Human Factors in medical device assurance cases:
What can we apply from safety critical industries?

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COMAH requirements

- COMAH regulations (Control Of Major Accident Hazards)
- "The 'predictive' parts of the report must show that the company understands how human as well as engineering fallibility can initiate incidents…"
- "…the parts that people play in protection, prevention, potential initiation and recovery to be addressed *with the same degree of rigour* that we traditionally expect for process and engineering issues."
- "Is there a systematic, competently applied method for identification of the potential role of human failure in accident initiation or escalation?"*

* COMAH Safety Report Assessment Manual, Appendix 4
http://www.hse.gov.uk/comah/sram/index.htm

HSE - 7 Step Process

1. Consider main site hazards
2. Identify manual activities that affect these hazards
3. Outline the key steps in these activities
4. Identify potential human failures in these steps
5. Identify factors that make these failures more likely
6. Manage the failures using the hierarchy of control
7. Manage error recovery

Example task classification

Initiating tasks	Preventative tasks	Mitigation tasks
• Import /export/ transfer material • Start-ups/ shut downs • Preparation for maintenance • Reinstatement after maintenance	• Maintenance/function testing/calibration of trips • Maintenance of relief valves • Inspection tasks • Operator routines	• Respond to alarm • Respond to trip • Respond to leak • Respond to fire

Requirements to predict human errors in medicine: Usability context

- Identify errors that could give rise to significant adverse events
- Identify features of the device design and user interaction that could induce these errors
- Identify aspects of the context of use that increases the probability of the errors
- Develop features of the device that minimise the likelihood of errors from these sources
- Usability engineering as part of the total risk management process

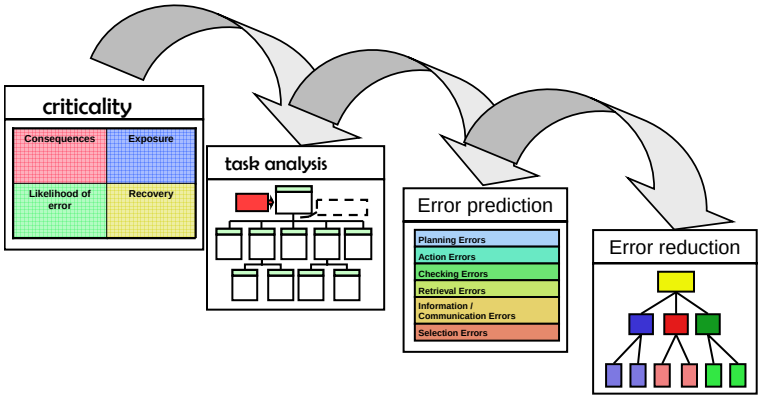
Requirements to predict human errors in medicine: Medical safety in general-1

- Joint Commission on Accreditation of Healthcare Organisations (JCAHO) patient Safety Standard LD5.2:

"Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented."

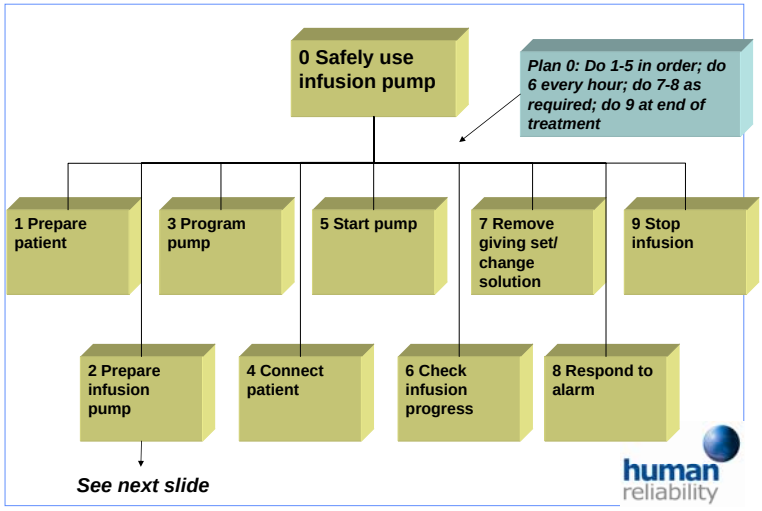
"For each failure mode, a possible effect and criticality must be identified"

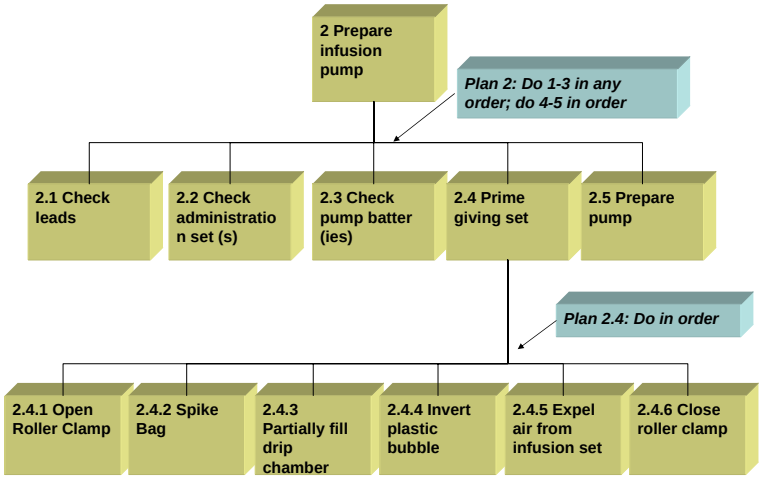
Task Error Assessment Method (TEAM)



