PIRS News

ISSUE 06 Jan 2018

ANZCP
Australian and New Zealand College of Perfusionists

PIRS

ANZCP PIRS IS UP AND RUNNING

PIRS access has been unavailable due to delays with the ANZCP website reconstruction project as well as an associated problem with the ANZCP PIRS email account. The ANZCP have now enabled PIRS on their new website.

To file reports go to:

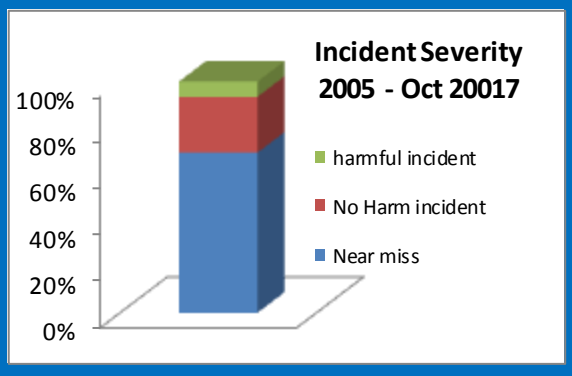
http://anzcp.org/pirs/

We encourage feedback and suggestions to PIRS@anzcp.org

this issue

The role of incident reporting in a changing safety paradigm .

Reporting incidents provides valuable incites into the management of unintended situations - in our case most likely in the operating room although we receive reports that occur outside of that environment. The shift in classification of incidents in PIRS to the WHO criteria - Near Miss (did not reach the patient) / No Harm (reached the patient with no discernable harm) / Harmful incident (reached the patient resulting in some harm) are much easier to apply. The vast majority of reports to PIRS are *no harm or near miss* where a number of practice variations have been made - often on the fly - that have prevented a serious adverse event. PIRS now asks reporters to describe *What went well*? This is a Safety-II concept that intertwines with a Safety-I activity and is designed to shift the thinking from a possible blame perspective to a well managed perspective. There are potentially important lessons by identifying what went well in the course of an unintended event.



Recently Professor Erik Hollnagel gave a master class in safety at the Ko Awatea Centre at Middlemore Hospital in Auckland NZ. Erik has kindly given his permission for PIRS to reproduce his slides from that event . *Tim Willcox PIRS Ed* - Email PIRS@anzcp.org .

NEW PIRS Submission Form.

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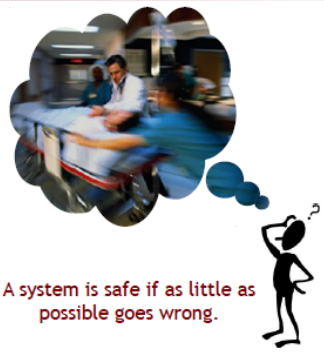
PIRS NEWS Featured Article -

printed with permission 31/5/2017 the original article can be found: Fann J, et al . Human Factors and Human Nature in Cardiothoracic Surgery. Ann Thorac Surg 2016;101:2059–66.

Health Care: Safety and Resilience

Erik Hollnagel, Ph.D.
Professor, Institute of Regional Health Research, University of Southern Denmark
Senior Professor, Jönköping Academy, Sweden
Email: hollnagel.erik@gmail.com

What does it mean to be safe?



When we think about safety, we usually think about accidents - about (low probability) events with adverse outcomes.

A system is safe if as little as possible goes wrong.

Safety-I – when nothing goes wrong

Safety is a condition where the number of adverse outcomes (accidents / incidents / near misses) is as low as possible.

Safety-I is defined by its opposite - by the lack of safety (accidents, incidents, risks).

→ The premise for Safety-I is the need to understand why accidents happen.

If we want something to increase, why do we use a proxy measure that decreases?

Accidents and incidents represent a lack of safety.

How can we learn about safety by studying situations where it isn't there?

Increasing safety by reducing failures

Function (work as imagined) → Success (no adverse events) → Acceptable outcomes

Hypothesis of different causes: Things that go right and things that go wrong happen in different ways and have different causes

Malfunction, non-compliance, error → Failure (accidents, incidents) → Unacceptable outcomes

Safety-I – when nothing goes wrong

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How can we learn about safety by studying situations where it isn't there?

