

# Early Australian Experience with CAST to Investigate Medical Events

Wal Grimmett

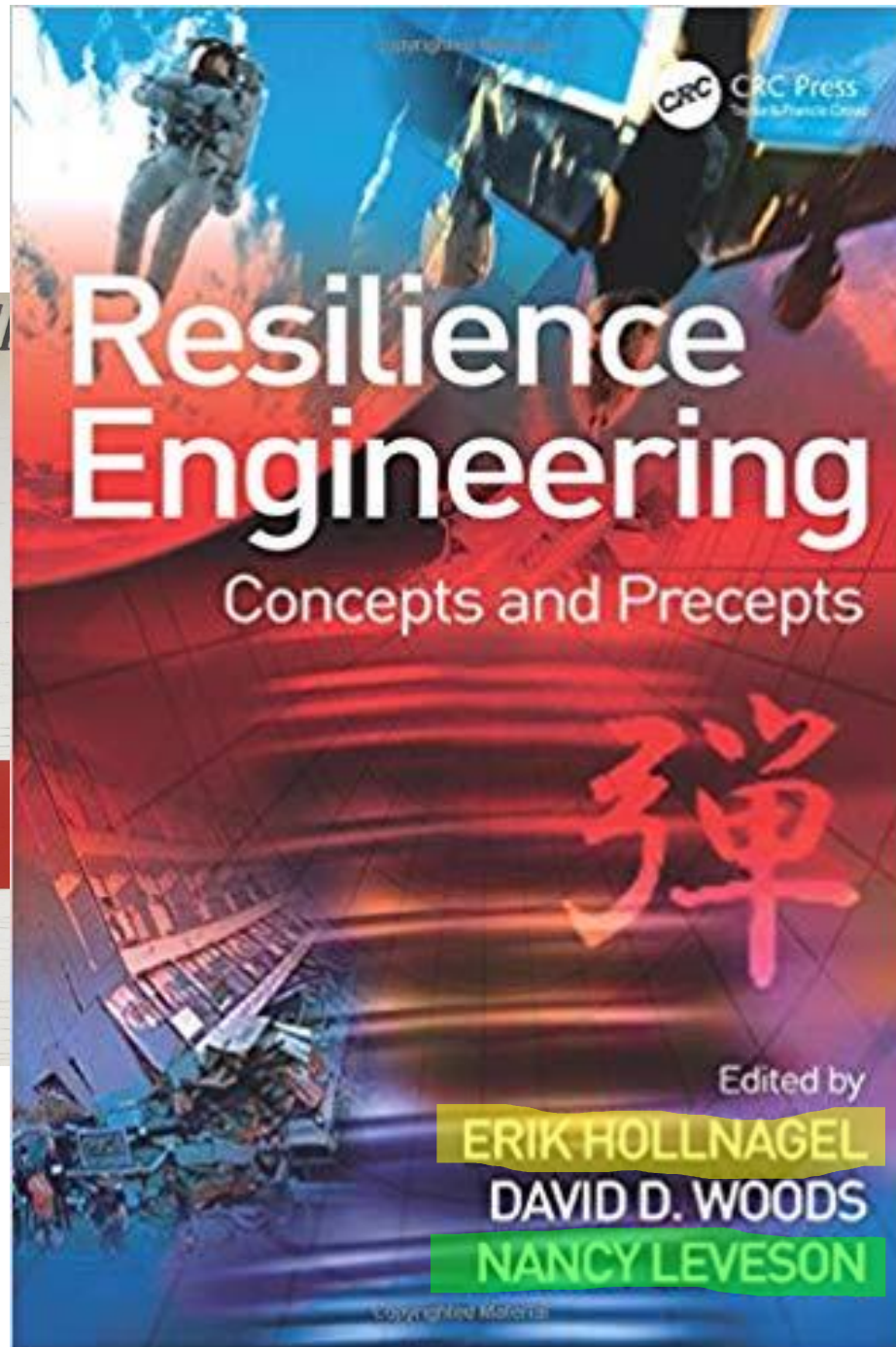
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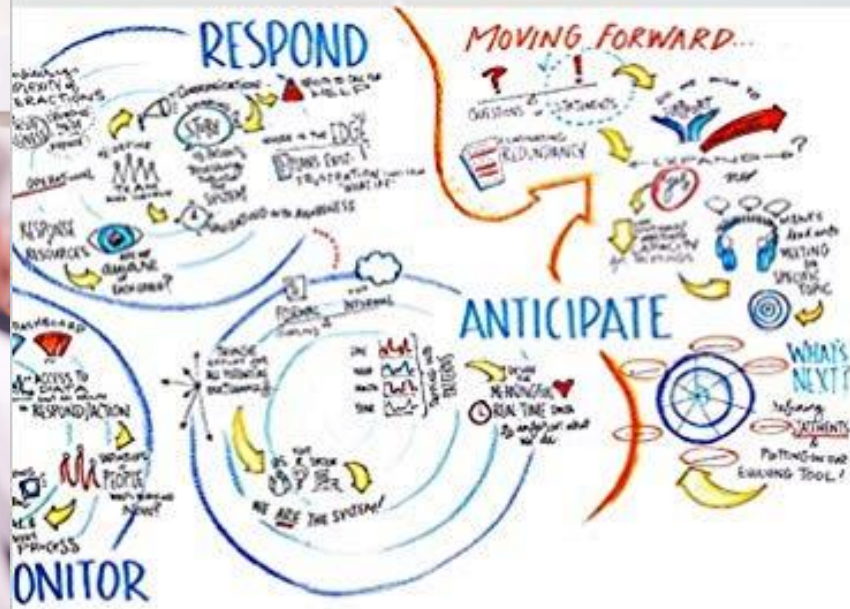


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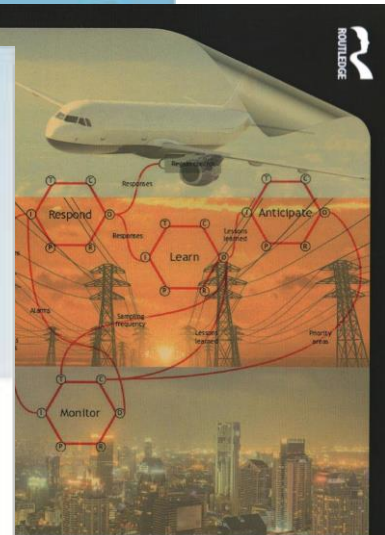




