USE ERROR ANALYSIS DURING MEDICAL DEVICE DEVELOPMENT

Dean Hooper • Principal Human Factors Scientist • HFES : 2013 Healthcare Symposium

AGENDA

1. The Human Error Problem
2. Current State of Human Error Assessment
3. The Problem with “Human Error”
    - Hindsight and the Illusion of Causation
4. Re-defining Error
    - From a System View
5. Designing a Use Error Assessment Process
    - Historical Obstacles
    - Assimilation and Accommodation
6. Case Studies

The Human Error Problem

70% of reported anesthetic incidents in OR are categorized as human error

69% of hospital in patient injuries were caused by human error.

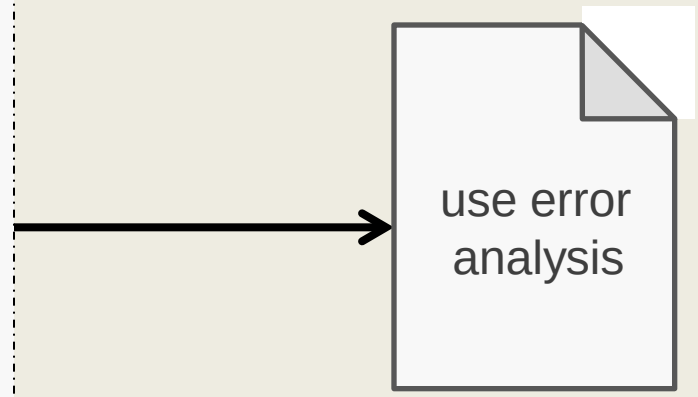
70% of aviation incidents attributed to crew error.

1.5m people every year harmed by medication errors

The Current State of Human Error

STEPS (From the FDA HF Guidelines)

1. Break down device use into discrete steps
2. Identify use-related hazard associated with each step of use
3. Identify potential cause and consequences of user encountering each hazard
4. Develop risk mitigation strategies, if needed



… a use error analysis document is born
…But thus is not enough

1. Use Step	2. Use Hazard	3a. Cause	3b. Consequence	4. Mitigation
Transmit data from remote monitor to clinic	User fails to transmit data	User presses wrong button. Cancels alarm only.	Clinic not notified of potential episode.	Label button “Transmit” Include picture and instruction in IFU

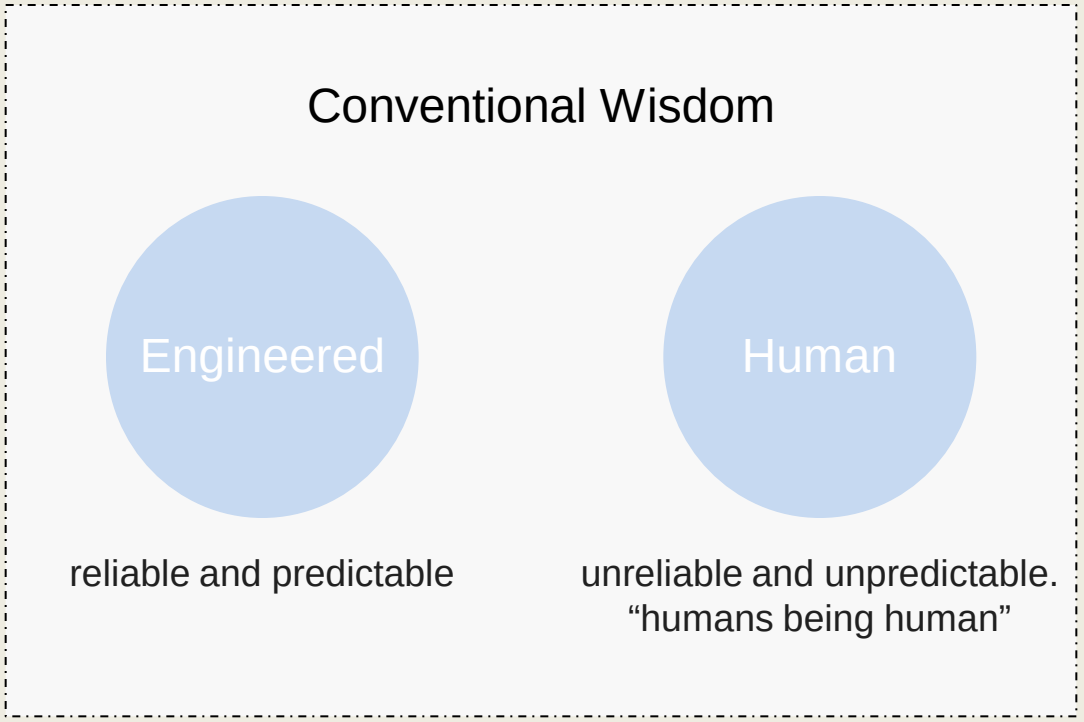
The Problem with “Human Error”

