



MONASH University

Medicine, Nursing and Health Sciences

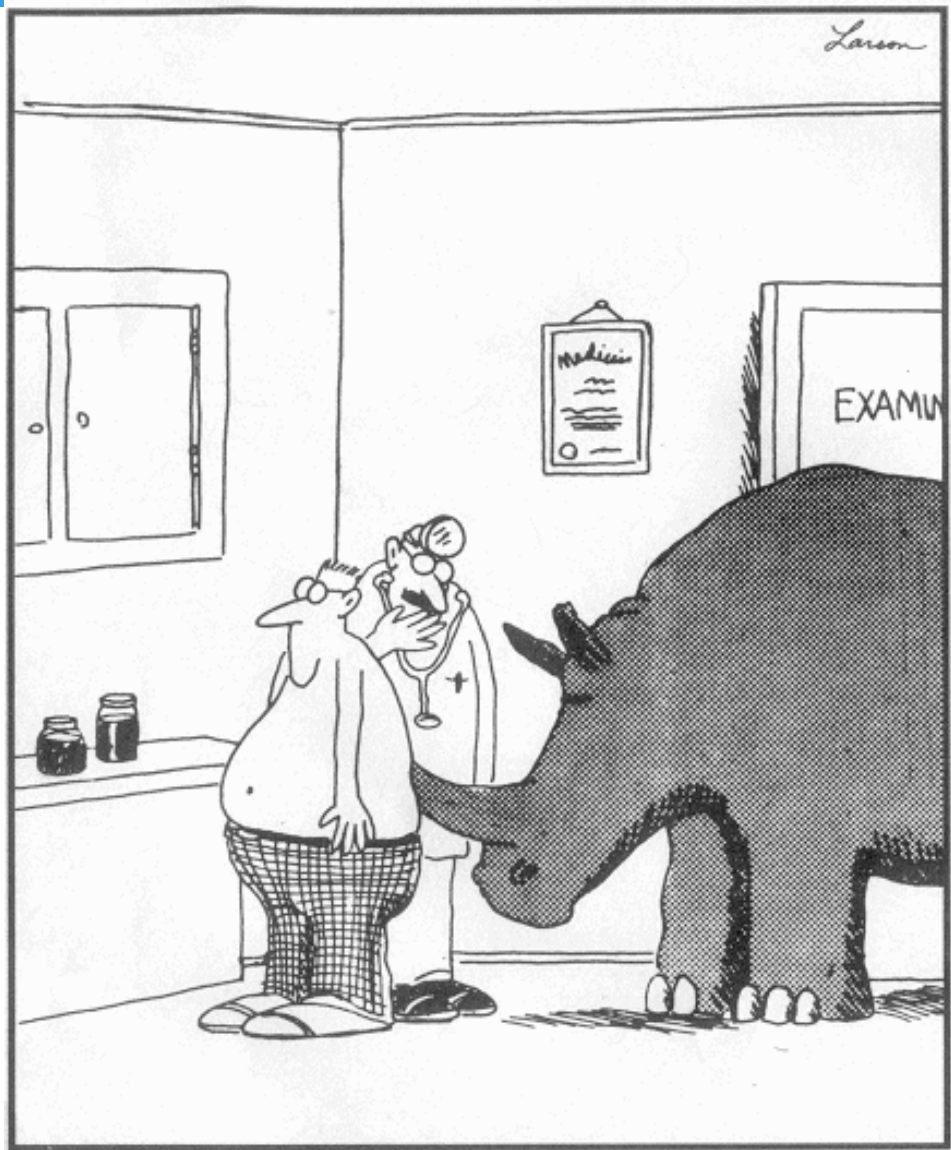
Proactive analysis of system vulnerabilities: Adapting into health

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The Alfred Centre
18th November 2011



Overview of Presentation

1. Focus on HFMEA®
 - i. Steps in HFMEA®
2. Evaluation & critique of HFMEA®
 - i. Problems identified in the literature
 - ii. Recommendations for future studies
3. Questions



“Wait a minute here, Mr. Crumbley. ...
Maybe it isn't kidney stones after all.”

