Critical Device Failure: *Now What?*

PICNet Education Conference 2018

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Introduction

- Medical Device Failures
- Human Factors Engineering
- Case Studies

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5 Common Reasons for Medical Device Failure

May 5, 2016

Top 8 Reasons For Medical Device Recalls

The FDA is on pace to recall more defective medical devices in 2016 than in any previous year.

- Manufacturing/Assembly error
- Software glitch/hacking
- Material selection
- Contamination
- Overstress

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No Fault Found!

Table 1
NFF reporting rates associated with select devices.

Device	UHN	
	Number of NFF reports	Normalized NFF rate
ForceFx Electrosurgical Unit	12	1.2
678 Suretemp Thermometer	329	1.79
52000 Vital Signs Monitor	11	0.92
Heartstart XL Defibrillator	64	2.29
Kangaroo Enteral feeding pump	192	2.7
245 Blood Warmer	121	3.78
Site averages	NA	0.56

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The use of fault reporting of medical equipment to identify latent design flaws

C.J. Flewwelling[a,b,*], A.C. Easty[a,c], K.J. Vicente[d], J.A. Cafazzo[a,b,e]

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Using "No Problem Found" in Infusion Pump Programming as a Springboard for Learning About Human Factors Engineering

Scott Draper M.S.B.E., A.T.P. (Clinical engineer), Gail A. Nielsen (Patient safety administrator), Mike Noland B.M.E.T. (Biomedical equipment technician)

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Investigating Causes of Failures

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Journal of Medical Engineering
Volume 2014 (2014), Article ID 314138, 13 pages
http://dx.doi.org/10.1155/2014/314138

Research Article

A Structured Approach for Investigating the Causes of Medical Device Adverse Events

John N. Amoore

Table 1: Shepherd's classification of medical device incidents [14].

Device	Operator	Facility	Environment	Patient
(i) Human factors design (ii) Parts/circuit design: unexpected failure (iii) Deterioration: predictable failure that requires preventative maintenance (e.g., battery) (iv) Maintainer error	(i) Education/training (ii) "Use" error (iii) Diverted attention (iv) Criminal intent	(i) Human factors design (ii) Parts/circuits designs: unexpected failure (iii) Deterioration: predictable deterioration that requires preventative maintenance (iv) Maintainer error	(i) Internal to hospital (ii) External to hospital	(i) Active: patient action affected the outcome (ii) Passive: patient's condition affected the outcome

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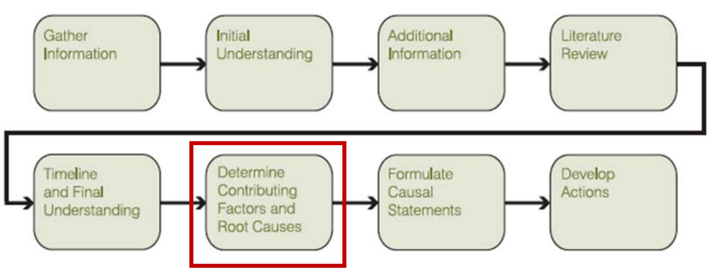
Root-Cause Analysis: What happened, why and what can be done to prevent



CPSI - Canadian RCA Framework, 2006

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What is human error?

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Inappropriate human behaviours that lowers levels of a system's effectiveness or safety, which may or may not result in accident or injury

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Is Human Error a cause or a symptom ?

OLD VIEW
'Bad Apple theory'

what goes wrong

- Human error is the cause of trouble
- To explain failure you seek failures
- You must discover people's failures in decisions, judgments, assessments

how to make it right

- Complex systems are basically safe
- Unreliable, erratic humans undermine rules, procedures, regulations & defenses
- To make systems safer, tighten procedures, more automation, better supervision
- Find and control the 'bad apple"

NEW VIEW
Why did that make sense at that time ?

what goes wrong

- Human error is a symptom of deeper problems
- Do not try to find where they 'screwed up'
- Understand how their decisions, judgments, assessments made sense to them at the time.

how to make it right

- Complex systems are not inherently safe
- Complex systems are dynamic tradeoffs between multiple irreconcilable goals (safety/efficiency)
- People create safety through practice at all levels
- Human error is not the conclusion of an investigation…it is the beginning

The Field Guide to Understanding Human Error S.Dekker 2006

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"Today we are going to decide who to blame."