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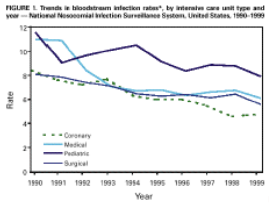
The first interpretation of safety

Safety is the prevention of harm to patients

There is an presence of failures (things that go wrong) due to risks and hazards. The number of harmful events can be counted.

$$\text{Safety} = \sum_{1}^{n} \text{Accident}_i$$

It is "easy" to count how much goes wrong, but does that measure safety?



AHRQ Patient Safety Indicators (PSIs)

PSI 04 Death among surgical inpatients with serious treatable complications.
PSI 06 Iatrogenic pneumothorax.
PSI 11 Postoperative respiratory failure.
PSI 12 Postoperative PE or DVT.
PSI 14 Postoperative wound dehiscence.
PSI 15 Accidental puncture or laceration.

Managing Safety-I

Safety-I is a condition where the number of adverse outcomes (accidents / incidents / near misses) is as low as possible.

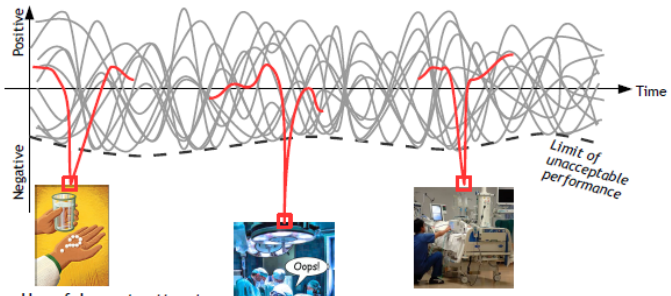
The belief in causality (Causality Credo)

(1) Adverse outcomes happen because something has gone wrong (cause-effect thinking + value congruence between cause and effect).
(2) Causes can be found and treated (rational deduction).
(3) All accidents are therefore preventable (zero harm principle).

PRIMUM NON NOCERE

Prevent, eliminate, constrain. Safety, quality, etc. are different and require different measures and methods.

Managing safety by snapshots

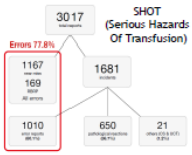


Harmful events attract attention. But they are rare and isolated.

Events are analysed step-by-step. Responses are developed for each problem found.

But do we really know what happens?

The numerator is how many there are of a type of event – accidents, incidents, etc. This number is known (with some uncertainty)



Numerator

Denominator

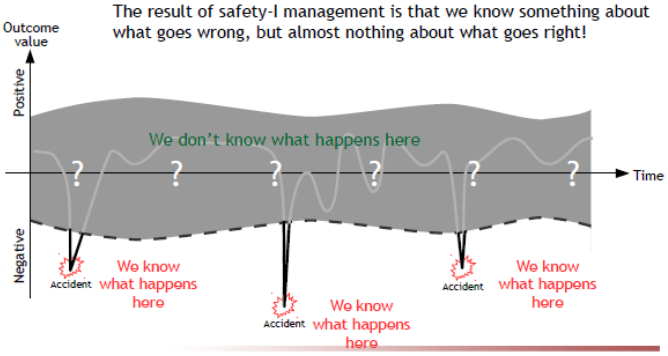
The denominator is how many cases something went well. This number is usually unknown.

We always count the number of times something goes wrong. We analyse the rare events.

We rarely count the number of times something goes well. We need to understand the common events.

Do we really know why things go well?

The result of safety-I management is that we know something about what goes wrong, but almost nothing about what goes right!



The problem is safety – or is it?

ANSI American National Standards Institute

3. DEFINITIONS
3.20 Safety. Freedom from unacceptable risk.

ICAO · OACI · ИКАО

Safety. A condition in which the risk of harm or damage is limited to an acceptable level.

Safety is defined and measured more by its absence than by its presence.
Reason, J. (2000). Safety paradoxes and safety culture. Injury Control & Safety Promotion, 7(1), 3-14.

