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# **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<sup>1</sup>”**
  - **Project Management**
  - **Technology Assessment**
  - **Technology Management**
  - **Risk Management**
  - **Standards Compliance**
  - **Training/Education**

# 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**

# 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**

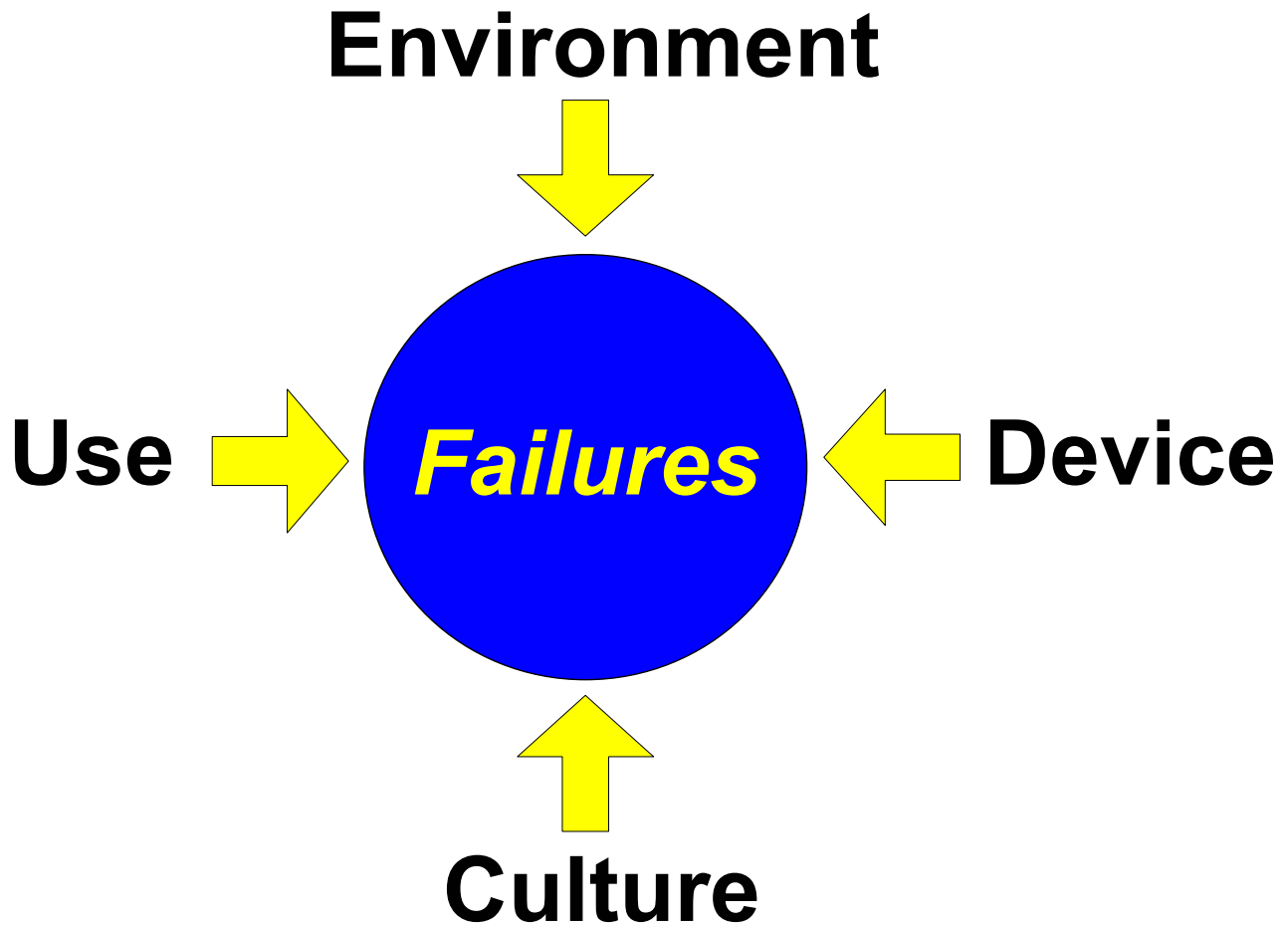
# Human Factors Engineering

- **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*



# Device Limitations

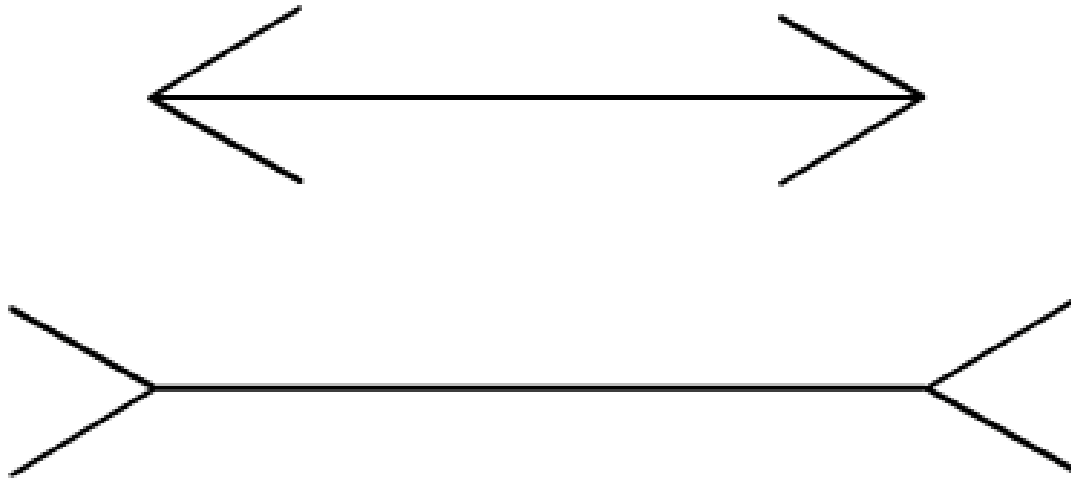
- The inconsistency and complexity of design can lead to improper use of medical devices and subsequent errors.