# Delivering Resilient Health Care



Edited by  
**Erik Hollnagel, Jeffrey Braithwaite  
and Robert L. Wears**



## SAFETY-II IN PRACTICE UNLOCKING THE RESILIENCE POTENTIALS

ERIK HOLLNAGEL



# Complexity Challenge of 21<sup>st</sup> Century

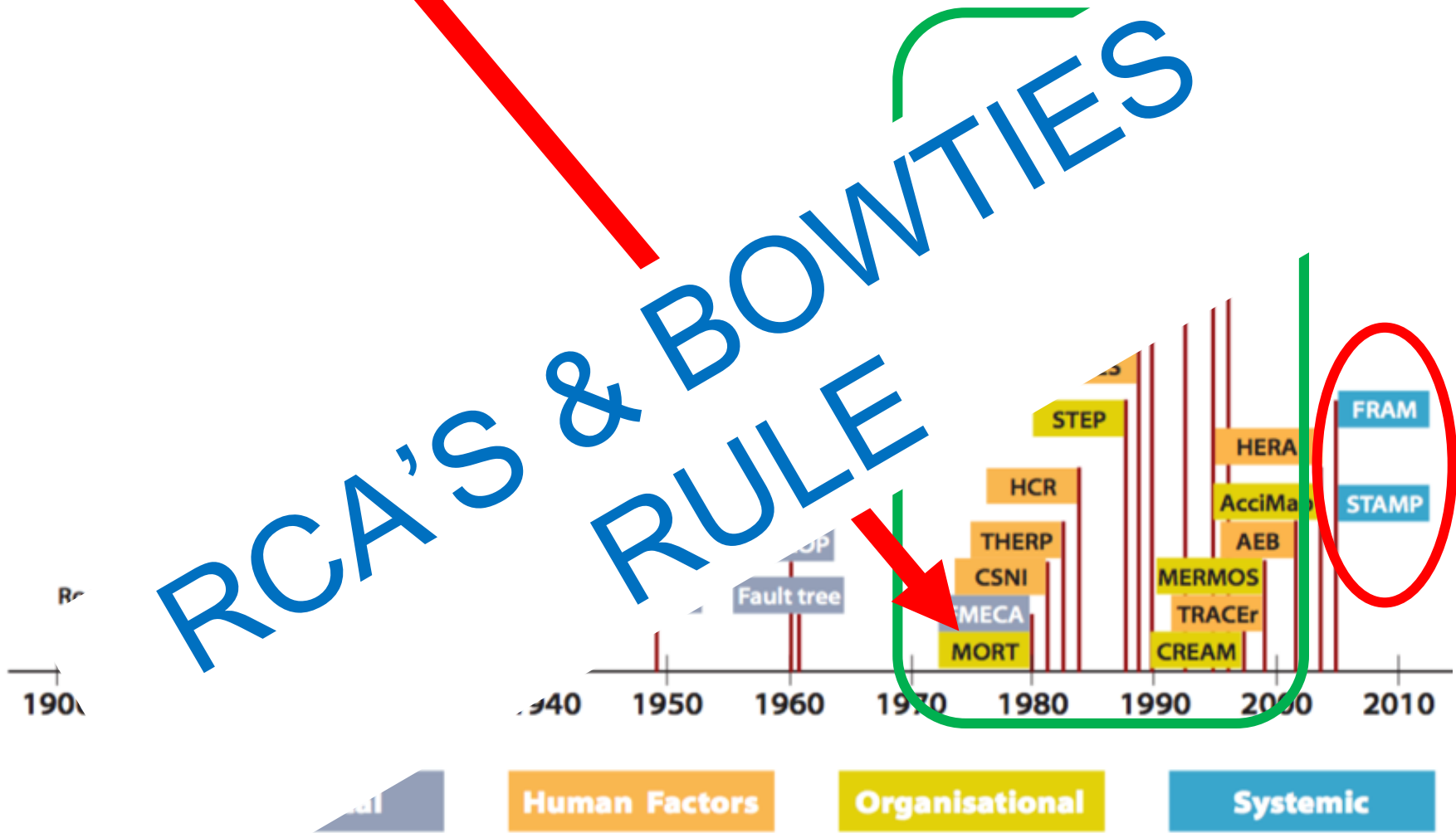


Figure 2: Accident Analysis and Risk Assessment Methods

# Bilateral Total Knee Replacement; Tourniquet Event

## TOTAL KNEE REPLACEMENT

- Commonly a pneumatic tourniquet is used to reduced intra-operative bleeding and help the cementing process.
- So the leg arteries are occluded for a time (hopefully less than 1 hour.) Then the tourniquet is released and the blood flow returns.

*Occasionally*

The artery is damaged leading to a dead leg

*Or*

The tourniquet simply stays up too long with the same result.  
(Which is what happened in the case to be investigated)

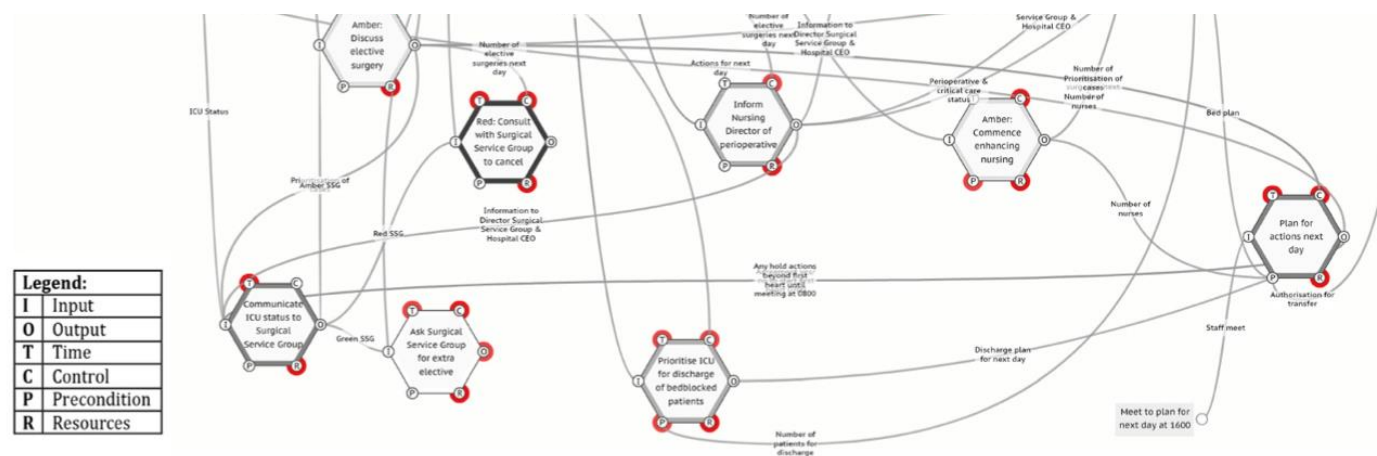
**METHODOLOGY**

**Open Access**



# Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines

Robyn Clay-Williams<sup>1\*</sup>, Jeanette Hounsgaard<sup>2</sup> and Erik Hollnagel<sup>2,3</sup>



**Fig. 3** FRAM of modified guideline draft

# What Makes a Good Model

- [The model] leads to a more comprehensive understanding of the accident and the factors that must be changed to prevent future accidents
- The use of [the model] during accident investigations should assist investigators in determining the questions necessary to ask in order to build a comprehensive model of the accident.
- [The model] should be useful not only in analysing accidents that have occurred but in developing system engineering methodologies to prevent accidents
- [The model] could also be used to improve performance analysis.
- [The model] could also point the way to very different approaches to risk assessment.

Leveson N. A new accident model for engineering safer systems. Safety science. 2004;42(4):237-70.