Reliability is a dynamic non-event … it is an ongoing condition in which problems are momentarily under control due to compensating changes (in components) … It is invisible (because) people often don't know how many mistakes they could have made but didn't … (and) also invisible in the sense that reliable outcomes are constant, which means there is nothing to pay attention to.
Weick, K. E. 1987. Organizational culture as a source of high reliability. California Management Review 29 (2), 112-128.

PIRS News

The second interpretation of safety

Safety is the prevention of harm to patients

$$\text{Safety} = \sum_{1}^{n} \text{Accident}_i$$

There is an presence of failures (things that go wrong) due to risks and hazards. The number of harmful events can be counted.

"Safety is a dynamic non-event"

$$\text{Safety} = \sum_{1}^{n} \neg\text{Accident}_i$$

There is an absence of failures (things that go wrong), but as a result of active engagement. If safety is a non-event, it can neither be observed, nor measured

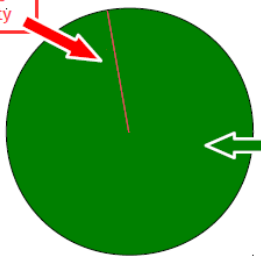
Is it possible to count the number of times something does not happen?

What should we be looking for?

10^{-4} := 1 failure in 10.000 events

Adverse outcomes = Absence of safety

Easy to see
Complicated aetiology
Difficult to change
Difficult to manage



'Difficult' to see
Uncomplicated aetiology
Easy to change
Easy to manage

Intended outcomes = Presence of safety

1 - 10^{-4} := 9.999 "successes" in 10.000 events

Why don't people bump into each other?

When we move in a crowd, we continuously adjust to what other people do.

Just as others continuously adjust to what we do – or will do.

Everyday clinical work must be flexible

Resources (time, manpower, materials, information, etc.) may be limited and uncertain.

People adjust what they do to match the situation.

Performance variability is inevitable, ubiquitous, and necessary.

Because of resource limitations, performance adjustments will always be approximate.

Performance variability is the reason why everyday work is safe and effective.

Performance variability is the reason why things sometimes go wrong.

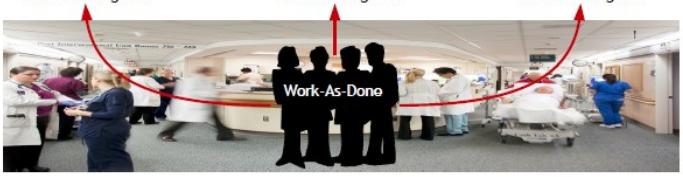
"Work-as-imagined" and "work-as-done"

Design (tools, roles, environment)

Work & production planning ("lean" - optimisation)

Safety management, investigations & auditing

Work-As-Imagined | Work-As-Imagined | Work-As-Imagined



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Work as imagined – follow the rules!

Box 1: Professional bodies and national agencies who publish guidelines for anaesthetists

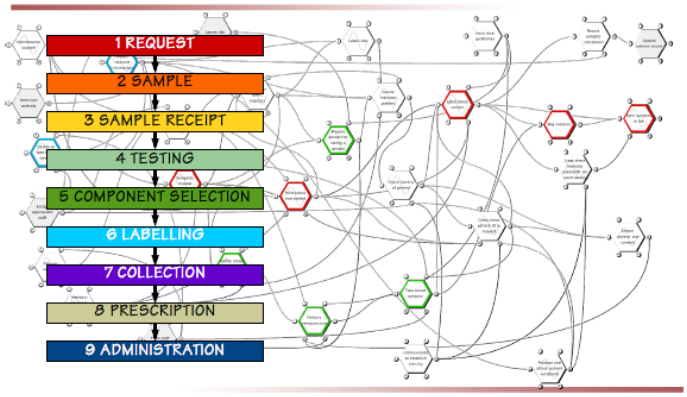
- Association of Anaesthetists of Great Britain and Ireland
- Academy of Medical Royal Colleges
- Association of Cardiac Anaesthetists
- Association of Paediatric Anaesthetists
- British Association of Day Surgery
- *British National Formulary*
- British Pain Society
- Department of Health
- Difficult Airway Society
- European Society of Anaesthesiology
- Faculty of Pain Medicine
- General Medical Council
- Health and Safety Executive
- Intensive Care Society
- Medicines and Healthcare Products Regulation Authority
- National Patient Safety Agency
- National Institute for Health and Clinical Excellence
- Obstetric Anaesthetists Association
- Resuscitation Council (UK)
- Royal College of Anaesthetists
- Scottish Intercollegiate Guidelines Network

Emergency surgery on a fractured neck of femur involves app. 75 clinical guidelines and policies.