There are two sides to every complex system, the engineered side and the human side

We are confident in the inherent safety of our engineered systems

The human side is susceptible to failure

By this model, mitigations would include training, filtering out unwanted user characteristics, and discipline



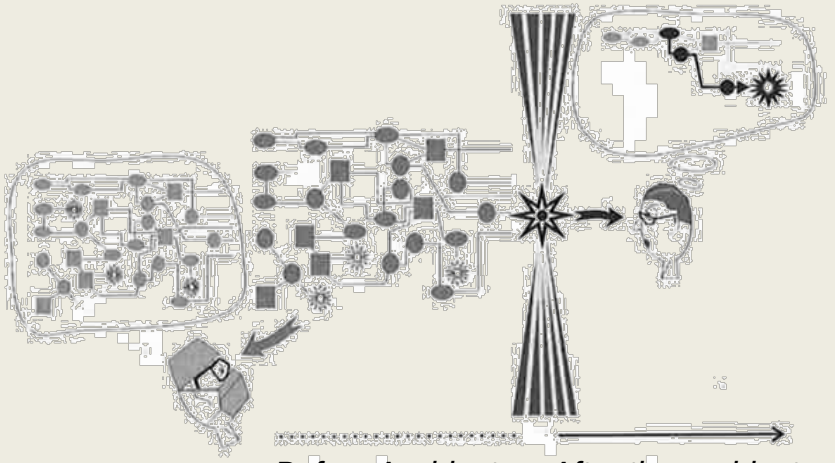
The Problem with “Human Error”

Knowledge of the outcome changes our perspective

Working backwards from an outcome makes “right” or “wrong” obvious

Hindsight bias oversimplifies the failure

Looking “into” the users mental state is difficult if not impossible



Investigations tend to stop at the first sign of deviation from the correct system state or process, go one step back to immediate user action, and call it a cause

However, considering human error as a cause may not address the real issues…

Expanding Causal Influences of Failures • A System View

Concerning Use Error and the Work Environment

Humans add safety to systems

Intrinsically, humans are highly reliable

- Error is extremely rare in relation to successes

Human Error is a symptom, not a cause!!!

Human Error is the starting point, not the end point of an investigation

- Treat Human Error as failure modes

System failure is a causal chain, not a single event

Error may not be predictable, but system vulnerabilities are

The nature of Error is not homogenous.

- The nature of error is as complex as the system

Definitions

Use Failure Mode (term previously known as Human Error)
The erroneous action (physical event) resulting in the failure

Mechanism of Failure (Use Error)
Mental event just preceding the failure mode

Root Causes
Vulnerable aspects of the system that led to the failure

The Complexity of Error • Managed Through Taxonomies

Failure Modes

- Omission of act or task
- Insertion of Extraneous task
- Substitution of Erroneous task
- Inaccurate performance
- Repetition

Root Cause

- Physical Environment
- Task Characteristics
- System Design
- Procedural and training issues
- Mental workload
- Individual goals
- Job role or personnel factors

Mechanisms of Error (Use Error)

- Lack of discrimination between meaningful system states
- Lack of recognition
- Lack of information recall
- Wrong inference

Use Error • Applying New Definitions & Taxonomies

Hazard: Directly injecting high concentration lidocaine in a heart patient.

Mechanism	Failure Mode	Cause	Mitigation

Use Error • Applying New Definitions & Taxonomies

A

Failure Modes

- **Omission of task**
- Insertion of Extraneous task
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- **Repetition**

Hazard: Directly injecting high concentration lidocaine in a heart patient.

Mechanism	Failure Mode	Cause	Mitigation
	EMT does not check concentration of syringe (**omission of task**) **Repetitive action.** Step taken many times in the past with success. EMT injects high concentration directly into patient **(Erroneous act performed).**		

Use Error • Applying New Definitions & Taxonomies

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Mechanisms of Error (Use Error)

- **Discrimination (lack of)**
- Recall (lack or incorrect)
- Recognition (lack or incorrect)
- **Inference (Incorrect)**
- Physical co-ordination (lack of)

Hazard: Directly injecting high concentration lidocaine in a heart patient.