Health Care Failure Mode and Effect Analysis

- A “systematic approach to identify product and process problems before they occur” (DeRosier et al., 2002)
- Adapted into health and developed from:
 - FMEA
 - Root Cause Analysis (RCA)
 - Hazard Analysis and Critical Control Point (HACCP)
- Joint Commission for the Accreditation of Hospital Organisations (JCAHO), now Joint Commission (JC), mandated all US hospitals begin using FMEA type analysis of all healthcare delivery process
 - One high risk process per annum
 - JCAHO audits began in June 2002

Steps in HFMEA®

- Step 1. Define the HFMEA™ Topic
 - High risk or vulnerable process
- Step 2. Assemble the Team
 - Multi-disciplinary team
- Step 3. Graphically Describe the Process
 - Recommends box-and-arrow diagrams

Steps in HFMEA®



Failure Mode:

- I Not available
- li Incorrect Patient (scanned into wrong file)
- lii Unreadable (illegible)
- Iv Scanned Incorrectly
- V Mis-labelled
- Vi outdated report
- Vii not completed
- Viii not verified
- Ix Not consistent
- X Forgotten
- Xi LANTIS crash (network failure)
- Xii Scanner failure
- Xiii

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 - Determine severity and probability of occurrence

Steps in HFMEA®

Catastrophic Event <i>(Traditional FMEA Rating of 10 - Failure could cause death or injury)</i>	Major Event <i>(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)</i>
<p><u>Patient Outcome:</u> Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family</p> <p><u>Visitor Outcome:</u> Death or hospitalization of 3 or more.</p> <p><u>Staff Outcome:</u> A death or hospitalization of 3 or more staff</p> <p><u>Equipment or facility:</u> Damage equal to or more than \$250,000</p> <p><u>Fire:</u> Any fire that grows larger than an incipient</p>	<p><u>Patient Outcome:</u> Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients</p> <p><u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors</p> <p><u>Staff Outcome:</u> Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses</p> <p><u>Equipment or facility:</u> Damage equal to or more than \$100,000</p> <p><u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p>

Steps in HFMEA®

<p>Moderate Event <i>(Traditional FMEA Rating of “4” – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)</i></p>	<p>Minor Event <i>(Traditional FMEA Rating of “1”– Failure would not be noticeable to the customer and would not affect delivery of the service or product.)</i></p>
<p><u>Patient Outcome:</u> Increased length of stay or increased level of care for 1 or 2 patients <u>Visitor Outcome:</u> Evaluation and treatment for 1 or 2 visitors (less than hospitalization) <u>Staff Outcome:</u> Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff <u>Equipment or facility:</u> Damage more than \$10,000 but less than \$100,000 <u>Fire:</u> Incipient stage or smaller</p>	<p><u>Patients Outcome:</u> No injury, nor increased length of stay nor increased level of care <u>Visitor Outcome:</u> Evaluated and no treatment required or refused treatment <u>Staff Outcome:</u> First aid treatment only with no lost time, nor restricted duty injuries nor illnesses <u>Equipment or facility:</u> Damage less than \$10,000 or loss of any utility without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning). <u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p>

Steps in HFMEA®

	Severity of Effect			
	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

Frequent - Likely to occur immediately or within a short period (may happen several times in 1 year)