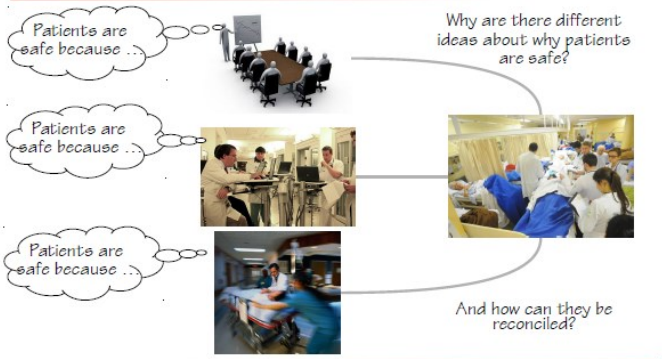
UK Government guideline on "Working Together to Safeguard Children" is 390 pages long!

Carthey et al (2011). Breaking the rules: understanding non-compliance with policies and guidelines. BMJ

Blood transfusion: WAI ≠ WAD

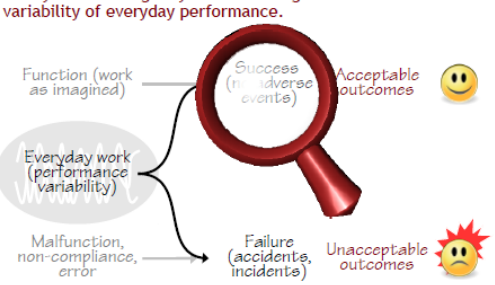


Different ideas about why work is safe



Increase safety by doing things right

Safety must be begin by understanding the variability of everyday performance.



Constraining performance variability to remove failures will also remove successful everyday work.

Safety II – when everything goes right

Safety-II: Safety is a condition where the number of successful outcomes (meaning everyday work) is as high as possible. It is the ability to succeed under varying conditions.

Safety-II is achieved by trying to make sure that things go right, rather than by preventing them from going wrong.

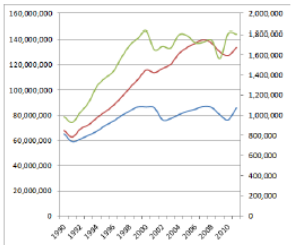
Safety is defined by its presence. → The focus is on everyday situations where things go right – as they should.

- Risk-based: Think about how something can go wrong and then try to prevent that.
- Opportunity-based: Think about how how something can go well and then try to support that.

Thinking about safety

A system is safe if as much as possible goes right.

We should think about safety in terms of how many things go well and how frequently we succeed.



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The third interpretation of safety

Safety is the prevention of harm to patients

$$\text{Safety} = \sum_{1}^{n} \text{Accident}_i$$

There is an presence of failures (things that go wrong) due to risks and hazards.
The number of harmful events can be counted.

"Safety is a dynamic non-event"

$$\text{Safety} = \sum_{1}^{n} \neg\text{Accident}_i$$

There is an absence of failures (things that go wrong), but as a result of active engagement.
If safety is a non-event, it can neither be observed, nor measured

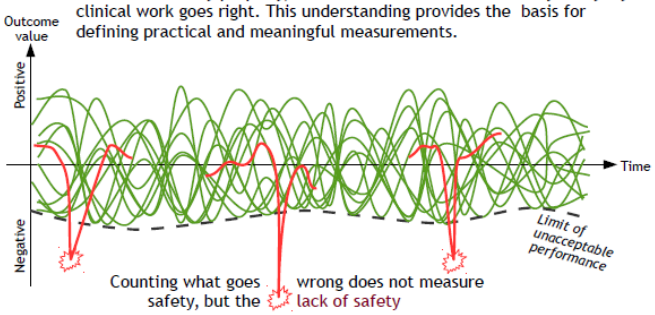
Safety is a dynamic event

$$\text{Safety} = \sum_{1}^{n} (\text{acceptable outcome})_i$$

Safety is the presence of acceptable outcomes.
The more there are, the safer the system is.