# STPA HANDBOOK

**NANCY G. LEVESON**  
**JOHN P. THOMAS**

**MARCH 2018**

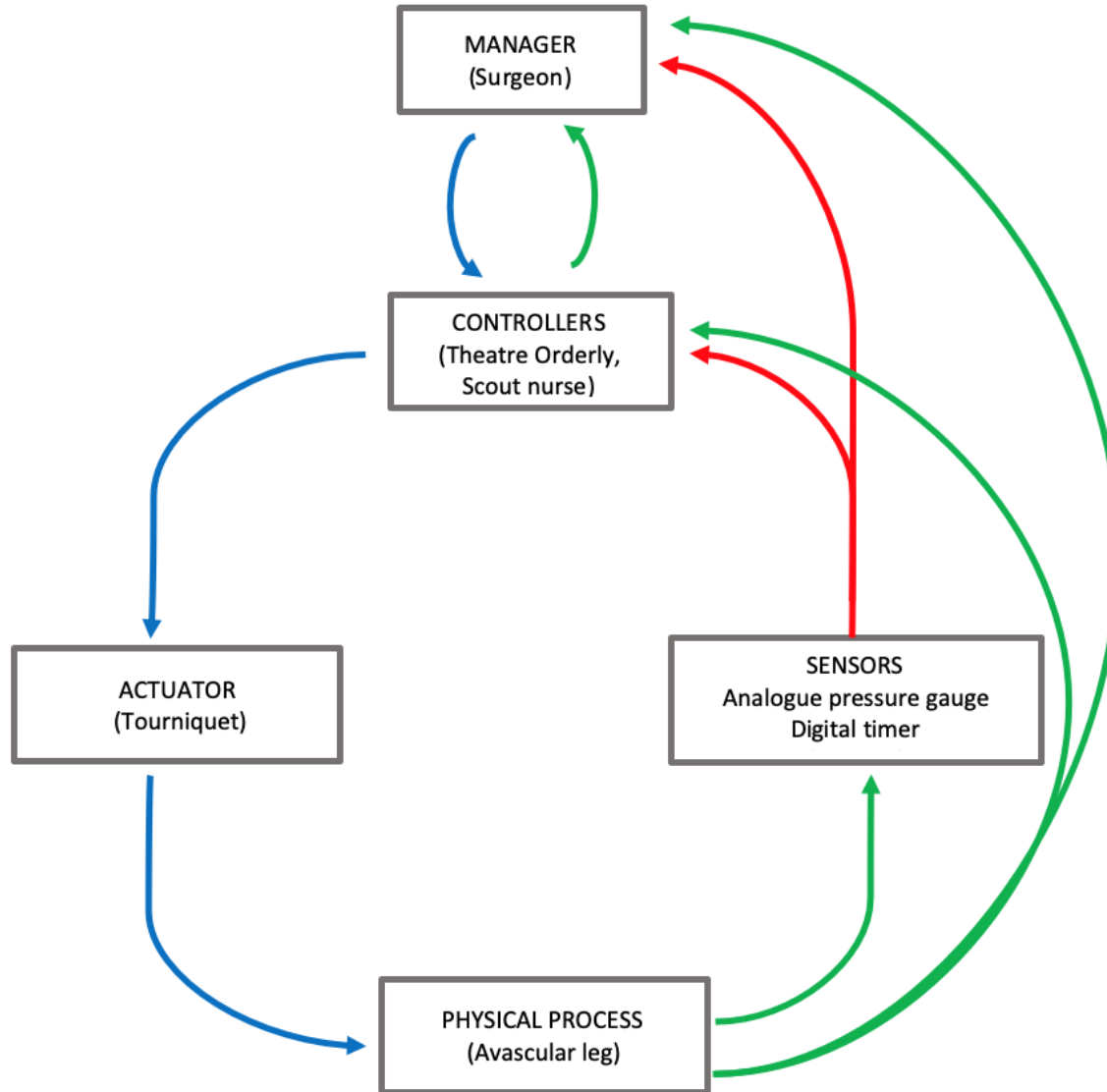
This handbook is intended for those interested in using STPA on real systems. It is not meant to introduce the theoretical foundation, which is described elsewhere. Here our goal is to provide direction for those starting out with STPA on a real project or to supplement other materials in a class teaching STPA.

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# BACK TO CAST

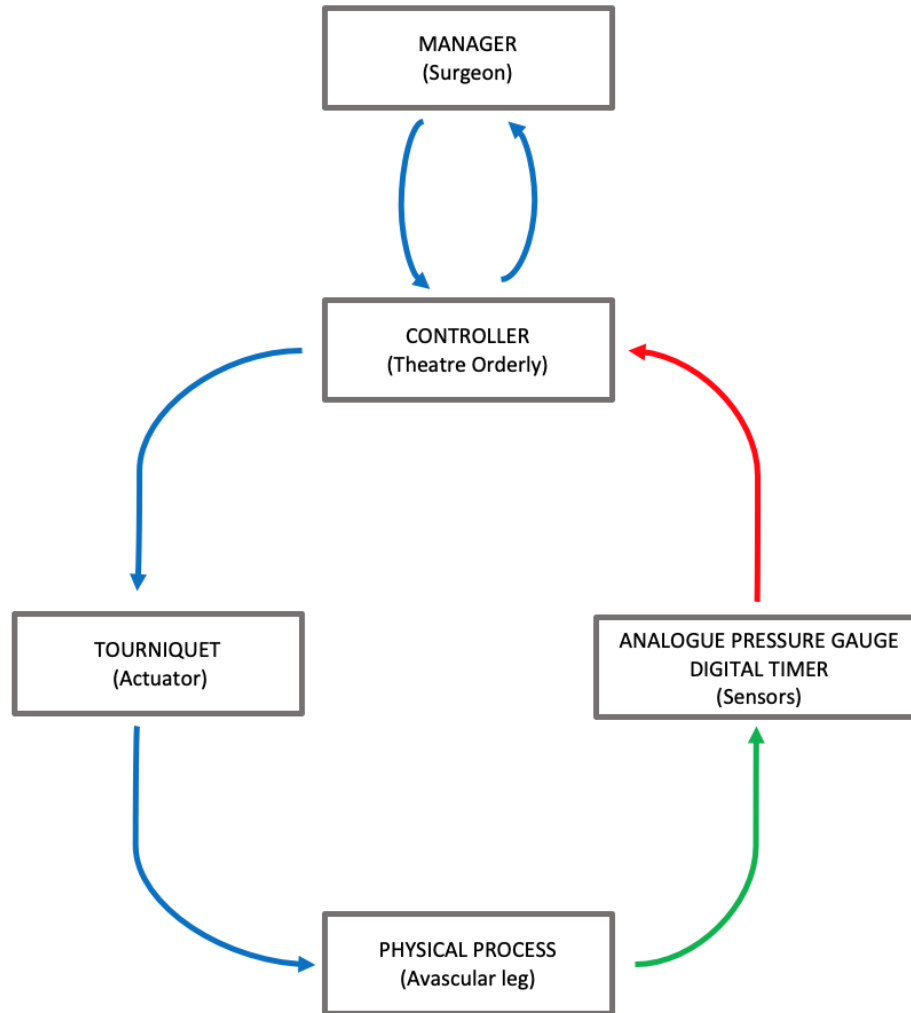
- Ease of use with special reference to training burden for investigators.
- Resources required with reference to number of personnel required including primary investigators and support staff.
- Time required to both investigate and report.
- The model's ability to assist in communicating the results to other audiences outside the investigating team. (For example communicating to an executive team of a hospital or legal positions such as coroners.)
- The ability of the model to integrate into the existing quality or safety processes of the organisation using the model.