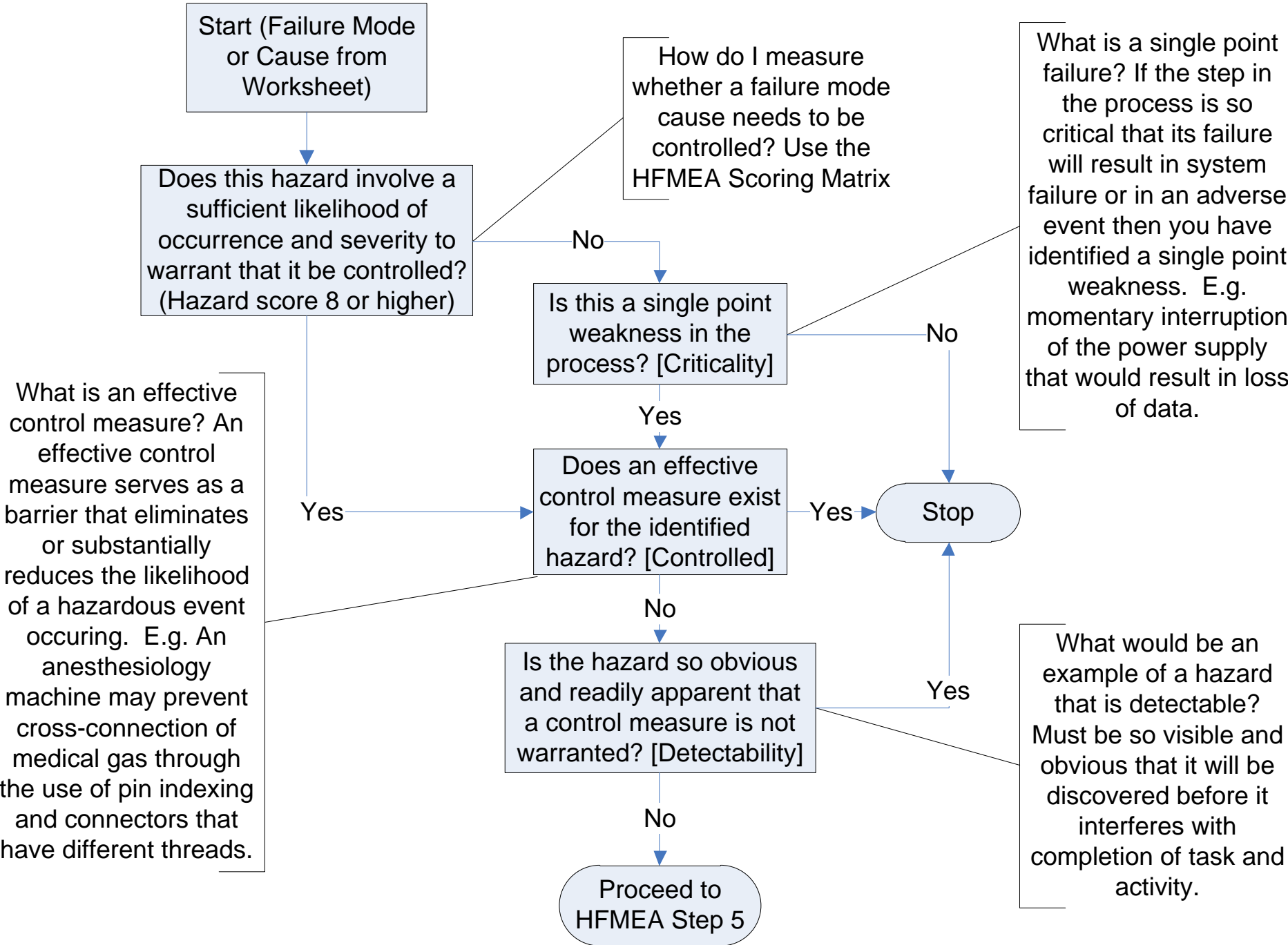
Occasional - Probably will occur (may happen several times in 1 to 2 years)

Uncommon - Possible to occur (may happen sometime in 2 to 5 years)

Remote - Unlikely to occur (may happen sometime in 5 to 30 years)

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 - Identify failure modes
 - Determine severity and probability of occurrence
 - Use HFMEA Decision Tree™



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- Step 5. Actions and Outcome Measures

Failure Mode	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure
			Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectability	Preced?			
Export Final Plan to the EMR: Machine parameters related to patient treatment (e.g. treatment plan) are exported from the treatment planning system to the EMR. Failure Mode (iv) Wrong Plan Exported			Major	Remote	3	Yes	-	-	Yes			
	iv A	Dosimetrist fatigued	Major	Uncommon	6	Yes	No	No	Yes	Control	<p>Once a plan has been approved all other plans for that patient should be deleted/removed from the file.</p> <p>Rationale: If two plans are generated for one patient it is possible that the wrong DRRs can be exported for the wrong plan. When imaging on day 1 it should be clear that the moves from CT reference to the isometric points don't match the DRRs.</p>	Auditing of new patient files should find only one plan present and approved for use.