- Common design flaws that can lead to error:
  - Lack of system indicators
  - Unclear messages
  - Non-intuitive programming requirements
  - No status of information
  - Ambiguous abbreviations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

Kaye R. and Crowley. J. Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, Center for Devices and Radiological Health (CDRH). <http://www.fda.gov/cdrh/HumanFactors.html>, July, 2000.

# Muller-Lyer Illusion

Line Lengths

● activate illusion



⚠ flash player required

# The Ponzo Illusion

With linear perspective

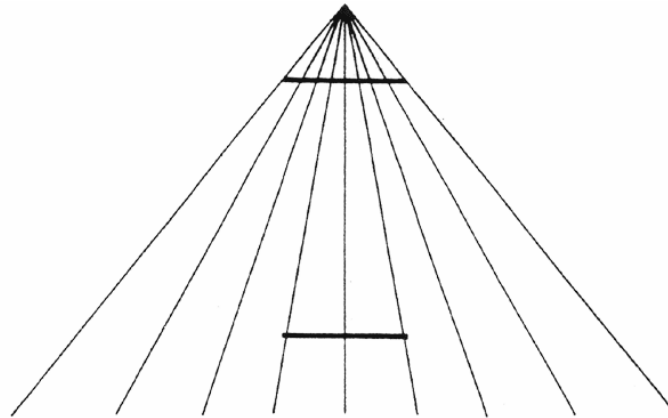
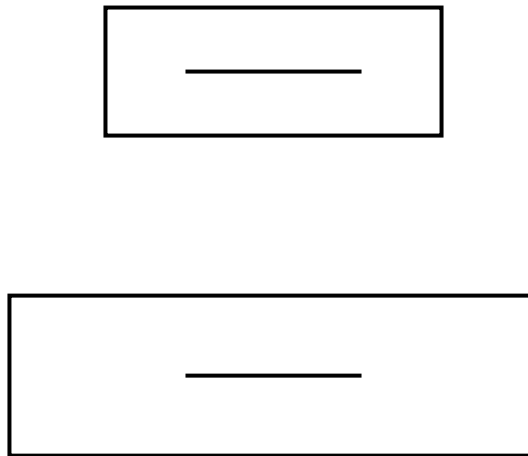