The proper measurement of safety

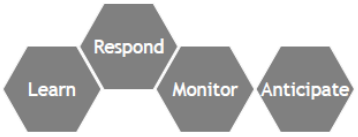
To measure safety properly, we must understand how and why everyday clinical work goes right. This understanding provides the basis for defining practical and meaningful measurements.



Resilience versus resilient performance

Resilience is an expression of how people, alone or together, cope with everyday situations - large and small – by adjusting their performance to the conditions.

Resilient performance means that an organisation can function as required under expected and unexpected conditions alike (changes / disturbances / opportunities).

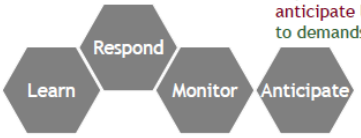


Resilient performance requires that an organisation has the potentials to **respond**, **monitor**, **learn**, and **anticipate**.

Four resilience potentials

Improve the potential to respond to threats and opportunities alike

Improve the potential to anticipate long-term changes to demands and resources.

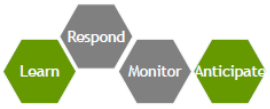


Improve the potential to learn both from what goes right and what goes wrong.

Improve the potential to monitor what happens externally and internally.

Resilience potentials are scale-invariant

Overall strategic goals and functioning of the healthcare organisation.



Organisational functions that support the work of the microsystem.

Clinical front line that works with patients in specific settings.

As high as reasonably practicable

Respond

For which events is there a response ready?
What is the threshold of response?
How many resources are allocated to response readiness?
…

Monitor

How have the indicators been defined?
How many indicators are leading and how many are lagging?
What is the delay between measurement and interpretation?
….

Learn

What is the learning based on (successes – failures)?
Is learning continuous or event-driven?
How are the effects of learning verified and maintained?
…

Anticipate

What is the implicit/explicit "model" of the future?
How far does the organisation look ahead ("horizon")?
What risks are the organisation willing to take?
…

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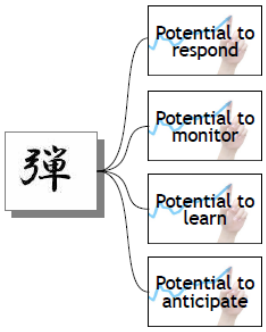
The Resilience Assessment Grid (RAG)



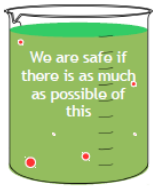
Comprises four sets of questions, one for each potential.
The questions are:
DIAGNOSTIC – point to details of a potential that are meaningful to assess.
FORMATIVE – answers can be used to make decisions about how to improve potentials
SPECIFIC – address issues that are important for a concrete organisation.

Example of RAG (St. Paul)

Question	Contents
1	We have a list of everyday and unexpected clinical, system, and environmental events for which we prepare and routinely practice action plans.
2	We revisit and revise our list of events and action plans on a systematic basis.
3	We follow defined thresholds, actions, and stopping rules to adapt/transform operations and proactively mobilize resources in order to maintain our capacity for response under conditions of increased volume and acuity.
4	We effectively team, communicate and work together within the department, and with other departments and services.
5	We have organizational support and resources to maintain our capability to meet acuity and volume demands.
6	We link our local department adaptations to organizational and health system changes.

Managing Safety-II

Safety-II is a condition where as much as possible goes well.



Support, augment, facilitate. Safety, quality, etc. are inseparable and need matching measures and methods.

1. Care about what happens all the time rather than what happens rarely. We always count the number of times something fails, but rarely the number of times it just works.
2. Look for 'work-as-done' - the habitual adjustments and why they are made. When something is done, as a part of work, it has usually been done before and gone well before.
3. Learning should be based on the frequency of events rather than their severity. Small improvements of everyday performance may be more important than large improvements of rare performance.