Mechanism	Failure Mode	Cause	Mitigation
EMT **infers** dose is low concentration	EMT does not check concentration of syringe (**omission of task**)		
EMT **fails to discriminate** between low and hi concentration.	**Repetitive action.** Step taken many times in the past with success.		
	EMT injects high concentration directly into patient **(Erroneous act performed).**		

Use Error • Applying New Definitions & Taxonomies

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Root Causes

Situation Factors
- Task characteristics
- **Physical Environment**
- System design

Organizational Factors
- **Procedural**
- Training

Factors Affecting Performance
- Subjective goals
- Mental workload

Causes of Human Malfunction
- External events (distractions)
- User state

Hazard: Directly injecting high concentration lidocaine in a heart patient.

Mechanism	Failure Mode	Cause	Mitigation
EMT **infers** dose is low concentration EMT **fails to discriminate** between low and hi concentration.	EMT does not check concentration of syringe (**omission of task**) **Repetitive action.** Step taken many times in the past with success. EMT injects high concentration directly into patient **(Erroneous act performed).**	**Procedural:** No process for organizing or selecting appropriate concentration or specifics on administration procedure. **The Environment** holds no salient cues as to the concentration level.	

Use Error • Applying New Definitions & Taxonomies

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Hazard: Directly injecting high concentration lidocaine in a heart patient.

Mechanism	Failure Mode	Cause	Mitigation
EMT **infers** dose is low concentration	EMT does not check concentration of syringe (**omission of task**)	**Procedural:** No process for organizing or selecting appropriate concentration or specifics on administration procedure.	Restrict EMT supply to low concentration
EMT **fails to discriminate** between low and hi concentration.	**Repetitive action.** Step taken many times in the past with success.	**The Environment** holds no salient cues as to the concentration level.	Organize supply to easily discriminate
	EMT injects high concentration directly into patient **(Erroneous act performed).**		Alter design to prohibit insertion of a hypodermic needle into high concentration bottles.

Re-defining Human Error

Original Example

Use Step	Use Hazard	Cause	Consequence	Mitigation
Transmit data from remote monitor to clinic upon hearing an alarm.	User fails to transmit data	User presses wrong button. Cancels alarm only.	Clinic not notified of potential episode.	Label button “Transmit” Include picture and instruction in IFU

Enhanced by Taxonomies – new root causes emerge, mitigations more effective

Use Step	Use Hazard/ Failure Mode	Mechanism of failure and Root Causes	Consequence	Mitigation
Transmit data from remote monitor to clinic upon hearing an alarm.	User fails to transmit data User presses wrong button. Cancels alarm only.	Execution error due to lack of physical coordination. Button too close to another button used to cancel the alarm without sending the data. User fails to discriminate between “alarm cancel” and “data sent” feedback. Audible and tactile feedback is identical for both system states.	Clinic not notified of potential episode.	Modify layout of user interface Alter system feedback to give distinct indication when data was sent. Allow user to recover from mistake.

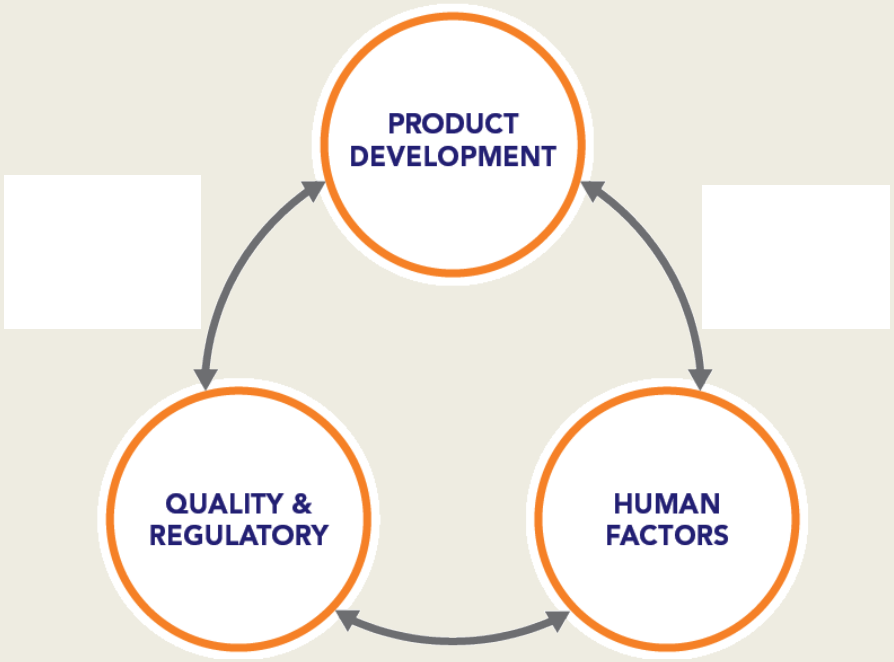
Implementing a Use Error Analysis Program