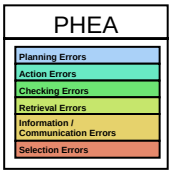
Develop Criticality Index to prioritise areas of intervention

Task	Conse-quences	X	Error Prob.	X	Exposure	X	Lack of Recovery	=	Risk ranking score
A	3		2		2		3		36
B	2		3		3		1		18
C	2		1		2		3		12
D	1		2		3		1		6





TEAM Stage 4: Identify significant errors using Predictive Human Error Analysis (PHEA)



- Uses a standardised set of possible human failure modes as guide words to assist error identification process
- Actions, communications & checks considered
- Could be extended to consider cognitive errors (e.g. misdiagnosis)

Examples of PHEA Error Types

Action	*Checking*	*Information Retrieval*	*Information Communication Errors (Person to person)*	*Selection (between two alternative objects)*
Right action, wrong object	Check omitted	Information not obtained	Information not communicated	Selection omitted
Action omitted	Check incomplete	Wrong information obtained	Wrong information communicated	Wrong selection made
Action too late/early		Information retrieval incomplete	Information communication incomplete	
in wrong direction		Information incorrectly interpreted	Information communication unclear	

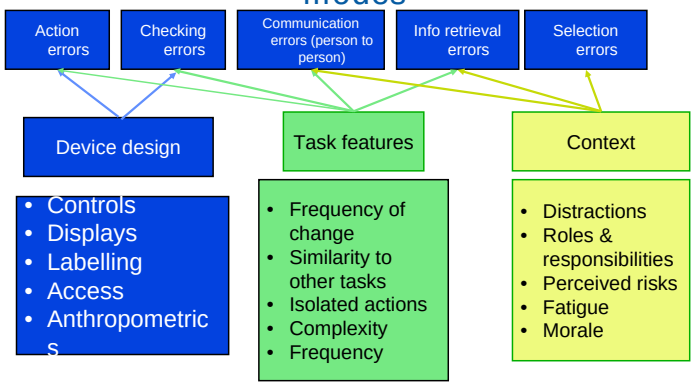
Predictive Human Error Analysis -1

Task Step	Error Type	Description	Consequences	Recovery	Error causes/prevention
2.1 Check leads	C1: Check Omitted	Operator fails to check lead connections	Possible loss of power to pump due to equipment failure	Supervisor /colleague checks	T1: Checklist C1: Training: identify risks D1: Make connections self indicating
2.2 Check administration set(s)	C1: Check Omitted	Operator fails to check integrity of administration set	Possible contamination of solution/pump	Supervisor /colleague checks	T1: Checklist C1: Training: identify risks
2.3 Check pump battery (ies)	C1: Check Omitted	Operator fails to check condition of one or more batteries	Possible loss of power due to failure to maintain battery	Supervisor /colleague checks	C1: Ensure fresh batteries readily available D1 Make battery condition self indicating

Predictive Human Error Analysis -2

Task Step	Error Type	Description	Consequences	Recovery	Error causes /prevention
2.4.1 Open Roller Clamp	Action omitted Action insufficient	Roller clamp remains closed		Task cannot proceed	N/A
2.4.2 Spike Bag	Action too much	Bag spiked excessively	Possible contamination of solution/pump from egress of fluid	Supervisor or colleague checks	Checklist Training point
2.4.3 Partially fill drip chamber	Action too much Action omitted	Drip chamber overfilled	Flow ineffective	Supervisor or colleague checks	Checklist Training point

Mapping Performance Influencing Factors (PIFs) on to PHEA error modes



Addressing identified errors

- Identify which factors have an impact on that type of error
- Evaluate these factors in the specific context of use (e.g. ward, A & E room, pharmacy, blood transfusion)
- Repeat for other errors identified in the analysis
- Decide on intervention strategy (may affect likelihood of a number of types of error)

Step 2.5 Reset Infusion rate at end of procedure	*Error type: Action too much*	*Infusion rate set too high*	*Recovery Likelihood: Low*	*Consequences: Possible fatality*

Decision table for interventions

PIF	Proposed solution	Cost	Imported risks?	Decision
D1 Quality of device controls & displays	D1: Enhance visibility of range markings D2: Increase pointer contrast	Low Medium	Need to consider population stereotypes	Y
T1 Degree of feedback (Low)	T1: Introduce infusion rate as a checklist item	Low		Y
C1:Roles & responsibility (No assignment of responsibility)	C1: Redesign task with clear assignments of responsibility	Low		Y
C2: Distracting environment	C2: Ensure no multitasking at critical phase of infusion	Medium		Y

Conclusions

- Usability cannot be considered in isolation from the nature of the task, and the context of use
- Tools such as TEAM originally developed in safety critical industries provide a systematic framework for identifying potential errors
- Benefits arise from using a task orientated analysis together with an error mode identification process
- Interventions to manage identified failure modes can be documented as part of the Assurance Case