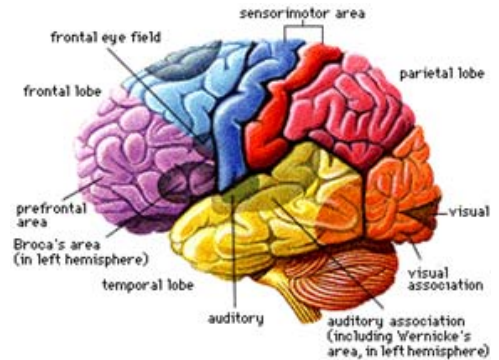
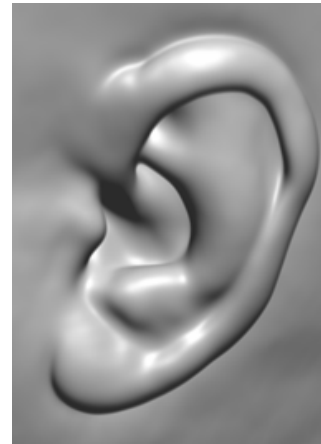
figure 10.20 A version of the Ponzo illusion. The two horizontal lines are equal. (Devised by M. Ponzo in 1913.)

Without linear perspective



# Use - *Human Capabilities*

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



(Kaye R. and Crowley J., FDA)