Evaluation & Critique of the HFMEA® Method

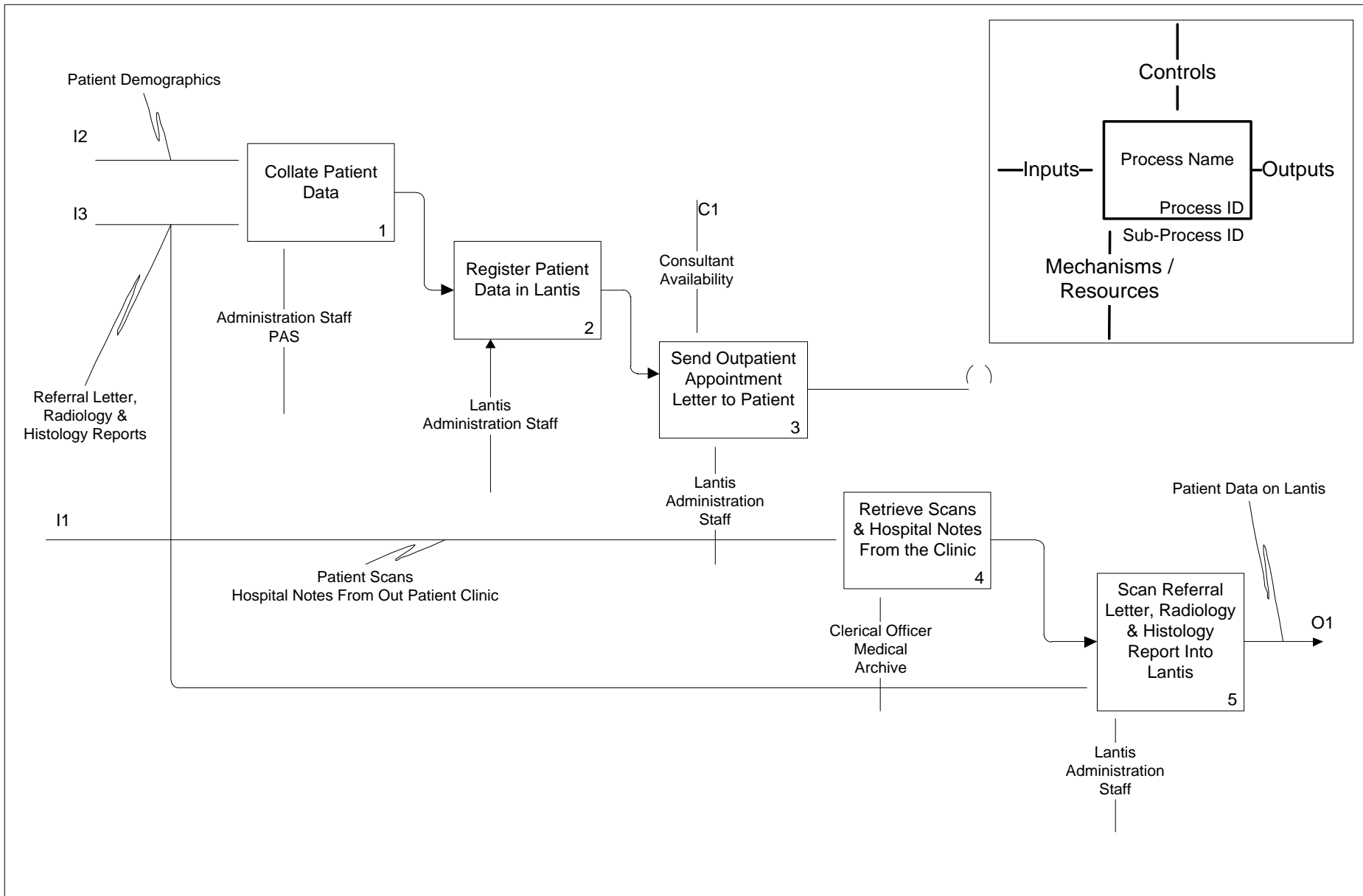
**... suggestions for
improvement**

Problems identified in the literature

HFMEA™ Step	Challenges/Weaknesses	Wetterneck et al. (2004)	Habraken et al. (2009)	Chadwick & Fallon (2012)
General Properties	Time & resources required	✓	✓	✓
	Dependency on the quality of the facilitator	✓	✓	✓
	No consideration of 'Data/ Information' failures or errors			✓
	Doesn't facilitate continuous improvement			✓
Graphically Describe the Process	Recommended changes to the process modelling method			✓
Hazard Analysis	No support for failure mode or human error assessment		✓	✓
	Problem with the hazard scoring system	✓	✓	✓
	Difficulty using the decision tree		✓	✓
Actions and Outcome Measures	Difficulty determining corrective measures		✓	✓

“Graphically Describe the Process”

- Simple ‘Box & Arrow’ diagrams recommended in HFMEA™ provide only minimum information to analysts.
- A richer modelling method such as IDEFØ can better support process understanding
 - IDEFØ provides detailed descriptions of processes and sub-processes and the relations between them.
 - Provide information about the Inputs, Controls, Outputs and Mechanisms (ICOMs) for each process and sub-process.



NODE:	A1	TITLE:	Compile Patient File & Schedule Outpatient Appointment	NO.:	3
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 - Provide information about the Inputs, Controls, Outputs and Mechanisms (ICOMs) for each process and sub-process.
- ICOMs can be used to prompt analysts of potential Failure Modes.
 - Can be used to identify process and information dependencies in a treatment process.

“Time Requirements”

- Time requirement for stakeholder participation in HFMEA® studies is particularly problematic.
 - Staff shortages, increased work loads.
- Use distributed teams within the department.
 - Use small interdisciplinary groups (2+ people) to work on distinct parts of the analysis.
 - Facilitator acts as a moderator and links the analysis work.
 - Convene group meetings to achieve consensus on the findings.

Hazard Scoring

- Hazard scoring severity descriptions have been found to be too broad
 - 4 level HFMEA® hazard scoring levels difficulty in scoring specification.
- A 5-level scoring system with multiple risk categories provides greater flexibility