# SINGLE LIMB KNEE ARTHROPLASTY CONTROL DIAGRAM



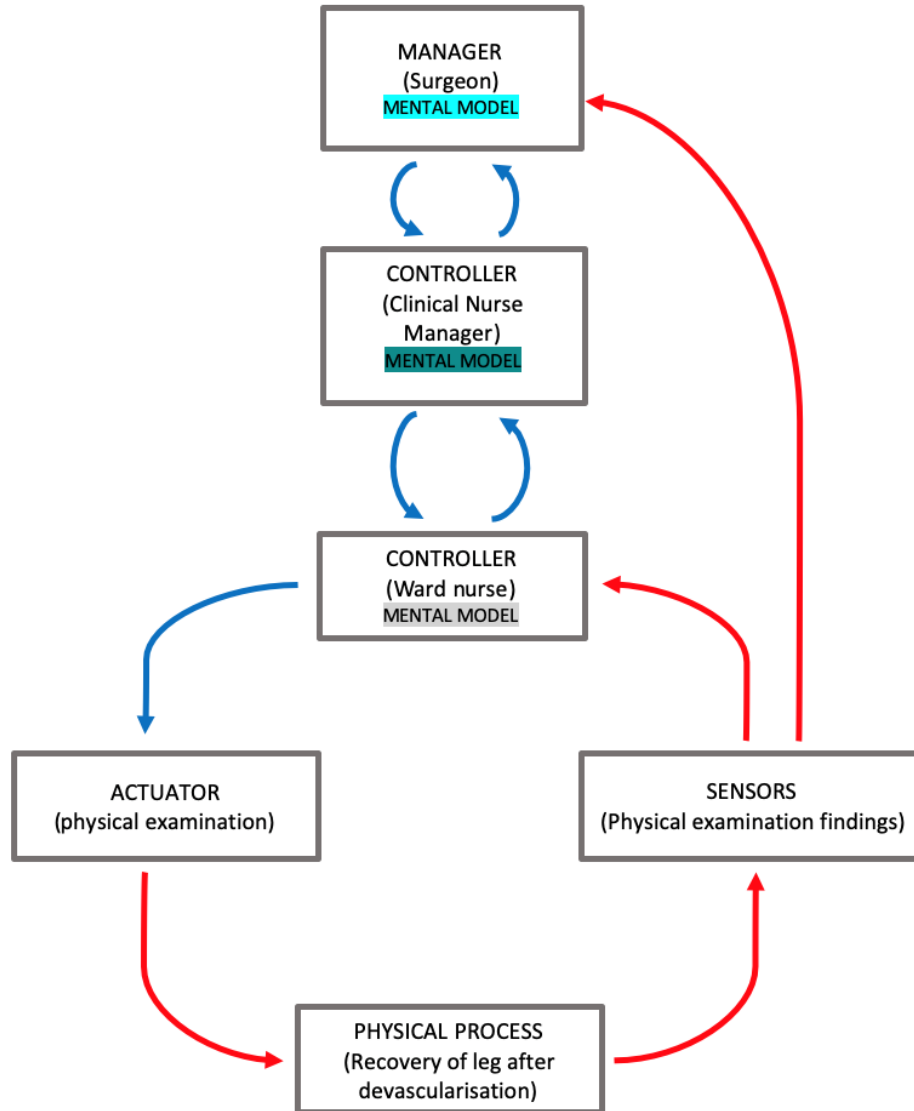
Control Actions; Blue  
Feedback; Green  
Red action/feedback that  
requires remedial controls.

BILATERAL KNEE ARTHROPLASTY CONTROL DIAGRAM  
FIRST KNEE



Control Actions; Blue  
Feedback; Green  
Red action/feedback that  
requires remedial controls.

# POST-OPERATIVE KNEE ARTHROPLASTY CONTROL DIAGRAM



Control Actions; Blue  
Feedback; Green  
Red action/feedback that  
requires remedial controls.

## They liked

- Understandable
- Intrinsically Just
- System based
- Cost. My bill was approx. \$2,600. 9 hrs on site and 3 hours to produce a report (I was charging out at \$200/hr). Add 2 other hospital staff assisting the total cost was approx. \$6000.

## They Disliked

- Systems based recommendations (nobody to shoot!)
- Tourniquet changes. Too simple
- Introduction of Dopplers. Too simple.
- Surgeons lawyers used the result to defer all compensation responsibility to the hospital



# I learnt

- CAST methodology focused you on the system.
- CAST minimised assumptions
- I needed to get more detail on mental models from both operators and designers
- You get what you pay for. More time would have produced a much more detailed report.
  
- First hints I need a psychology degree to do medical investigations, especially after meeting the patient and reading all the legal exchanges.
- Emotional burden on investigators to deliver a systems based result in the face of the often conflicting agendas of the actors.

# CHEST OPENING IN INTENSIVE CARE

Large tertiary level Cardiac Intensive Care Unit

Patient returned to intensive care after revision infected previously replaced aortic arch and aortic valve.

Intubated, ventilated, multiple drug infusion.

Junior ICU nurse takes over care. ICU nurse manager in ward resetting a pacemaker.

Intensive Care specialist up stairs assisting with cardiac imaging.

Patient drops BP and junior nurse pulls one drug out of infusion pump to use pump for fluid bolus.

BP falls precipitously and patient arrests

Chest opened but no pericardial tamponade.

Then education nurse notices first drug line not clamped and a massive dose of sodium nitroprusside given.

Appropriate resuscitation given and no sequelae.

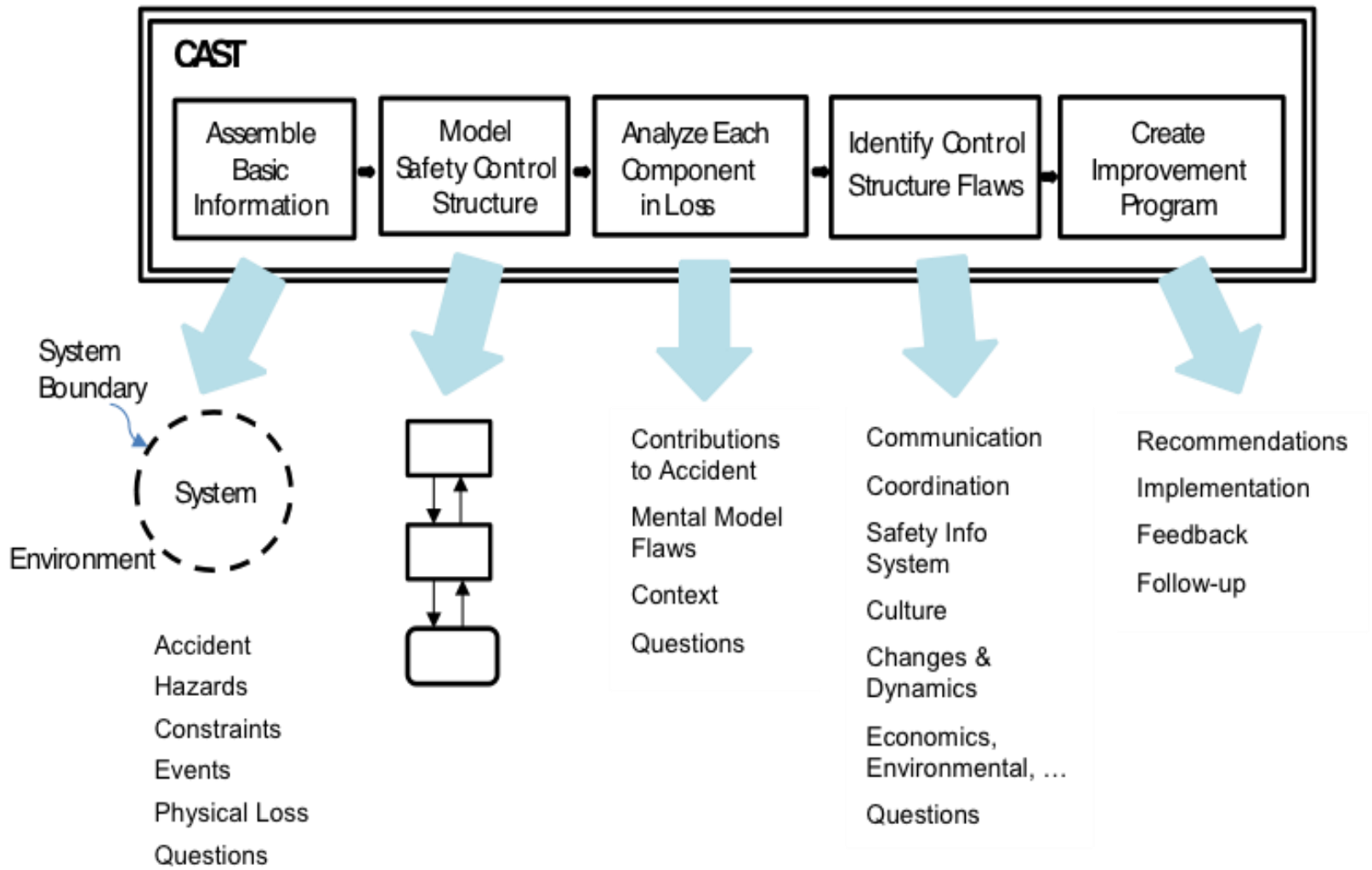
# Larger Investigation by many magnitudes.