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"The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes."

Lucian Leape

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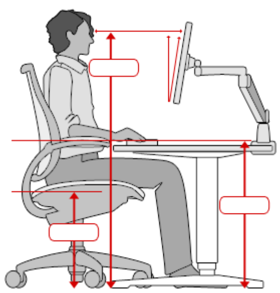
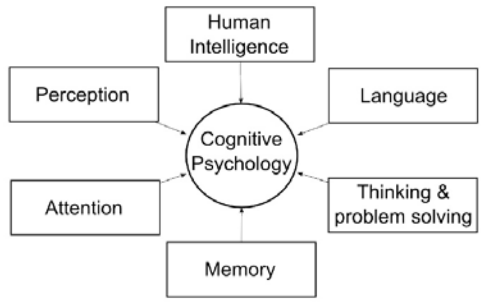
Human Limitations





Physical

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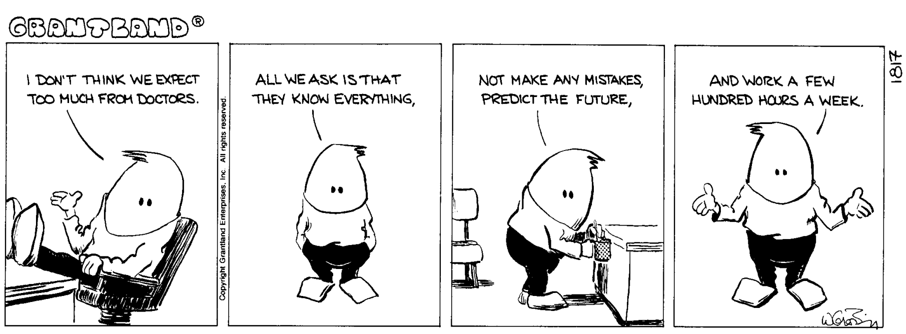
Expectations



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Understanding human limitations

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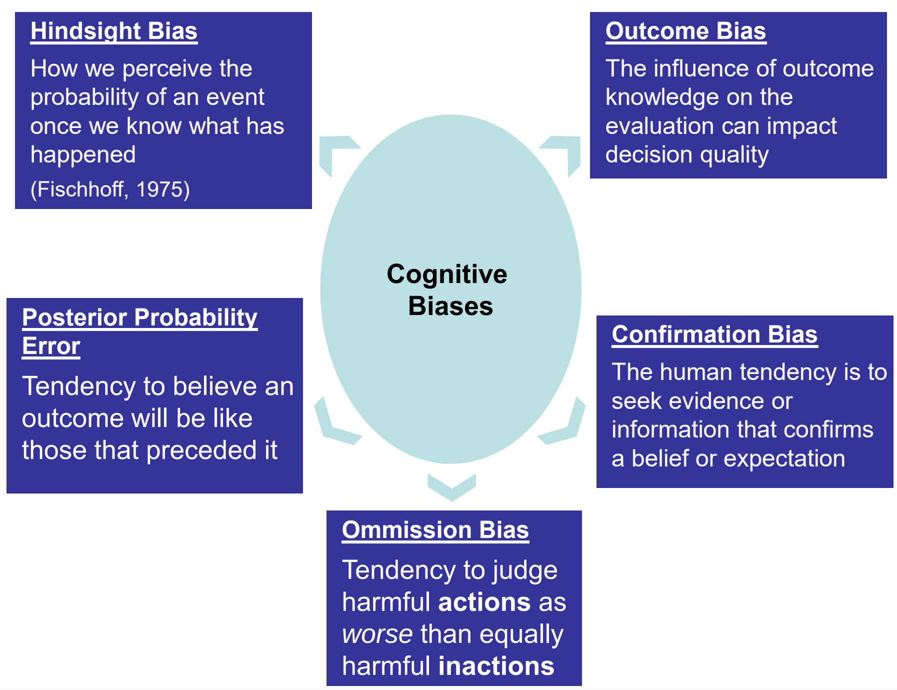

What is Human Factors?