Work with RA/QA to get Use Error Analysis as part of Risk Management Process

- Usually includes revising documents and forms.
- Basic processes already in place.

Work with Engineering culture

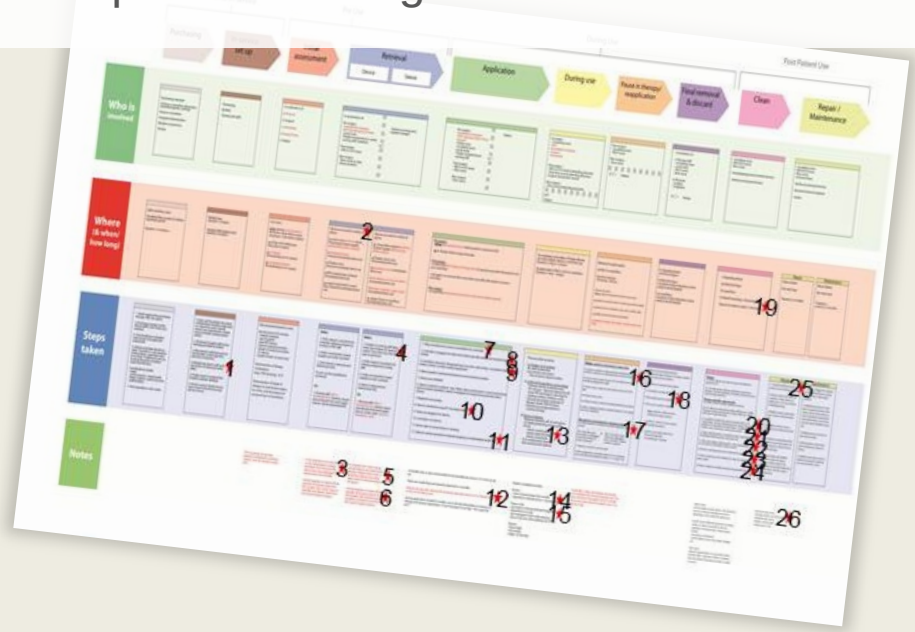
- Train hazard analysis teams on terminology and process.
- Use error analysis champion initially sits on hazard team.



Performing a Predictive Error Analysis
Streamlining by formalizing

For the Project

- Conduct Task Analysis (determine task steps)
- Assign Failure Modes to each task
- Assign all possible error mechanisms to each failure mode
- Determine potential root causes
- Incorporate known failures (from previous testing, post market surveillance, etc)
- Assign Risk Priorities using field personnel or internal clinical experts
- Determine mitigations if needed.
- Implement changes and test for residual effect



Omission of act or task

Inaccurate performance

Insertion of Extraneous task

Substitution of Erroneous task

Use Step
Transmit data from remote monitor to clinic upon hearing an alarm.

Assimilating into Existing Process

Common assessment

Part Number and Function or Use step or Process step	Hazard	Potential Harm From Hazard	Potential Failure Mode	S (1 - 5)	Potential Causes Of Failure Mode	Current Risk Controls
User opens package	Loss of sterility	Infection	User error		Use beyond expiration date	Expiration date on package

Revision using formal method

Part Number and Function or Use step or Process step	Hazard	Potential Harm From Hazard	Potential Failure Mode	S (1 - 5)	Potential Causes Of Failure Mode	Current Risk Controls
User checks expiration date	Loss of sterility	Infection	User fails to check expiration date		User infers product is within shelf life from past successes	Require user to acknowledge expiry date during product registration
			User incorrectly assesses expiration date		User fails to recognize expiry date is in the past due to lack of salient cues as to the current state of the device	Ensure date is in clear print in an easily accessed area.