Desperate for help, especially the promised CAST handbook I emailed Prof Leveson expressing my frustrations with FRAM and my early positive experience with STAMP

*“I have never been able to get FRAM to work on anything. I assigned a very bright Ph.D. student at MIT to try to figure it out, and she gave up..... So you are not alone.”* Warm Regards, Nancy

and

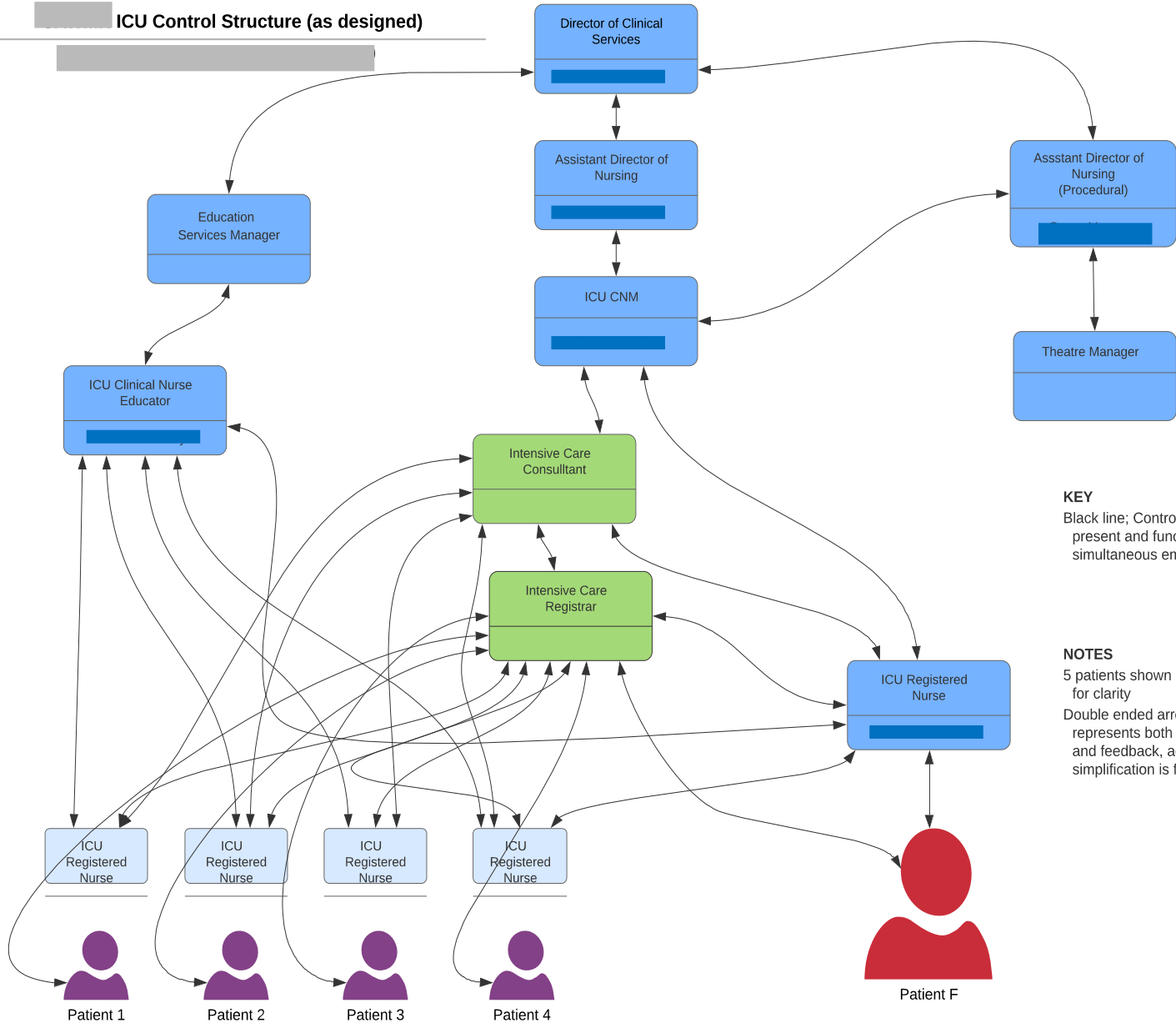
The CAST Handbook is available at: <http://psas.scripts.mit.edu/home/>



# Investigation

- 4 team members.
  - After initial interviews and establishment of the time line the team split
  - 3 Concentrated on RCA
  - 1 performed a CAST analysis
- CAST
  - Greater emphasis on Mental Models for both designers and operators
  - Better flow diagram software (Lucid Chart)

