
HFE Techniques

Heuristic Evaluation (HE)

- Helps identify general problematic areas in the user interface (Graphical User Interfaces, GUI)
  - Ventilators, physiologic monitors, infusion pumps…etc
- Jakob Nielsen’s 10 steps to a Heuristic Analysis
  - Visibility of system status
    - The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.
  - Recognition rather than recall
    - Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another.

Conclusions

Human factors engineering has contributed to the prevention of human error in many high reliability and complex environments

Clinical Engineers are integral in patient safety

- Knowledgeable of medical device instrumentation and the regulations that surround them
- The environment in which they are used
- The users who use them
- The culture that surrounds them
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References

- Do it by Design: An Introduction to Human Factors in Medical Devices, *Dick Sawyer, December 1996*
  www.fda.gov/cdrh/HumanFactors.html
- Human Factors and Medical Devices: Murff H.J., Gosbee J.W., Bates D.W.  
  http://www.ahrq.gov/clinic/ptsafety/chap41a.html
THANK YOU!

Rani Gebara
Beaumont Services Company
3601 W. 13 Mile Rd
Royal Oak, MI 48073
Phone: 248-551-7324
E-mail: rgebara@beaumontservices.com