Root Cause Analysis of Use Validation Testing Data For FDA Submission

Failure: Non-compliance to 60-day limit on therapy.

"I thought it indicated the negative pressure setting. Would get a new pump for the patient if it were blinking."

"It looks like the pump has reset itself to the -60 pressure. It shouldn't do that."

Sub-task	**Failure mode**	**Mechanism of error**	**Root cause**	**Assessment and further actions**
Remedy a 60-day therapy limit condition Assess device state	User erroneously concluded state was normal	**Did not recognize** a faulty state. **Failure to discriminate** between a normal and a faulty condition	Test **environment provided insufficient cues** as to expiration duration . **Device** did not signal an error condition other than the visual display.	Probably an artifact of the testing environment. The 60-day limit error was simulated without the normally presented blinking signal or acoustic signal. Also, the context of 60-days of use could not be simulated.

Use Error Causal Analysis with Error Taxonomies

- Assimilates will into and enhances risk management activities
  - Streamlines the process by providing common ground for assessment
    - Hazard scenarios understood by whole team
  - Inputs the design control process
  - Formalizes use risk assessment
  - Good communication tool among hazard analysis team
  - Can be used to assess any error, no matter its source
  - Simple, fairly atheoretical application

- Adheres to 21 CFR Part 820 (.30 and .100)
  - For example – Adheres to good CAPA practice
    - Provides source of error identification
    - Identifies root cause through clear methodology
    - Directs user testing objectives and scenarios
    - Clear connection between errors, their causes, and mitigations

Bibliography

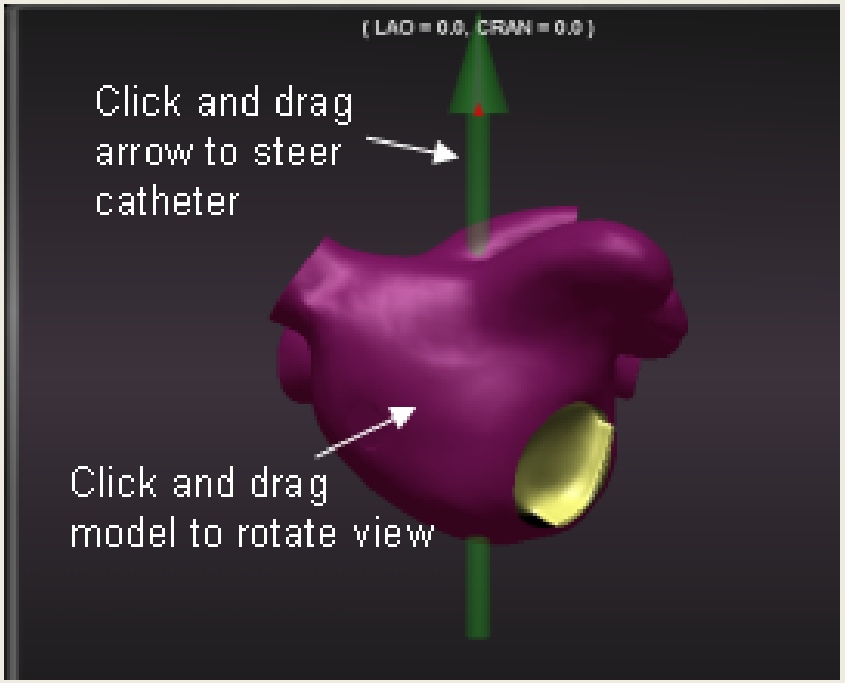
Bogner, M.S. (ed.). (1994) *Human Error in Medicine*. Lawrence Erlbaum Associates. Hillsdale, NJ.

Woods, et. al. (2010). *Beyond Human Error*. Ashgate Publishing Company. Burlington, VT.

Thank You

Dean Hooper
Principal
T: 763 753 9922
Dean.hooper@heconsultingllc.com
www.heconsultingllc.com

Using Taxonomies
Addressing a CAPA issue



Part/Process/ Feature	Potential hazard/failure	Mechanism of failure and root causes	O C C	Harm	S E V	Proposed risk control measure
Manual Vessel navigation	**Substitution error.** User meant to rotate model but moved catheter instead.	**Lack of target discrimination** due to task requirements closely resembling other, unrelated tasks. Salient cues that vector is being selected not provided by **device interface**		Delay patient care		Highlight vector on mouse over (i.e., when it becomes a target)