 - Injury, patient experience, compliance with standards, business continuity, ability to meet objectives, adverse publicity, financial loss and environmental impact. (Office of Quality and Risk, 2008; National Patient Safety Authority, 2008)

Hazard Scoring

	<u>Negligible</u>	<u>Minor</u>	<u>Moderate</u>	<u>Major</u>	<u>Extreme</u>
<u>Injury</u>	Adverse event leading to no apparent injury or minor injury not requiring first aid.	Minor injury or illness, first aid treatment required, <3 days absence, < 3 days extended hospital stay, emotional distress	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). >3 Days absence, 3-8 Days extended hospital stay, Emotional Trauma	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling Physical /emotional disability	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public (Emotional / Physical trauma)

Hazard Scoring

Likelihood Scoring

Rare/Remote		Unlikely		Possible		Likely		Almost Certain	
Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability
May occur every 5 years or more	1%	May occur every 2-5 years	10%	May occur every 1-2 years	50%	Bimonthly	75%	At least monthly	99%

Hazard Scoring

Severity Scoring

	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	5	10	15	20	25
Likely	4	8	12	16	20
Possible	3	6	9	12	15
Unlikely	2	4	6	8	10
Rare/ Remote	1	2	3	4	5

Hazard Scoring

- Hazard scoring severity descriptions have been found to be too broad
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- A 5-level scoring system with multiple risk categories provides greater flexibility
 - Injury, patient experience, compliance with standards, business continuity, ability to meet objectives, adverse publicity, financial loss and environmental impact. (Office of Quality and Risk, 2008; National Patient Safety Authority, 2008)
- No consideration of patient ‘Data/Information’ failures or errors
 - Particularly relevant for errors related to treatment plans, pathology results, medical history
 - Need to include a patient ‘Data/Information’ severity category

Hazard Scoring

5-Level Severity Categorisation for 'Data' Failures

	Negligible	Minor	Moderate	Major	Extreme
Data/ Information	A data failure resulting in no apparent injury, inconvenience or temporary discomfort	A data failure resulting in temporary injury or impairment not requiring a medical intervention.	A data failure resulting in an injury or impairment requiring medical treatment.	A data failure resulting in permanent impairment or life-threatening injury.	A data failure resulting in death.