**ICU Control Structure (as designed)**

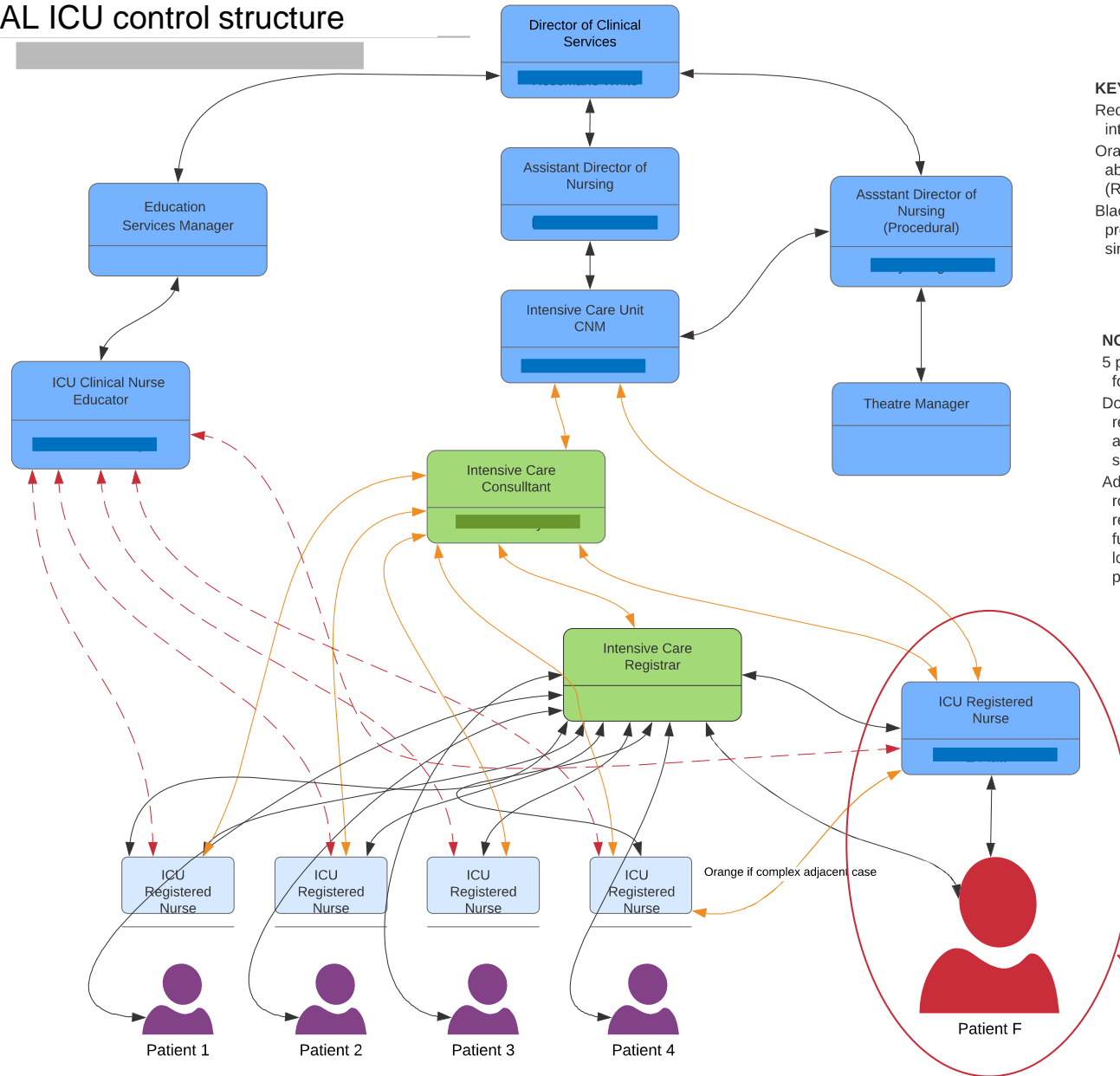


**KEY**  
 Black line; Control loop consistently present and functional, barring simultaneous emergencies.

**NOTES**  
 5 patients shown out of total of 15 for clarity  
 Double ended arrowed line represents both control actions and feedback, again the simplification is for clarity



# ACTUAL ICU control structure



**KEY**  
 Red Dashed line; Control loop intermittent at best. Commonly absent.  
 Orange line; Control loop occasionally absent but usually functional. (Routinely absent after hours)  
 Black line; Control loop consistently present and functional, barring simultaneous emergencies.

**NOTES**  
 5 patients shown out of total of 15 for clarity  
 Double ended arrowed line represent both control actions and feedback, again the simplification is for clarity  
 Admin level control structures are routinely black as don't always require physical presence to function reliably. Clinical control loops often, but always require a physical presence.

Orange if complex adjacent case

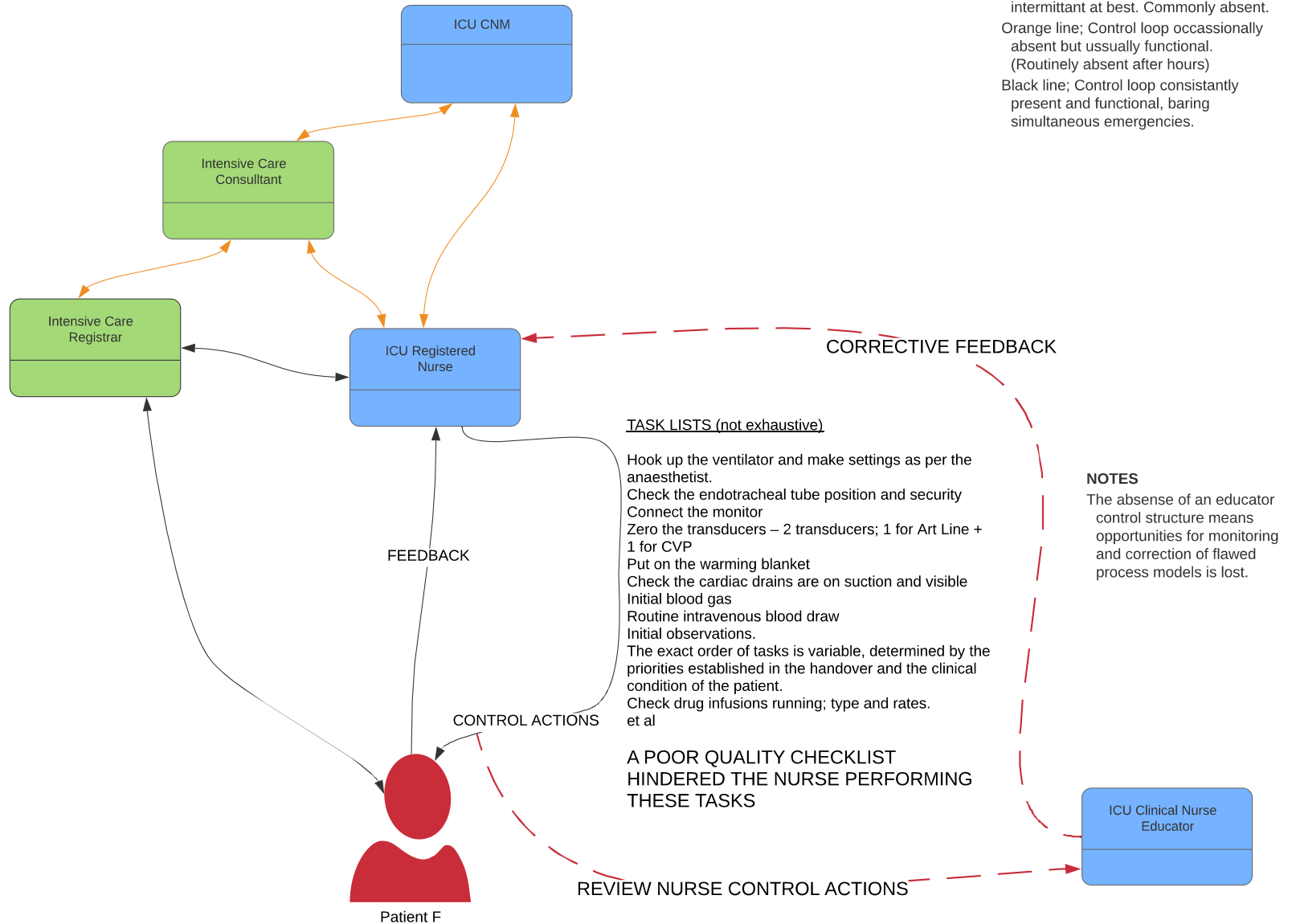
See Nurse/Patient expanded control structure

# Nurse/ Patient Expanded Control Structure

Wal Grimmatt | September 3, 2019

### KEY

Red Dashed line; Control loop intermittent at best. Commonly absent.  
 Orange line; Control loop occasionally absent but usually functional. (Routinely absent after hours)  
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# RCA Result

2 Barriers recommended

- Communication; better handover
- Better policy & procedures regarding the pump

Education hours to be increased.

