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.
PIRS NEWS Featured Article -

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.ERIC@KISMAIL.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.

Increasing safety by reducing failures

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

Safety-1 – when nothing goes wrong

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

Safety-1 is defined by its opposite - by the lack of safety (accidents, incidents, risks).

The premise for Safety-1 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?

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PIRS News

The first interpretation of safety

Safety is the prevention of harm to patients
Safety = \sum \text{Accident}

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

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

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 (causation = logical relationship 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

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).

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

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

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.

We don’t know what happens here

The problem is safety – or is it?

Safety is defined and measured more by its absence than by its presence.


Reliability is a dynamic non-event... It is an ongoing condition in which problems are momentary under control due to compensating changes (in compensation).

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 common, which means there is nothing to pay attention to.

Weick, K. E. 1987, Organisational 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.

\[ \text{Safety} = \sum \frac{\text{Accident}_i}{n} \]

"Safety is a dynamic non-event".

\[ \text{Safety} = \sum \frac{1}{\text{Accident}_i} \]

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

- Adverse outcomes = Absence of safety
- Intended outcomes = Presence of safety
- Easy to see
- Complicated etiology
- Difficult to change
- Difficult to manage

**What should we be looking for?**

- 10^-1 failure in 10,000 events
- 1 - 10^-7 = 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 in safe and effective.

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

Work as imagined – follow the rules!

Emergency surgery on a fractured neck of femur involving app 30 clinical guidelines and policies.

UK Governments guidelines on “Working Together to Safeguard Children” is 300 pages long!

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

Blood transfusion: WAI ≠ WAD

1 REQUEST
2 SAMPLE
3 COMPONENT SELECTION
4 TESTING
5 LABELLING
6 COLLECTION
7 PRESCRIPTION
8 ADMINISTRATION

Different ideas about why work is safe

Why are there different ideas about why patients are safe?

And how can they be reconciled?

Increase safety by doing things right

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

Daily work (normal events)

Everyday work (variable events)

Function (work as imagined)

Malfuction, non-compliance, error

Failure (accidents, incidents)

Unacceptable outcomes

Safety II – when everything goes right

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 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.
PIRS News

The third interpretation of safety

Safety is the prevention of harm to patients

\[ Safety = \sum_{i=1}^{n} \text{Accident}_i \]

“Safety is a dynamic non-event”

\[ Safety = \sum_{i=1}^{n} -\text{Accident}_i \]

Safety is a dynamic event

\[ Safety = \sum_{i=1}^{n} \text{(acceptable outcome)} \]

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).

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.

Four resilience potentials

- Improve the potential to respond to threats and opportunities alike
- Improve the potential to learn both from what goes right and what goes wrong
- Improve the potential to monitor what happens externally and internally
- Improve the potential to anticipate long-term changes to demands and resources

As high as reasonably practicable

- For which events is there a response ready?
- How many resources are allocated to response readiness?
- …
- How have the indicators been defined?
- How many indicators are lagging and how many are leading?
- …
- What is the delay between measurement and interpretation?
- …
- What is the learning based on (successes — failures)?
- Is learning continuous or event-driven?
- …
- How are the effects of learning verified and maintained?
- …
- What is the implicit/explicit "model" of the future?
- How far does the organisation look ahead ("horizon")?
- …
- What rate is the organisation willing to take?
- …
PIRS News

The Resilience Assessment Grid (RAG)

Comprises four sets of questions, one for each potential.

- Potential to respond
- Potential to monitor
- Potential to learn
- Potential to anticipate

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 potential.

PRODUCTIVE - addresses issues that are important for an organization.

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.

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

- IMPROVED SAFETY
  - Reduce unacceptable outcomes (accidents, incidents, etc)
  - Increase acceptable outcomes (everyday work)

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

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.
### Latest

<table>
<thead>
<tr>
<th>Permission to print:</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident type</td>
<td>No Harm Incident</td>
</tr>
<tr>
<td>Type of incident</td>
<td>patient mediated</td>
</tr>
<tr>
<td>Category</td>
<td>Oxygenator</td>
</tr>
<tr>
<td>Description:</td>
<td>There was an unexplained resistance across the oxygenator (Sorin Inspire 5 non-integrated) 30 minutes during bypass [using Sorin SS] 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. Transmembrane 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 at 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 anassemia 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.</td>
</tr>
<tr>
<td>Preventive actions</td>
<td>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</td>
</tr>
<tr>
<td>GOOD CATCH - what went</td>
<td>The technology of the Stockert 55 heart lung machine to recognise the problem. Fantastic back up by the perfusion department</td>
</tr>
<tr>
<td>Protocol issue</td>
<td>No</td>
</tr>
<tr>
<td>Rule issue</td>
<td>No</td>
</tr>
<tr>
<td>Skill issue</td>
<td>No</td>
</tr>
<tr>
<td>Team Issue</td>
<td>No</td>
</tr>
<tr>
<td>Violation</td>
<td>No</td>
</tr>
<tr>
<td>Manufacturer advised:</td>
<td>Yes</td>
</tr>
<tr>
<td>Discussed with team:</td>
<td>Yes</td>
</tr>
<tr>
<td>Hospital incident filed:</td>
<td>Yes</td>
</tr>
<tr>
<td>Ext Authority Advised:</td>
<td>No</td>
</tr>
<tr>
<td>Patient outcome variance</td>
<td>Nil</td>
</tr>
<tr>
<td>Commentary</td>
<td>This is a very unusual problem that does not appear to have been previously reported. The systematic problem management avoided potential further problems that may have been associated with further cooling to facilitate oxygenator change out.</td>
</tr>
</tbody>
</table>

**Thursday, 19 October 2017**