Adapted from: *ISO 14971:2009 - Medical devices — Application of risk management to medical devices. London, UK. Standards Board*

Detection F

asures & S



**"Whoa! Watch where that thing lands—
we'll probably need it."**

Detection Methods, Control Measures & Recovery Mechanisms

- No identification of the detection method or control measure.
 - Information is not requested from users and not described elsewhere.
- No description of the 'Effect' of a failure mode.
 - HFMEA® → HF~~M~~A???
- Implies that detectable failures are recoverable.
 - Not always true! e.g. medication overdose.
 - HFMEA® does not require the identification of the recovery mechanisms for failure modes that are detectable.

Identification of Corrective Actions

- Analysts have difficulty identifying corrective measures for the identified failure modes.
 - Particularly true for human errors – health care analysts can have little experience analysing human errors and determining associated corrective actions.
 - No support information provided for Human Error Assessment (HEA).
- Could support HFMEA® with human error taxonomies
 - SHERPA (Embrey, 1986), OCHRA (Tang et al., 2004), CREAM (Hollnagel, 1998)
 - Link human errors to appropriate corrective measures.



Action Errors	C4 – Wrong Check on Right Object
A1 – Operation Too Long/Short	C5 – Check Mistimed
A2 – Operation Mistimed	C6 – Wrong Check on Wrong Object
A3 – Operation in Wrong Direction	Retrieval Errors
A4 – Operation Too Little/Much	R1 – Information not Obtained
A5 – Misalign	R2 – Wrong Information Obtained
A6 – Right Operation on Wrong Object	R3 – Information Retrieval Incomplete
A7 – Wrong Operation on Right Object	Communication Errors
A8 – Operation Omitted	I1 – Information Not Communicated
A9 – Operation Incomplete	I2 – Wrong Information Communicated
A10 – Wrong Operation on Wrong Object	I3 – Information Communication
Checking Errors	Selection Errors
C1 – Check Omitted	S1 – Selection Omitted
C2 – Check Incomplete	S2 - Wrong Selection Made
C3 - Right Check on Wrong Object	

System Failures

- System related Failure Modes Support Info. (IEC, 2006)
 - the function of the system/process;
 - the particular system element involved;
 - the mode of operation;
 - the pertinent operational specifications;
 - the time constraints;
 - the environmental stresses;
 - the operational stresses.
- Also IDEFØ model can provide prompts related to process ICOMs.