However no reason was given why this was a critically required *system* change. (Based on the assumption education was single step process required by the operator. This highlights the failing of RCA, designed for industry vs STAMP designed for complex socio-technical systems)

# CAST Result

1. Education
2. Role Descriptions to be enhanced

OVERALL; CAST allowed me to explain why these things were important.

A greater emphasis on mental models facilitated a greater, less judgemental, understanding of why people behaved as they did.

Thus I explained why communication was an issue, what effect it had and what had to be done to rectify the associated issues. (mostly of the communication issues were caused by absence of personnel negating effective communication.)

# What is the Educator's Role?

## *the importance of trust & mental models*

Initially

“Clinical training, ensuring competencies and skills development”

Once trust was established that answer changed

“at the coal-face, constantly in the staff's face”,



# EDUCATION RECOMMENDATION (a result of mental model exploration)

- Education in a complex system cannot be treated as a single classroom event aimed at obtaining a qualification
- Education in ICU in particular is a continuous process with *each individual nurse* having unique process models requiring constant review and remediation.
- As such *education acts as a critical quality review process* remediating process models in real-time. This review occurs *before* hazardous decisions based on faulty process models can combine with circumstance to inflict an accident. (Such as occurred with Patient F)
- This requirement will become more pressing as the use of agency staff, with often unknown process models, continues to be an inevitable requirement to meet fluctuating workflow demands.
- While the education “control loop” is absent it can be expected that accidents of this type will continue to emerge in an apparently random manner. **THIS WILL NOT BE SOLVED BY ONE STOP CLASSROOM ACTIVITIES**

# Elephant in the Room?

## Lessons in Implementation

*“My biggest fear is that you will come up with a recommendation requiring more funds in some direction and I will be simply left to slice the pie differently”.*

Third recommendation.

The report be directly presented to the organisation executive by the investigator. The Hospital’s senior management understood the problem but were powerless to implement the changes required. “Re-slicing the pie”, without adequate risk assessment, would simply transfer the control problems and random errors to another area of the hospital. Investigation of the control structures above the Hospital Executive is required to remove doubt of where the actual interventions for positive change will need to be made.

## CAST Result (and RCA); ....road not taken or opportunity missed?

TGA INFUSION PUMP warning issued 5 days before the event.

The DON & Risk & Quality manager spent a few hours trying to make sense of the warning from the TGA (FDA equivalent)

The Hospital Biomedical Engineer, knew exactly what it meant. He said the pump could “free flow” if an internal cam malfunctioned. ie It would mimic our Nurse initiated event.

This warning affected every pump in 5 separate hospitals. Immediate cessation of use would shut-down the hospitals.

Not explored.

# LEARNING POINTS

- CAST handbook invaluable
- Good software essential to reducing hours
- Mental models invaluable for insight into Complex STS. (As an aside I abandoned referring to WAD vs WAI. WAI is too judgemental. Both the operators and designers models are equally valid.)
- Be Bold (ie Honest) with implementation recommendations
- You can't investigate everything.
- Enormous psychological burden on those being questioned.

One resigned, multiple interviews involved tears, most had support people.

# LEARNING POINTS

## Disadvantages

- Complex (4 page RCA report vs 26 page CAST report)
- Time-Consuming to do (50hrs vs 20hrs)
- Thus costly. (my Bill \$6000-)
- Little subject matter mentoring available. (so I tried to come to Boston)
- Communication of results requires time.

## Frustrations

- Unable to present report.
- No feedback. (except they paid and asked me back!)

# Awareness Case

## “Awake During Surgery”

10 yo male for cosmetic ear surgery.

Needle phobic and mother a Dr at same hospital.

Intravenous anaesthesia used.

At one point the pump was noticed to be inadvertently off BEFORE surgery commenced. Turned on immediately.

Patient said he was “awake” the next day.

My brief was, “Do we need to investigate this”

# Complicating Emotional Circumstances

Mother extremely worried about PTSD

Mother a doctor who worked in same OR complex as the anesthesiologist

Mother openly talking about the case in OR

Awareness story inconsistent with what occurred in the OR (as it always is)

Anesthesiologist known at the hospital for his competence and diligence.

This outcome always attracts lay person judgement.

- *“Something terrible must have gone wrong.”*
- *“How could this possibly happen in a modern hospital?”*

# Grounded Theory

Seemed a logical way to maintain an open mind rather than immediately apply an analysis technique

I was worried that my initial positive experience for CAST maybe biasing my analysis choice.

So in a series of interviews I examined;

- Reporting Culture; excellent
- Open Disclosure; excellent
- Escalation of Events & Risk Management; excellent
- “Second victim” support; recommendations readily accepted
- Emergency Psychological Support; available but somewhat ad-hoc. Recommendations readily accepted



# Back to CAST and Control Theory

## Control loops provide the logic

### AWARENESS 1:9000

Pandit, J. J., Andrade, J., Bogod, D. G., Hitchman, J. M., Jonker, W. R., Lucas, N., . . . Ireland. (2014). 5th National Audit Project (NAP5) on accidental awareness during general anaesthesia: summary of main findings and risk factors. *Br J Anaesth*, 113(4), 549-559.

### HUMAN VIGILANCE SHOULD NOT BE REPLIED UPON

Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (2000). *To Err Is Human: Building a Safer Health System*.

(This anaesthesiologist had do this 1000 times a year for 20 years and this was his first case. He is above average!)

### NO AWARENESS MONITOR APART FROM VIGILANCE

Schuller, P. J., Newell, S., Strickland, P. A., & Barry, J. J. (2015). Response of bispectral index to neuromuscular block in awake volunteers†. *Br J Anaesth*, 115 Suppl 1, i95-i103.

# Conclusions

*“The un-palatable truth in anaesthesia at the moment is we have no way of guaranteeing a zero-awareness rate with our current technology. We have to rely on the least reliable monitoring methodology available, human vigilance.”*

So.....

It is unlikely that further investment of time and resources in this incident will produce significant lessons that will improve how SAWMH systems operate.

This finding is based purely on a systems design perspective. It lacks a legal perspective.

So.....

A legal opinion be obtained to whether further investigation may be required to mitigate legal risk in this case. (They didn't as far as I'm aware)

# Retrospective Investigation

## Is it possible?

Tasked to retrospectively review a Critical Systems Analysis (mini-RCA)

Busy endoscopy unit.

New staff member helping anesthesiologist.

Scope from patient 1 inadvertently re-used on patient 2.

Retrospective at least referred to as possible in CAST handbook.

CSA Report gave me;

- Timeline and a recommendation they need to follow procedures

- Staffing experience recommendations

- Audits recommended to ensure compliance

But

- I couldn't access interview notes nor request

# Frustration

- Report was dramatically limited by the RCA methodology
- At its core it ignored Poppers Rationality Principle
- All the staff decisions were examined in the light of non-compliance with Procedures.
- There was no examination of mental models, operator or designer.
- Quiet rightly the original investigator about staff fears if the original investigation was seen to be "re-opened". The potential for harm outweighed the risk.