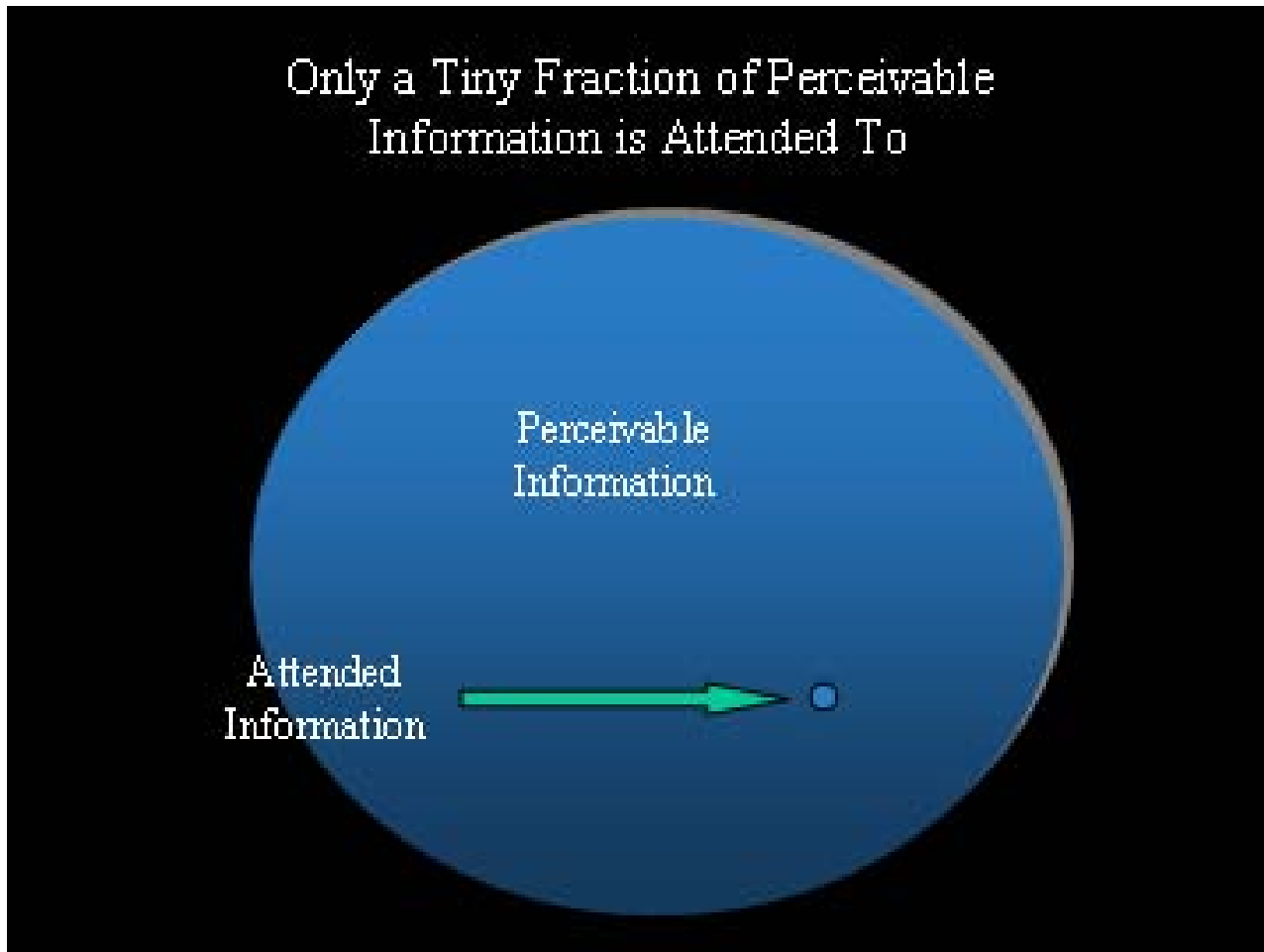
# Visual

- **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

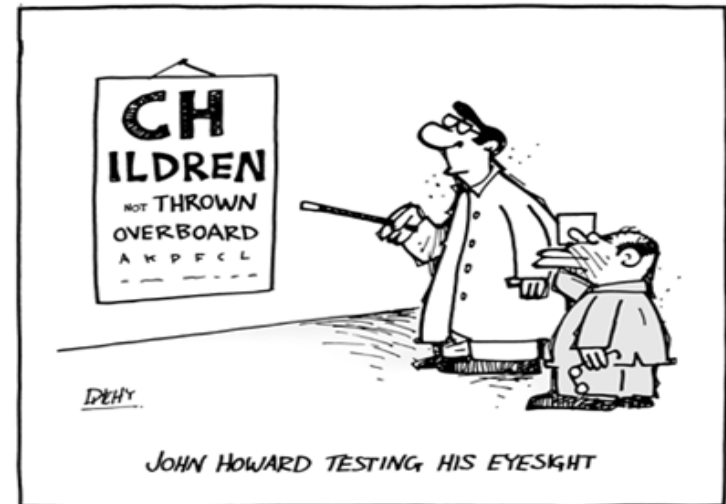
- **Range of audible frequencies is 20 Hz to 20,000 Hz**
- **We are maximally sensitive to sounds around 3,000 Hz (Ex. Child screaming)**
- **16% of adults have 25 dB loss or more**
- **New phone ring tone “Teen Buzz”**

# Cognition: Perception vs Attention



# Environmental Factors

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

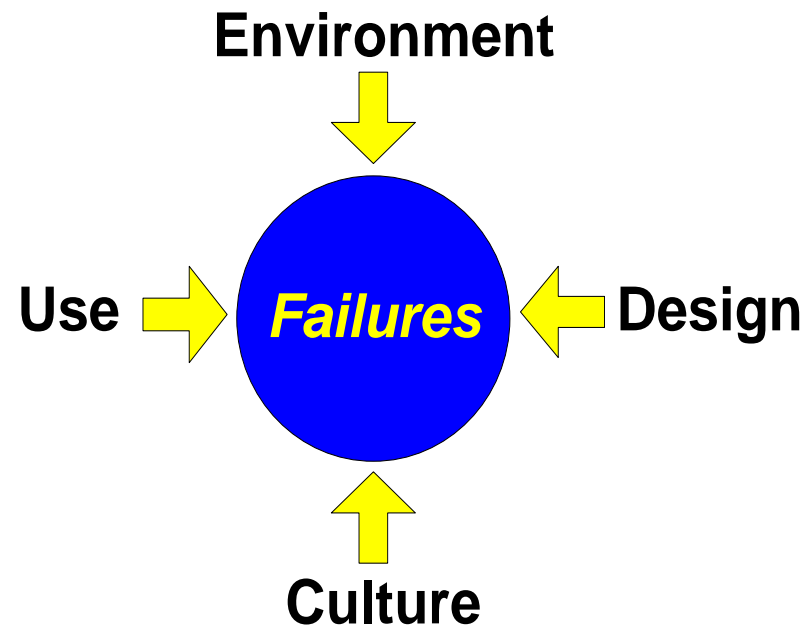


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Kaye R. and Crowley. J. Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, Center for Devices and Radiological Health (CDRH). <http://www.fda.gov/cdrh/HumanFactors.html>, July, 2000.

# 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**

# Acknowledgements

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**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](mailto:rgebara@beaumontservices.com)