HFMEA Decision Tree™ Design

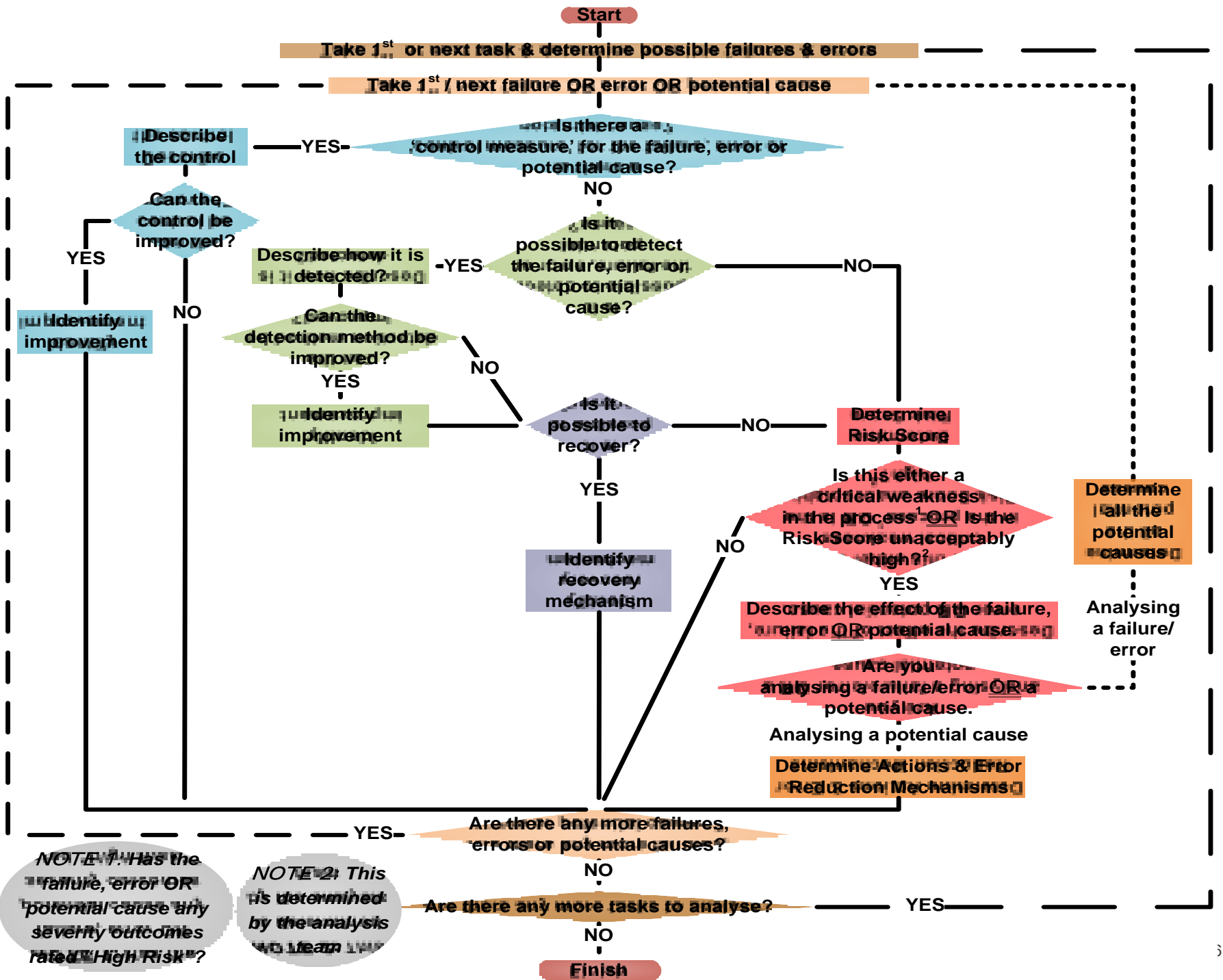
- Using the HFMEA™ Tree, analysts have difficulty following the rules:
 - to ‘Stop’ the analysis and move onto the next failure mode
 - determine the potential causes for the failure modes
 - proceed to Step 5 detailed analysis (identify actions & outcome measures).
- A more specific Decision Tree with a clearer ‘Stop/Proceed’ rule should be developed to prevent confusion.

HFMEA® and Continuous Improvement


- Analysts want to make recommendations to improve process safety (detection methods or control measures)
 - According to the Tree the process is considered safe, i.e. the failure mode was considered controlled or detectable.
 - Staff had improvements to the existing controls or detection methods that would make the process safer, more efficient or more reliable.
- Facilitate Continuous Improvement by first identifying the detection method and/or control and then querying if either can be improved.