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designing for human use

a body of information about human abilities, human limitations, and other human characteristics that are relevant to design

Chapanis, A. (1995, p. 11). Human Factors in Systems Engineering. Toronto: John Wiley.

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Human Factors Engineering

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the application of human factors information to the design of tools, machines, systems, tasks, jobs, and environments for safe, comfortable and effective human use

Chapanis, A. (1995, p. 11). Human Factors in Systems Engineering. Toronto: John Wiley.

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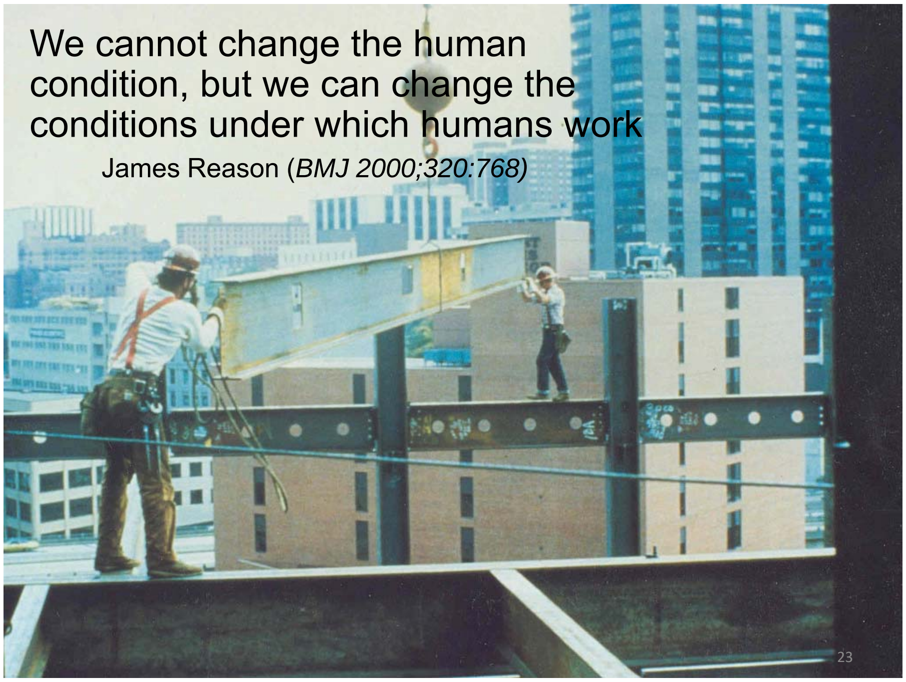
We cannot change the human condition, but we can change the conditions under which humans work
James Reason (*BMJ 2000;320:768)*

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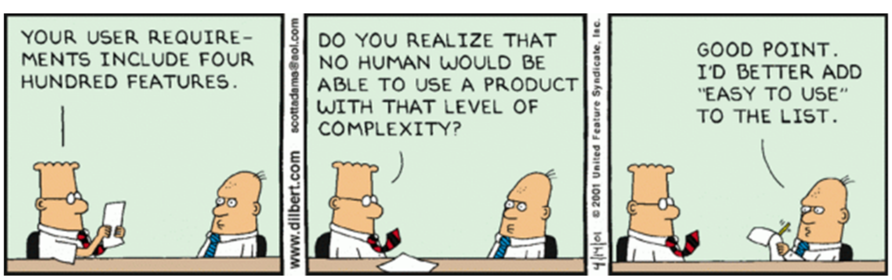
YOUR USER REQUIREMENTS INCLUDE FOUR HUNDRED FEATURES.
DO YOU REALIZE THAT NO HUMAN WOULD BE ABLE TO USE A PRODUCT WITH THAT LEVEL OF COMPLEXITY?
GOOD POINT. I'D BETTER ADD "EASY TO USE" TO THE LIST.
www.dilbert.com
scottadams@aol.com
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Assumptions