PRIMUM BENE FACERE

From Safety-I to Safety-II

World Health Organization

Health is 'a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity'.

IMPROVED SAFETY

Safety-I:
Safety is the freedom from unacceptable risk

Safety-II:
"Safety" is the ability to sustain required operations under both expected and unexpected conditions.

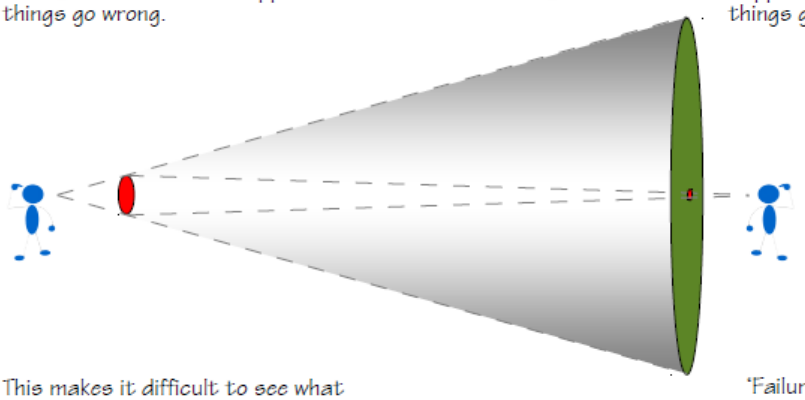
Reduce unacceptable outcomes (accidents, incidents, etc)

Increase acceptable outcomes (everyday work)

The importance of having the right focus

Safety-I looks at what happens when things go wrong.

Safety-II looks at what happens when things go well.



This makes it difficult to see what goes well.

'Failures' no longer dominate the picture.

Perfusion Incident Reporting System – PIRS

Latest

Permission to print:	Yes
Incident type	No Harm Incident
Type of incident:	patient mediated
Catagory	Oxygenator
Description:	There was an unexplained resistance across the oxygenator (Sorin Inspire 6 non-integrated) 30 minutes during bypass [using Sorin S5] a Pump error fault appeared (672 - maximum load limit is reached). The silicone replacement pump boot was distending at the pump outlet indicating severe resistance across the oxygenator. Trans menbrane pressure is not monitored. The ACT was 800 and the line pressure measured proximal to the arterial filter (20 micron) was normal and unchanged precluding coagulation throughout the circuit. Notified surgeon / anaesthetist of the problem. Called for colleagues to look into the fault / discuss the issue. Patient was at 33 degrees. Flows were dropped to 1.8-2.0 index - SvO2, MAPs and blood gases were adequately maintained. . Patient was haemodiluted from Hct of 0.38 to 0.26 to reduce blood viscosity. An oxygenator change-out kit and spare arterial pump were brought into the operating room as precautionary measures. Further discussed problem with the surgeon and it was decided that it's safe enough to continue bypass without changing the oxygenator as all patient parameters [SvO2, acid-base and ABGs] were within normal limits at reduced flows. With one distal anasamosis remaining if the problem exacerbated the plan on removal of the cross clamp was to further reduce flow and maintain partial CPB (heart ejecting) or to wean from CPB and complete proximals off bypass. Unexpectedly the problem was alleviated upon rewarming of the patient. The oxygenator was kept at the end of the case for further testing.
Preventive actions	As above: review and assessment of the problem with staged management plan including: peer review, for adequacy of perfusion at reduced flows, early termination of CPB and oxygenator changeout
GOOD CATCH - what went	The technology of the Stockert S5 heart lung machine to recognise the problem. Fantastic back-up by the perfusion department
Protocol issue	No
Rule issue	No
Skill issue	
Team Issue	No
Violation	
Manufacturer advised:	Yes
Discussed with team:	Yes
Hospital incident filed:	Yes
Ext Authority Advised	No
Patient outcome variance f	Nil
Commentary	This is a very unusual problem that does not appear to have been prevouisly reported. The systematic problem management avoided potential further problems that may have been associated with further cooling to faciitiate oxygenator change out.

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