## PROSPECTIVE INVESTIGATION IS STILL THE IDEAL

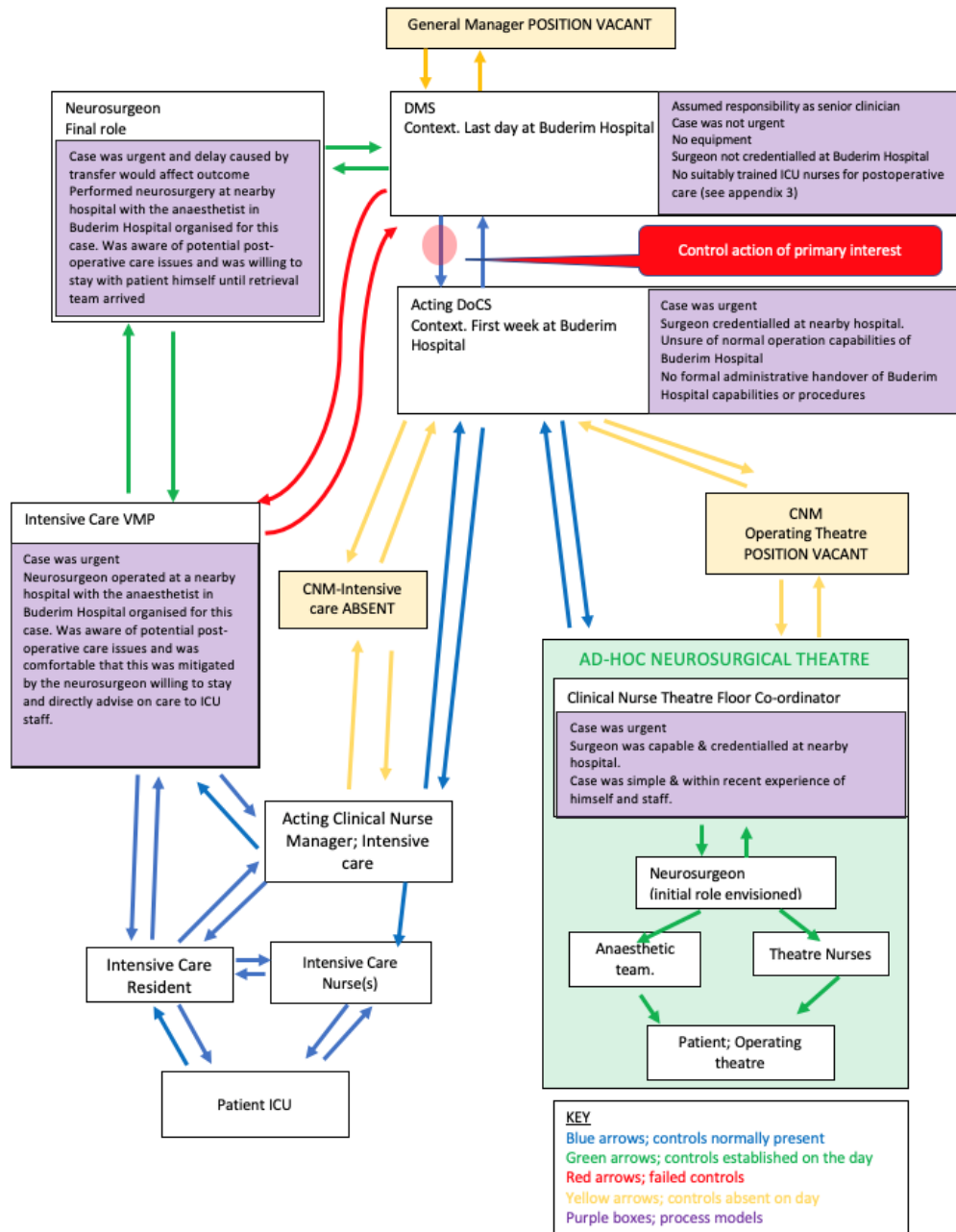
“superficial analysis of accidents are occurring in your organization or industry will primarily be a waste of resources and have little impact on future events.” page 6 CAST handbook

# Sub arachnoid haemorrhage case. Nothing Happened, why investigate? Why was everyone worried.

By definition, there was not an accident as there was no loss. However, there was *a serious incident where emergency care was not provided in a timely manner*. The aim of the investigation is to find out why the system entered into a “hazardous state” where harm could have occurred and to make recommendations that would prevent such episodes in the future.

The danger of a hazardous state being;

~~HAZARDOUS STATE + ENVIRONMENTAL CONDITIONS = LOSS~~



# Rasmussen and drift towards danger

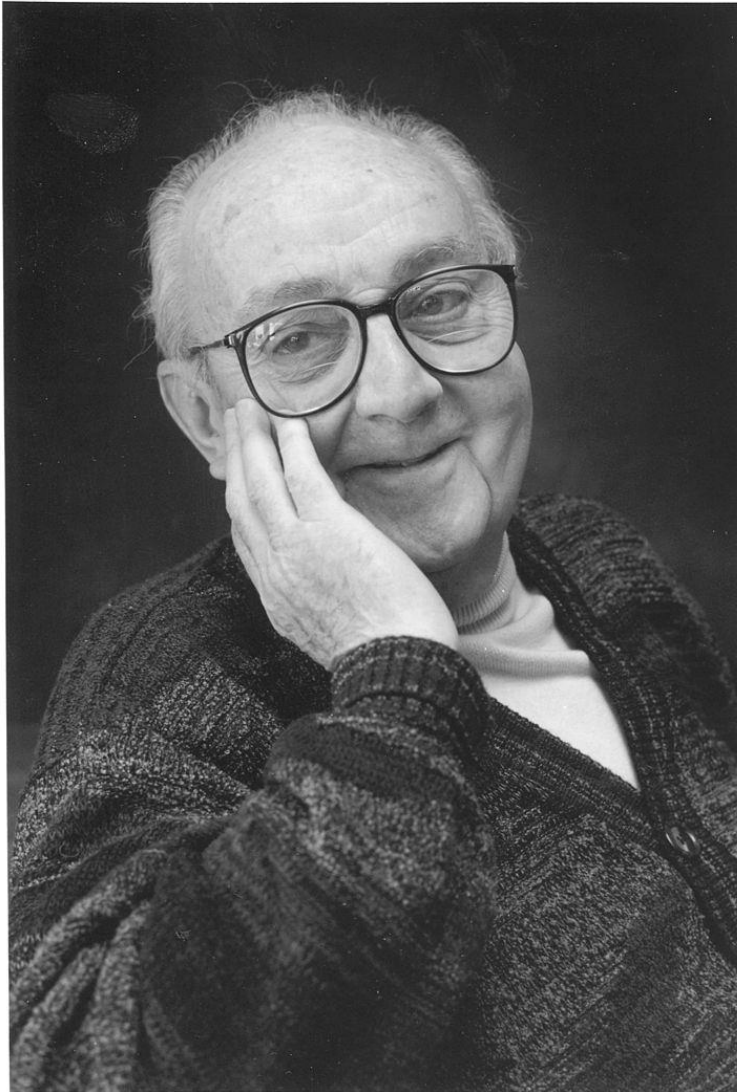
economic failure

Does DRIFT =  
~~Variability~~ in a CAS?

*drift towards  
failure*

unsafe

unacceptable  
workload



*“All models are wrong, some  
are useful”*

*George E. Box (statistician)*