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A perfectly designed system will be easy to use and minimize adverse events

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A poorly designed system will be **difficult to use** and **be prone to adverse events**

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Human Factors methods evaluate these differences and make recommendations for improvement to support human work

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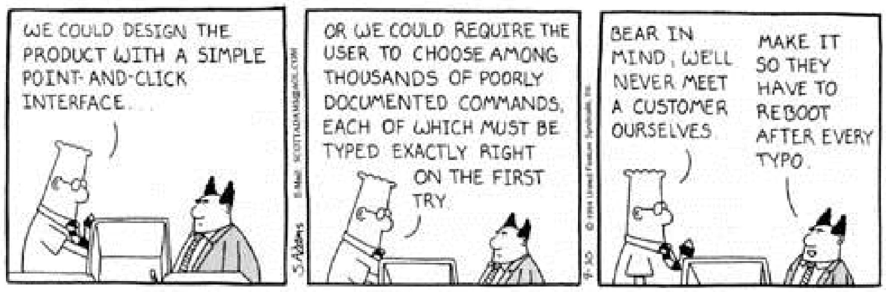

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Why is this important?

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We cannot assume that all users can complete a task simply because you can

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- Performance of the system depends on the user
- Users are adaptable
- Users can learn to use a poorly designed system

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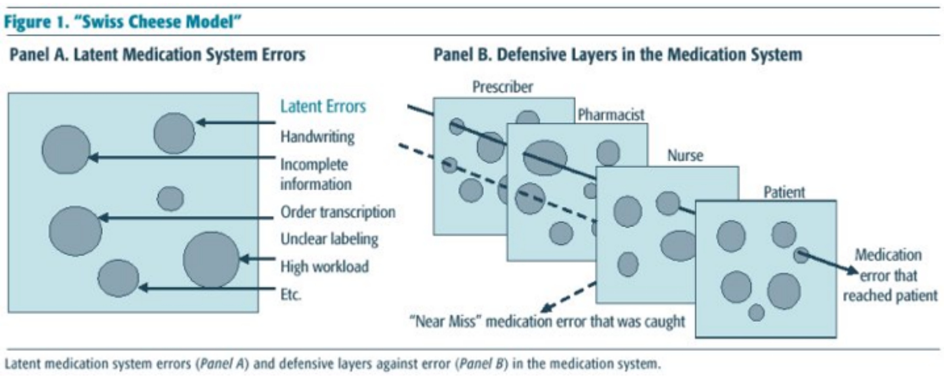
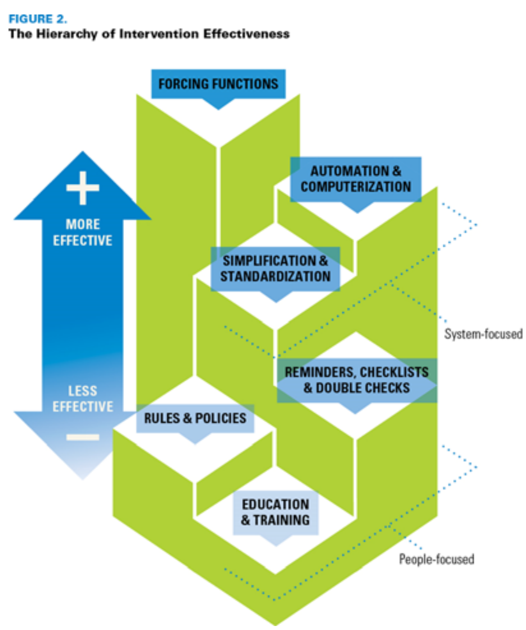
Every step in a process has the potential for failure – "it's like Swiss Cheese"