New Decision Tree

- Use logical structure and concepts of HFMEA® to redesign the flowchart
 - Improve efficiency of the method
 - Reduce confusion around the ‘Stop’ rule
 - Require descriptions of the detection method, recovery mechanism or control measure



New Pro-forma

Failure, Error OR Potential Causes		Hazard & Risk Analysis										Recommendations		
Failure, error: (No. & Description)	Potential Causes (No. & Description)	Control Measure			Recovery		Detection Method				Risk Scoring & Effect			Actions & ERMs
		Control (Y?N)	Describe the Control?	Control adequate?	Identify control improvement	Recovery Possible?	Identify recovery	Detectable (Y/N)	Describe how it is detected?	Detection adequate?	Identify detection Improvement	Risk Score	Critical Weakness (C) / Risk Score Unacceptable (U)	Effect of the failure, error OR potential cause
														

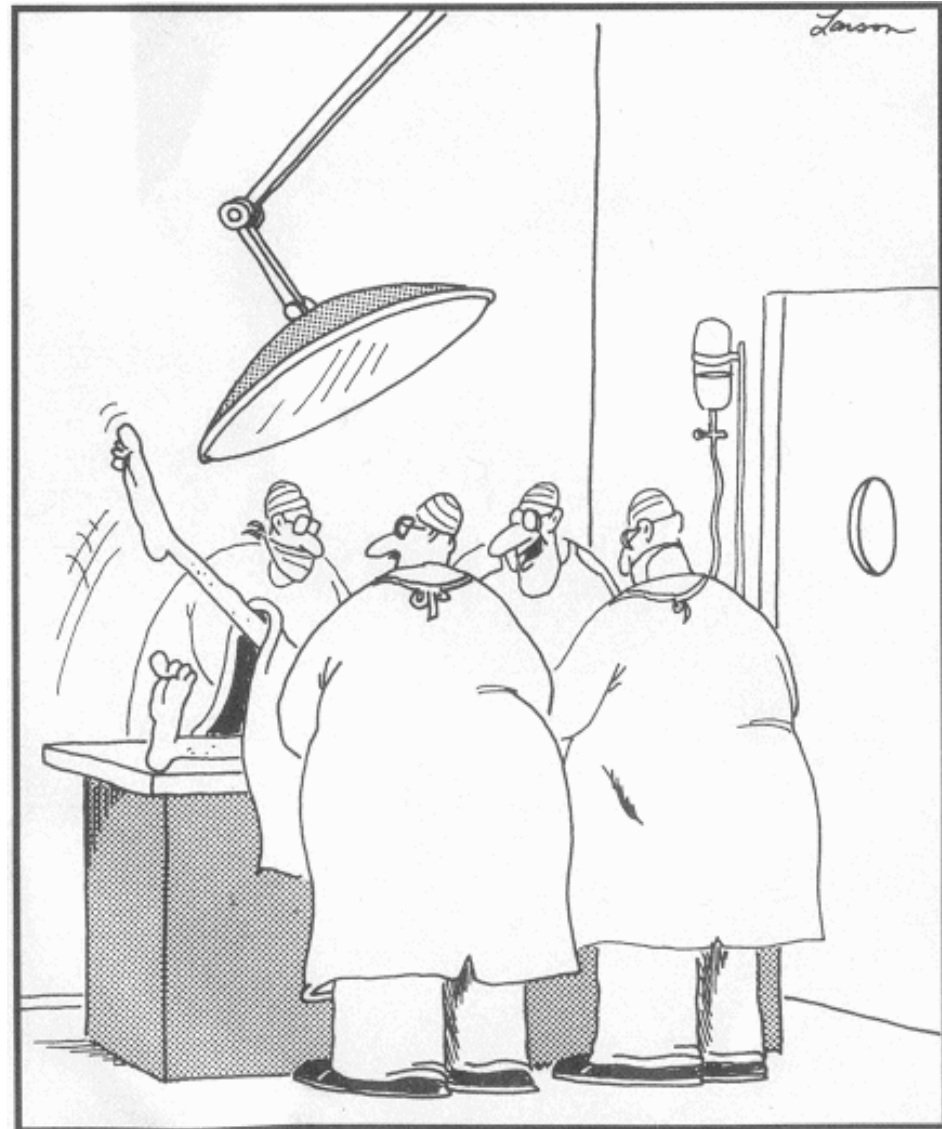


Thought for the break...

“When it is obvious that the goals cannot be reached, don't adjust the goals, adjust the action steps.”

Confucius, 551 BC - 479 BC

Thank you



“Whoa! *That* was a good one! Try it, Hobbs—just poke his brain right where my finger is.”

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