James Reason, 1990

Designing for our limitations



Cafazzo JA and St-Cyr O. From discovery to design: the evolution of human factors in healthcare. Healthcare Quarterly 2012;15:24-29

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Heuristic Evaluation

- General guidelines or informal “rules of thumb”
- Used as a first step towards evaluating usability

- Evaluate independently
- Judge compliance with guidelines
- Identify positive & negative features

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1. Visibility of System Status
2. Match Between System and Real World (focus on user)
3. User Control and Freedom
4. Consistency and Standardization
5. Error Prevention (focus on users and tasks)
6. Recognition Rather Than Recall
7. Flexibility and Efficiency of Use
8. Aesthetics and Minimalist Design
9. Help Users Recognize, Diagnose, and Recover From Errors
10. Visual Representation
11. Auditory Representation

Adapted from J. Nielson, 1990

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Case Studies

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1. Human Nature
2. Human Error
3. Medical Device Error
    - Retrospective Analysis

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“Splash Back”

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- Typical trajectory
- Porcelain Curvature
- Reflection angle

http://www.cromwell-intl.com/toilet/netherlands.html

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Take advantage of the inherent human male tendency

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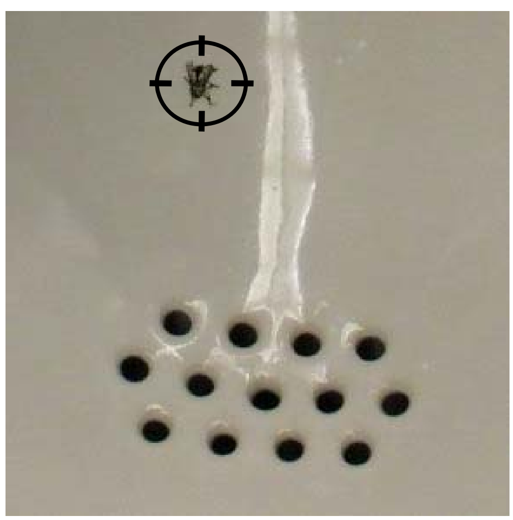

http://www.cromwell-intl.com/toilet/netherlands.html

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User analysis
+ Intelligent design
good hygiene

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Hawaii **False** Missile Alert

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Hawaii **False** Missile Alert

https://en.wikipedia.org/wiki/2018_Hawaii_false_missile_alert

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Defibrillator **Failure** to Discharge

During a cardiac arrest, several attempts were made to defibrillate a patient using paddles. The staff noted that the defibrillator was not discharging into the patient.

- ECG strips after the event revealed no electrical activity
- ECG strips recorded only a dotted line and documented "no shock delivered" -> implied no paddle contact with the patient

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Defibrillator **Failure** to Discharge

Investigation revealed:

- staff had used adult-sized disposable defibrillation electrodes with the paddles rather than with the hands-free cable attached to the disposable electrodes
- the disposable electrodes adhere to the patient and are intended to connect directly to the defibrillator and be used in place of the paddles
- paddles were placed on the nonconductive foam backing of the disposable electrodes and the wires for those electrodes were ignored
- staff should have used the supplied defibrillation electrode pads that are designed to be a conductive interface between the patient and paddles

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Design of the hands-free pads may not clearly differentiate them from other types of commonly used interface pads

Causative factors:

- labeling ignored
- incorrect clinical use
- failure to train and credential
- systems problems in equipment storage

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Conclusions

- "Training is the last bastion of poor design"
- Proactive about potential failure modes rather than reacting to harm
- Evaluate potential adoption of new technologies for user interaction and performance prior to procurement

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Human Factors Readings

- Vicente, K (2003). **The Human Factor**, Toronto, Kanopf Canada.
- Chapanis, A. (1995). **Human Factors in Systems Engineering.** Toronto: John Wiley.
- Wickens & Hollands (2000). **Engineering Psychology and Human Performance Engineering.** New Jersey: Prentice Hall.
- Canadian Patient Safety Institute (CPSI) website
- World Health Organization (WHO) website

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